2025 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 001-40603

TScan Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**82-5282075** **(I.R.S. Employer Identification No.)**
830 Winter Street **Waltham, Massachusetts** **(Address of principal executive offices)**	**02451** **(Zip Code)**

Registrant's telephone number, including area code: (857) 399-9500

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, $0.0001 par value per share	TCRX	The Nasdaq Global 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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market, LLC on June 30, 2025, was $56,871,577.

The number of shares of Registrant's Common Stock outstanding as of February 27, 2026 was 52,625,035 shares of voting common stock, $0.0001 par value per share, outstanding and 4,276,588 shares of non-voting common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report are forward-looking statements.

In some cases, you can identify forward-looking statements by words such as "may," "can," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "seek," "contemplate," "believe," "estimate," "predict," "potential," "possible" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our T cell receptor (TCR)-engineered T cell, or TCR-T, therapy product candidates;
- our expectations regarding our preclinical studies being predictive of clinical trial results;
- the timing of the initiation, progress and expected results of our preclinical studies, clinical trials and our research and development programs;
- the timing of and our ability to submit applications for, and obtain and, if approved, maintain regulatory approvals for our TCR-T therapy product candidates;
- our expectations regarding clinical trial results being predictive of continued development and commercial success of our product candidates;
- our plans relating to developing and commercializing our TCR-T therapy product candidates, if approved, including sales strategy;
- estimates of the size of the addressable market for our TCR-T therapy product candidates;
- our manufacturing capabilities and the scalable nature of our manufacturing process;
- our estimates regarding expenses, future milestone payments and revenue, capital requirements and needs for additional financing;
- our expectations regarding competition;
- our anticipated growth strategies;
- our ability to attract or retain key personnel;
- our ability to establish and maintain development partnerships and collaborations;
- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the U.S. and foreign countries;
- our ability to obtain and maintain intellectual property protection for our proprietary platform technology and our product candidates;
- the anticipated trends and challenges in our business and the market in which we operate;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- the effects of any public health crises in regions where we, our partners, or other third parties on which we rely, on any of the foregoing or other aspects of our business or operations;
- the effects of rising inflation rates and the impact on operating costs, liquidity and access to credit on any of the foregoing or other aspects of our business operations;
- the effects of global economic uncertainty and financial market volatility caused by political instability, new or increased international tariffs and retaliatory tariffs, changes in U.S. policy, changes in governmental agencies, changes in international trade relationships and conflicts on any of the foregoing or other aspects of our business or operations including our ability to obtain additional financing; and
- our anticipated use of our existing cash resources and our ability to obtain additional financing in the future.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important 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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions included in this Annual Report, particularly those described in the "Risk Factors" section in Part I, Item 1A of this Annual Report, that could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the impact of all 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 we may make. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report, and although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report and the documents that we have filed as an exhibit to this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

In addition, this Annual Report contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained industry, market and similar data set forth in this Annual Report from our internal estimates and research, and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable. Our estimates of the potential market opportunities for our product candidates include key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. Information based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by us and third parties, industry, medical and general publications, government data and similar sources. This Annual Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents.

Unless stated otherwise, references in this Annual Report to "us," "we," "our," "our Company," or "the Company" and similar terms refer to TScan Therapeutics, Inc.

RISK FACTOR SUMMARY

Our business operations are subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations, and future growth prospects. These risks are discussed more fully in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. These risks include, but are not limited to, the following:

Risks Related to Our Business and Industry

- 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.
- Our business depends upon the success of our proprietary platform.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We have never generated any revenue from sales of our TCR-T therapy product candidates, and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.
- We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates on unfavorable terms to us.
- Global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts could make it more difficult for us to access financing and could adversely affect our business and operations.
- The U.S. Congress and the Trump administration have made and may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.
- Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may impact our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

Risks Related to the Development of Our Product Candidates

- Our approach to the discovery and development of product candidates based on our proprietary platform represents a novel approach to cancer treatment, which creates significant challenges for us.
- We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Although many of our personnel have extensive experience in clinical development and manufacturing at other companies, we have limited direct experience as a company in conducting clinical trials and managing a manufacturing facility for our product candidates.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, potency and purity of any of our product candidates, which would prevent or delay development, regulatory approval and commercialization.
- Our business could be adversely affected by the effects of health epidemics in regions where we, our partners or other third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.

- We may rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if licensed.
- We cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment.
- Allogeneic hematopoietic cell transplantation (HCT) is a high-risk procedure that may result in complications or adverse events for patients in our clinical trials including those unrelated to the use of our product candidates.
- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in other significant negative consequences.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The market opportunities for our product candidates may be relatively small. In addition, our estimates of the prevalence of our target patient populations may be inaccurate.
- We face significant competition, and our operating results will suffer if we fail to compete effectively.

Risks Related to Manufacturing

- Manufacturing and administering our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our TCR-T therapy product candidates for clinical trials or, if approved, for commercial purposes, could be delayed or stopped.
- Although many of our personnel have experience in clinical manufacturing at other companies, we have limited experience as a company managing manufacturing for our product candidates, which will be costly and time-consuming, and which may not be successful.
- We may have difficulty validating our manufacturing process as we manufacture TCR-T therapy product candidates from an increasingly diverse patient population for our clinical trials.

Risks Related to Government Regulation

- The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Risks Related to Our Intellectual Property

- If we are unable to obtain and maintain patent protection for any product candidates we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products, product candidates and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop and our technology may be adversely affected.
- We are currently, and expect in the future to be, party to material license or collaboration agreements, which may impose numerous obligations and restrictions on us.
- Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product candidate discovery and development efforts.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to help us conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.
- We have in the past and may in the future form or seek collaborations or strategic alliances or enter into additional licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

General Risk Factors

- Rising inflation rates may result in increased operating costs and reduced liquidity and affect our ability to access credit.

PART I

Item 1. Business

Overview

We are a fully integrated clinical-stage biotechnology company focused on developing a robust pipeline of T cell receptor (TCR)-engineered T cell, or TCR-T, therapies for the treatment of patients with cancer. Our lead product candidate, TSC-101, is in development for the treatment of patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) who are undergoing allogeneic hematopoietic cell transplantation (HCT). The product is designed to eliminate residual disease and promote complete donor chimerism, thereby preventing relapse. TSC-101 targets HA-2, an antigen that is present on all blood cells, malignant or benign, in patients with the HLA type A*02:01. We are currently conducting a Phase 1 clinical study of TSC-101 (the ALLOHA™ trial, NCT05473910) and during the fourth quarter of 2025, following a productive End-of-Phase meeting with the U.S. Food and Drug Administration (FDA), we reached agreement on a registrational path forward for the TSC-101 program as a potential treatment for patients with AML and MDS. The pivotal study will mirror our ongoing Phase 1 ALLOHA study, using a biologically-assigned (genetically randomized) control arm to support relapse-free survival as the primary endpoint.

We are further expanding our hematologic (heme) malignancies program with the addition of TCRs targeting other HLA types. TSC-102-A01 and TSC-102-A03 are allogeneic, donor-derived TCR-T therapy candidates targeting epitopes derived from CD45. Like TSC-101, these candidates are designed to eliminate residual cancer cells and prevent relapse in patients undergoing HCT. TSC-102-A01 and TSC-102-A03 are designed for patients with HLA types A*01:01 and A*03:01, respectively.

We are also developing multiple TCR-T therapy product candidates for the treatment of solid tumors. One of the challenges of treating solid tumors is that they are heterogeneous – not every tumor cell expresses a given target. To address this challenge, we are developing what we refer to as multiplex TCR-T therapy, in which we treat a patient with more than one TCR-T therapy product candidate at a time. We are designing these multiplex therapies to be a simultaneous administration of up to three highly active TCR-Ts that are customized for each patient based on which targets are expressed in their tumors. On November 3, 2025, following our alignment with the U.S. Food and Drug Administration (FDA) on the registrational path forward for the TSC-101 program, we made the strategic decision to prioritize clinical development of our heme program and pause further enrollment in our solid tumor Phase 1 trial (PLEXI-T™), while focusing our preclinical efforts on *in vivo* engineering for solid tumors. We believe an *in vivo* approach represents a promising and more cost-efficient way to deliver off-the-shelf, multiplexed TCR-T therapy for solid tumors.

While primarily focused on oncology, we believe our target discovery platform is well suited to identify targets that cause T cell-driven autoimmune disorders. We have identified a set of indications in which T cells play a key role and are currently identifying targets and developing potential treatment options for these disorders. Initial indications include ankylosing spondylitis, ulcerative colitis and scleroderma. In addition, the Company is continuing to discover targets for Crohn's disease in partnership with Amgen.

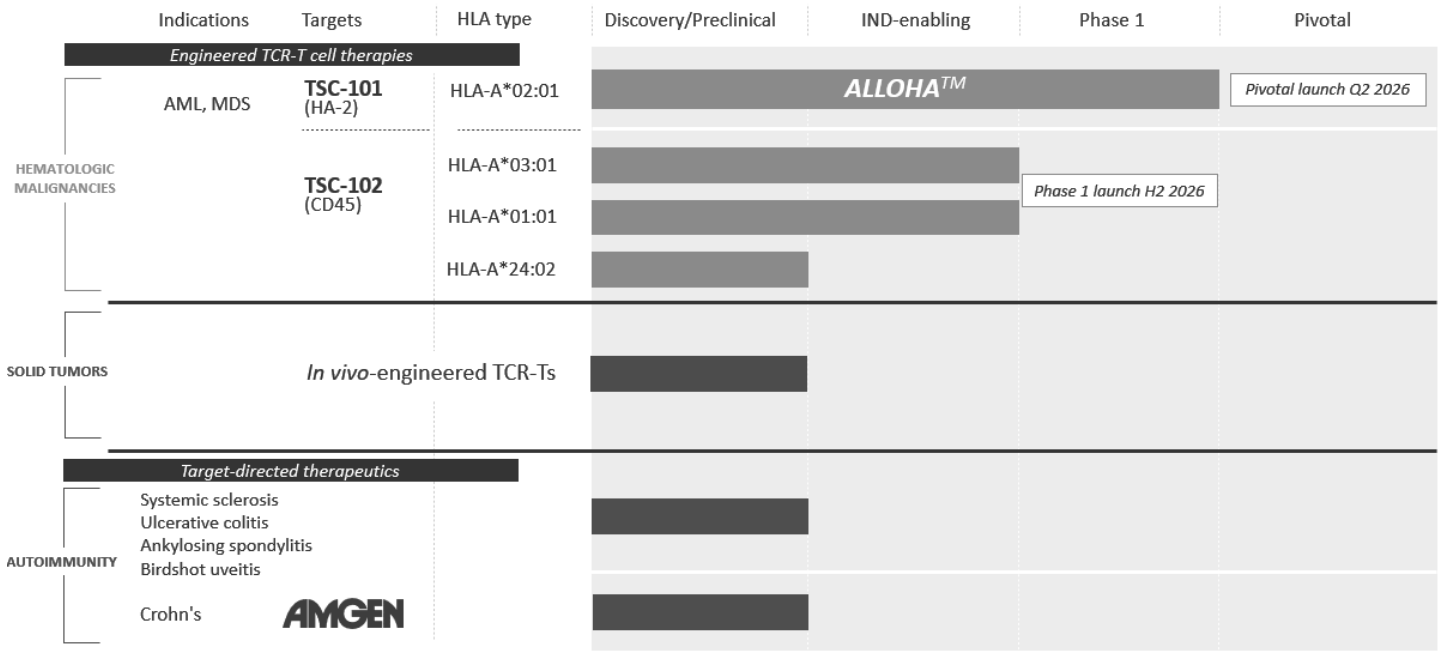
We have an internal good manufacturing practices, or GMP, facility to manufacture clinical supply for our TCR-T therapy product candidates. To provide an operationally flexible and cost-effective approach for our heme program, we have developed a manufacturing platform to genetically engineer T cells using a transposon/transposase system. This non-viral platform can be rapidly applied to new TCR-T therapy product candidates without the need for extensive process development. Our non-viral vector delivery system allows us to include additional T cell enhancements in our product candidates. In our heme program, we are introducing the gene for CD8α/β along with the TCR gene, which enables us to engineer both cytotoxic and helper T cells. We believe this enhancement has the potential to improve responses to TCR-T therapy in the clinic compared to engineering cytotoxic T cells alone. To further increase our existing clinical manufacturing capacity and prepare for potential commercialization, we have engaged a global contract development and manufacturing organization, or CDMO, with worldwide commercial capabilities.

Our Pipeline

Our lead product candidate, TSC-101, is a T cell receptor (TCR)-engineered T cell (TCR-T) therapy candidate in development for the treatment of patients with heme malignancies to eliminate residual disease and prevent relapse following allogeneic bone marrow transplantation (hematopoietic cell transplantation or HCT) (the ALLOHA™ trial, NCT05473910). We are further expanding this program with TCRs targeting additional antigens across different HLA types, such as TSC-102-A01 and TSC-102-A03.

We are also developing multiplex TCR-T therapy candidates for the treatment of various solid tumors. We have built a diverse collection of therapeutic TCRs that recognize cancer-specific targets and are associated with multiple human leukocyte antigen (HLA) types, to provide customized multiplex TCR-T treatments for patients with a variety of solid tumors. We are currently engaged in preclinical development of an *in vivo* engineering platform to deliver off-the-shelf TCR-T therapy.

In addition, we are using our target discovery platform to identify targets that cause T cell-driven autoimmune disorders. We have identified a set of indications in which T cells play a key role and are currently identifying targets and developing potential treatment options for these disorders. Initial indications include ankylosing spondylitis, ulcerative colitis, and scleroderma. Our current proprietary pipeline is summarized in the figure below.



In addition to our proprietary pipeline programs noted above, we have also entered into collaborations with strategic partners for applications of our platform technologies. We have a collaboration with Amgen Inc., or Amgen, to identify the antigens recognized by T cells in patients with Crohn's disease. Amgen will evaluate a variety of modalities to create therapeutic candidates based on targets discovered by us and will retain all global development and commercial rights.

Our Strategy

Our mission is to create life-changing T cell therapies for patients with cancer and autoimmune disorders. Our strategy includes the following key elements:

- ***Advance our lead product candidate, TSC-101, through clinical development.*** Our lead program, TSC-101, is designed to target HA-2 and we are currently enrolling patients in a Phase 1 clinical study of TSC-101 with over 20 clinical sites activated. In addition, through our heme program, we have established a foundation of manufacturing, clinical and regulatory capabilities to support the development of our broad portfolio of TCR-T therapy product candidates.
- ***Advance our* in vivo *solid tumor program through pre-clinical development.*** We are initially developing our solid tumor TCR-T therapy product candidates against three selected target antigens, HPV16, MAGE-A4, and PRAME, frequently expressed across multiple solid tumor types. We believe that the treatment of solid tumors will require a combination of therapeutic TCRs, which we refer to as 'multiplex therapy'. We have built a diverse collection of therapeutic TCRs that recognize cancer-specific targets, and are associated with multiple HLA types, to provide customized multiplex treatments for patients with solid tumor malignancies.
- ***Advance our autoimmune program through pre-clinical development.*** We are leveraging our target discovery platform to identify targets that cause T cell-driven autoimmune disorders. We have identified a set of indications in which T cells play a key role and are currently identifying targets and developing potential treatment options for these disorders. Initial indications include ankylosing spondylitis, ulcerative colitis, and scleroderma.
- ***Maintain manufacturing capabilities.*** We believe that in-house manufacturing capabilities substantially facilitate the successful early development of cell therapies. For our heme program, we have developed a non-viral gene delivery system based on transposons that are designed to enable cost-effective and consistent cell manufacturing with short development times. We have built an internal, fully operational GMP manufacturing facility that we believe provides

sufficient capacity to support our clinical program. Additionally, we have engaged a global CDMO with commercial capabilities to further increase manufacturing capacity for the heme program and prepare for potential commercial manufacturing.

- ***Develop next generation T cell engineering capabilities.*** We are developing off-the-shelf product candidates through *in vivo* engineering with the goal of providing customized multiplex TCR-T therapy to patients with a wide range of malignancies. We are in early stages of developing T cell engineering technologies and in-house manufacturing capabilities.
- ***Opportunistically pursue strategic partnerships and collaborations to maximize the full potential of our platform.*** Our platform represents a powerful tool to identify targets in therapeutic areas outside of oncology, such as autoimmune disorders. We intend to seek strategic partners with proven clinical development and commercialization capabilities for certain targets and/or assets that do not overlap with our internal programs or our core focus. To date, we have a research collaboration and license agreement with Amgen to identify the antigens recognized by T cells in patients with Crohn's disease. Under the terms of the agreement, we received a $30.0 million upfront payment and is eligible to earn success-based milestone payments of over $500 million, based upon the achievement of certain development and commercial milestones as well as tiered single-digit royalty payments on net sales of products developed from the collaboration. Amgen will evaluate a variety of modalities to create therapeutics based on targets discovered by us and will retain all global development and commercial rights to such therapeutics. We have also expanded our target discovery capabilities to include both CD8+ and CD4+ T-cells by engineering our platform to include class II antigen presentation. This capability allows for us to expand discovery efforts into T cell-mediated autoimmune disorders that have a strong Major Histocompatibility Complexes, or MHC, class II linkage. We intend to leverage this new capability to identify the pathogenic autoantigens driving T-cell mediated autoimmune disorders.

Background on T Cell Therapies

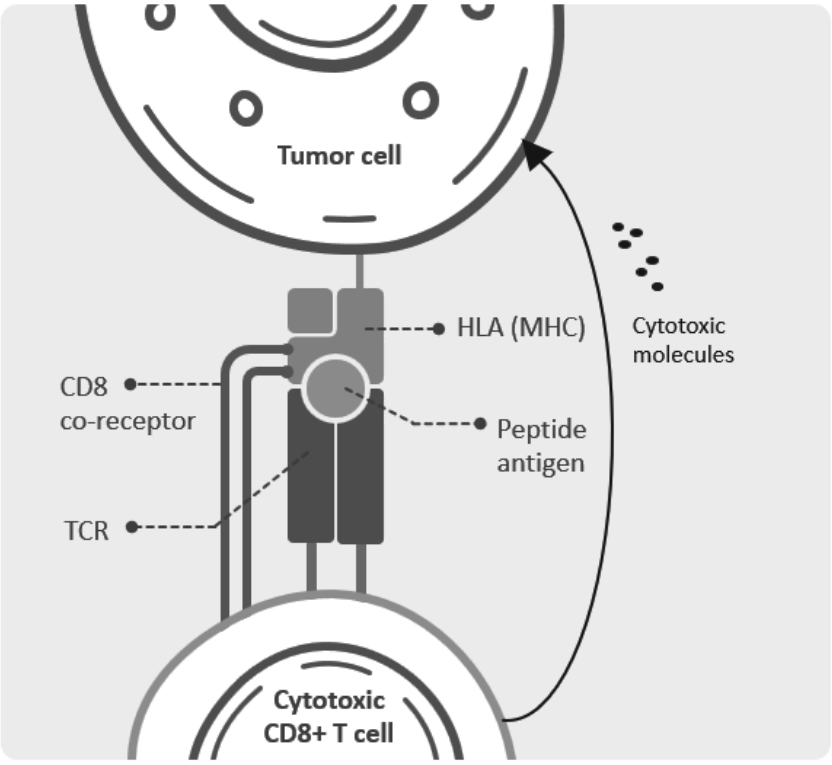
The human immune system constantly provides a natural and highly effective defense against cancer, which only forms when tumor cells find a way to evade the immune system. The treatment of cancer was revolutionized over a decade ago with the advent of immunotherapy – therapeutic approaches designed to re-enable or re-direct immune cells to recognize and fight cancer. Over the past 10 years, a suite of immuno-oncology drugs has been approved and adopted as part of routine clinical practice. Successes in immuno-oncology came initially from the approval of immune checkpoint inhibitors and more recently from the development of cellular therapies, such as CAR-T and TIL therapies. These therapies all harness the power of cytotoxic T cells in fighting both heme malignancies and solid tumors. Although these therapies have demonstrated compelling efficacy, they are only effective in a subset of patients. To address a broader patient population, we believe additional T cell-based approaches are needed that more closely mimic the way the immune system recognizes and fights cancer in patients who are responding to immunotherapy.

Overview of T Cell Biology

T cells are an essential component of the adaptive immune system and provide protection against cancer, infection, and autoimmune disorders. T cells are classically divided into two primary types of activating cells: helper T cells and cytotoxic T cells. Helper T cells, which express the CD4 co-receptor, function by providing signals to other immune cells for activation and recruitment. Cytotoxic T cells, which express the CD8 co-receptor, function by killing any cells in the human body that are expressing unnatural proteins, including proteins that are not expressed in normal tissue, proteins that arise from mutated genes, or proteins derived from pathogens. By definition, tumor cells are abnormal and make a wide variety of unnatural proteins. T cells are activated and exert their helper or cytotoxic function when their TCRs recognize antigens displayed on the surface of malignant or infected cells.

Virtually every cell in the body has a mechanism for displaying on its surface a sampling of every protein that is being made by the cell. This includes all normal proteins as well as aberrant proteins if the cell is cancerous or proteins from pathogens if the cell has been infected. Cellular proteins are broken down into short fragments, or peptides, by the proteasome, and these peptides are loaded into MHCs to be displayed on the outside of the cell. These peptide/MHC complexes are recognized by TCRs on cytotoxic CD8+ T cells, as shown in the graphic below. Because the TCR recognizes both the peptide and the MHC, a TCR only functions correctly when both the peptide and the correct MHC are present.

TCRs on Cytotoxic CD8+ T Cells Recognize the Peptide/MHC Complexes of Tumor Cells



MHC proteins, which present different peptides to the human immune system, are highly variable among people. An individual's MHC proteins are determined by their HLA type. Although there are many different HLA types, some are quite common. For example, 42% of individuals in the U.S. are positive for the HLA-A*02:01 allele, or variant. TCRs are often referred to as "HLA-restricted" because they are only able to interact with specific HLA types. For this reason, TCR-Ts harness the specificity of the TCR-peptide-MHC interaction to selectively target tumor cells.

Current Approaches to T Cell Therapy

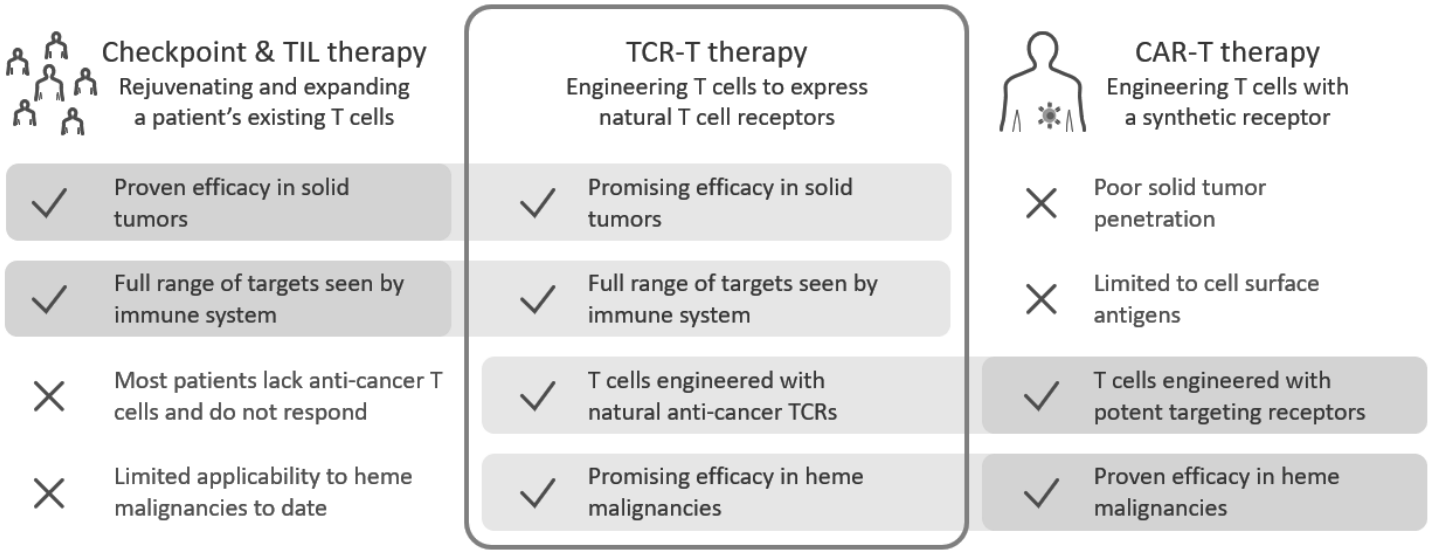
Multiple approaches are being explored to develop effective T cell-based therapies for the treatment of cancer. One approach is to isolate naturally occurring T cells from a patient's tumor, referred to as TILs, expand and activate those cells *ex vivo*, and then return them to the patient via intravenous infusion. Although the targets of these T cells are not known, it is presumed that T cells isolated from a tumor are enriched in T cells directed against cancer cells. This approach, however, depends on the anti-cancer T cells present in the patient. If the patient's TILs do not have appropriate anti-cancer specificities or if their anti-cancer TILs cannot be adequately expanded *ex vivo*, the therapy is unlikely to be effective.

A different approach that has proven effective in certain heme malignancies is to identify targets that are highly expressed on the surface of tumor cells, such as CD19. Antibody fragments that recognize these targets are used to create an artificial construct that links the antibody to key signaling elements required for T cell activation. The resulting CAR is incorporated genetically into a patient's T cells, thereby redirecting those cells to recognize and fight the patient's cancer. Although CAR-T therapies have been highly effective in certain tumor types, leading to multiple approved products, the benefit of these therapies and the addressable cancer indications have been limited by several factors. First, it is likely that there is a relatively limited set of truly tumor-specific cell surface antigens. In general, most antigens expressed on the surface of tumor cells are also expressed on normal cells, resulting in therapies that, even if effective, have a narrow therapeutic window and are vulnerable to potentially life-threatening toxicities. Second, CAR-T cells rely on antibody fragments that recognize cell-surface proteins, precluding intracellular proteins as potential targets. Third, CAR-T therapies generally do not efficiently penetrate solid tumors, which to date has limited their applicability to heme malignancies.

In contrast to CAR-T therapies, naturally occurring TCRs offer two important benefits compared to antibody-containing artificial receptors. First, TCRs are the natural receptors used by the T cell to recognize foreign antigens. As such, they are optimized

to stimulate the T cell appropriately when they engage their targets on a tumor cell. An appropriately stimulated T cell will not only kill the tumor cell, but also produce cytokines that stimulate other immune cells and make copies of itself, or proliferate, to further augment the immune response. Balancing all the cellular responses of a T cell is something that has been finely tuned over millions of years of evolution and is best mediated by naturally occurring TCRs, rather than by artificial constructs. Second, TCRs can recognize a much broader set of antigens, including peptides derived from both cell surface and intracellular proteins, whereas CARs are restricted to recognizing only cell surface proteins. MHC-I peptides are predominantly derived from intracellular proteins rather than extracellular proteins, which dramatically increases the universe of potential cancer-specific antigens that can be recognized by TCRs compared to CARs. We believe TCR-T therapy combines the benefits of TIL and CAR-T therapies while uniquely addressing their key limitations, as shown below.

Building on the Remarkable Success of Immunotherapy

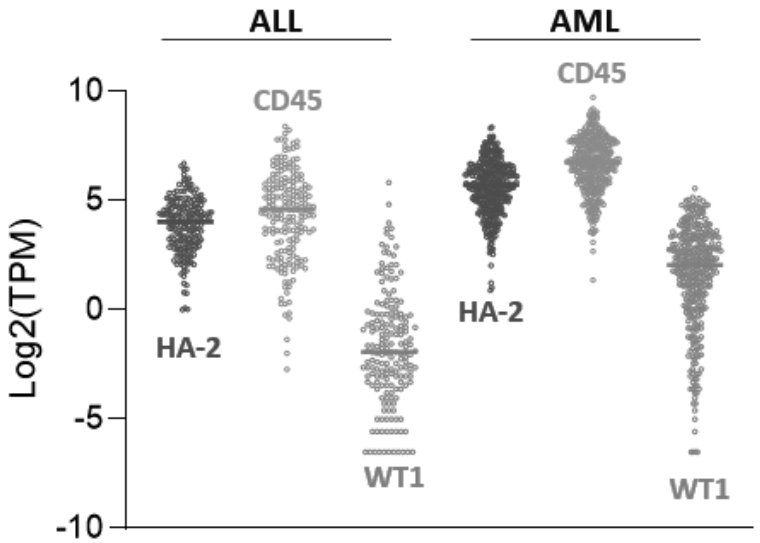


Our Heme Malignancies Program

We are developing our heme program for patients with hematologic malignancies undergoing allogeneic HCT. In the first phase of our clinical development strategy, we are initially focusing on HA-2, an antigen found on the blood cells of patients who are HLA-A*02:01 positive. Our program is based on the well-established observation that patients who are mismatched with their donors for patient-specific antigens, such as HA-2, and mount a T cell response against those antigens, show significantly lower relapse rates following HCT. By developing TSC-101, we aim to recreate this natural graft versus leukemia response to prevent relapse in patients undergoing HCT.

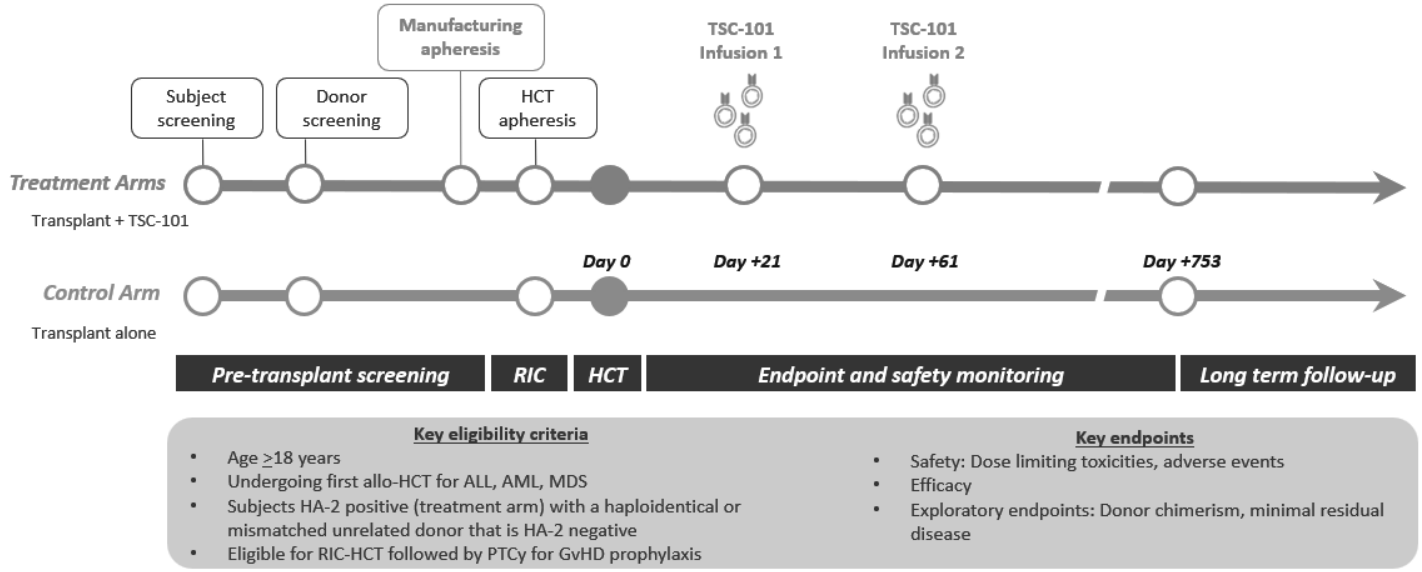
We are further expanding this program with the addition of TCRs targeting additional antigens across different HLA types. For example, TSC-102-A01 and TSC-102-A03, TCR-T therapy product candidates targeting CD45 in patients who are HLA-A*01:01- and HLA-A*03:01-positive, respectively.

Antigens like HA-2 and CD45 are distinct from other cancer-associated antigens such as WT1 previously targeted by TCR-Ts in heme malignancies. As shown below, cancer-associated antigens like WT1 have low and heterogenous expression and were previously selected so that normal blood cells in the patient would be spared. WT1-targeted TCR-Ts proved to have relatively poor efficacy in patients with ALL and AML, potentially due to the rapid emergence of resistant tumor cells that lacked WT1 expression and thus escaped killing by engineered T cells. HA-2 and CD45, in contrast, have high and homogenous expression, making it less likely for tumors cells to escape due to low antigen expression. Although HA-2 and CD45 are also expressed in normal blood cells, treating patients who are positive for the HLA types that present these antigens with HCT donors who are negative for those HLA types ensures that the engineered T cells selectively eliminate the patient's blood cells – malignant, pre-malignant, or normal – while sparing the healthy donor-derived normal blood cells. This strategy enables high levels of anti-cancer efficacy with potentially less risk of life-threatening toxicities to other cells in the body.



We are conducting a Phase 1 clinical trial of our lead TCR-T therapy product candidate, TSC-101, with patients enrolled in the treatment arm based on their genotype, as shown below. Patients who are positive for the target antigen, HA-2, as well as the HLA-A*02:01 allele (the HLA type required to display HA-2 on the cell surface for recognition by a T cell) are eligible for enrollment, provided they are paired with a donor who is negative for the HLA-A*02:01 allele.

ALLOHA™, a Phase 1 Trial Evaluating TSC-101 in Patients Undergoing Allo-HCT



Background on Heme Malignancies

HCT has become the standard of care for many heme malignancies. When a patient with leukemia undergoes HCT, they start by receiving a conditioning regimen of high dose chemotherapy with or without radiation. This regimen is intended to kill both the patient's leukemia cells as well as their native blood cells and blood cell precursors, including hematopoietic stem cells in their bone marrow. The patient then receives hematopoietic stem cells from an appropriately-matched donor. The stem cells engraft in their bone marrow and start to repopulate their body with new blood cells, which are now genetically identical to the donor. HCT has demonstrated the rare opportunity in cancer treatment to generate long-term remissions or cures. For example, patients with AML who receive HCT have a five-year post-transplant survival rate of up to 50%.

Approximately 5,600 allogeneic HCT procedures are performed yearly in the U.S. in patients with AML and MDS. As a curative therapy for many heme malignancies, use of HCT has been steadily increasing over the last two decades, with increased use driven largely by increasing donor qualification, an increase in disease prevalence due to aging populations, and alternative conditioning regimens permitting broader use in patients, including older and frailer patient segments. In addition, newer, more effective leukemia therapies continue to drive an increasing use of HCT in patients who previously failed to achieve proper remission prior to transplant.

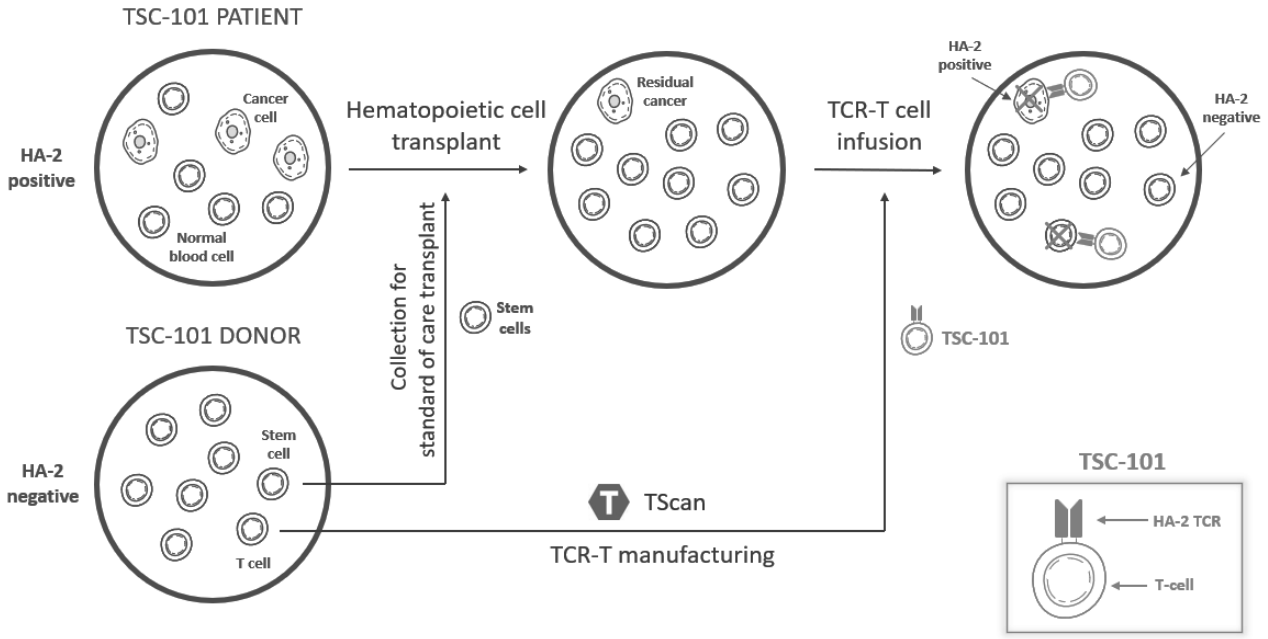
However, despite the increasing use of HCT, there are limited treatment options for patients who relapse post-HCT, and the prognosis is very poor. Clinical observations have shown that if the T cells of the donor recognize certain antigens in the patient's leukemia cells, but not the donor's blood cells, the T cells of the donor drive a specific graft vs. leukemia, or GvL, effect, whereby the engrafted donor T cells detect remaining leukemia as foreign and eliminate the remaining disease. As a result, the patient often experiences a long-term remission from their cancer, or even a complete cure. If the antigens are also expressed in non-hematopoietic tissues, the patient may develop graft vs. host disease, or GvHD, but if the antigens are only expressed in blood cells, a specific GvL effect is observed without an increase in GvHD. Our heme malignancies program is focused on targeting patient-specific antigens that are exclusively expressed in hematopoietic cells in order to induce the GvL effect while potentially mitigating the risk of GvHD.

TSC-101

TSC-101 is an allogeneic, donor derived TCR-T therapy product candidate directed at eliminating residual cancer cells in HA-2-positive and HLA-A*02:01-positive patients with heme malignancies who undergo HCT. The treatment includes selecting a donor who is HLA-A*02:01-negative. TSC-101 targets HA-2, which is an antigen derived from the protein MYO1G, and was selected as a product candidate based on its superior affinity, cytotoxic activity, and specificity compared to other potential TCR-T cell candidates we discovered.

The HA-2 antigen is highly prevalent, with approximately 95% of individuals in the U.S. being HA-2-positive. However, a specific HLA type, HLA-A*02:01, which is present in approximately 42% of individuals in the U.S., is required to display the HA-2 antigen on the cell surface for recognition by a T cell. As a result, approximately 40% of HCT patients would be positive for both HA-2 and HLA-A*02:01 and therefore be eligible for treatment with TSC-101 using a donor who is negative for HLA-A*02:01. Such donors are straightforward to identify and should be available to most patients who undergo half-matched (haploidentical) from a family member or mismatched unrelated donors (MMUD) identified through donor registries such as the National Marrow Donor Program (NMDP). A summary of the treatment paradigm for TSC-101 is shown below.

Patient Journey for TSC-101



TSC-102-A01 and TSC-102-A03

Like TSC-101, TSC-102-A01 and TSC-102-A03 are allogeneic, donor derived TCR-T therapy product candidates directed at eliminating residual cancer cells in patients with heme malignancies who are HLA-A*01:01- and HLA-A*03:01-positive, respectively, undergoing HCT using a donor who is negative for the HLA type. CD45, which is derived from the protein PTPRC, is an antigen that has been identified to be clinically relevant. For example, radiolabeled CD45 is in clinical trials for relapsed AML, and a CAR-T product candidate targeting CD45 with epitope-edited HSCs is in pre-clinical development. We are developing TSC-102-A01 and TSC-102-A03 based on highly active TCRs we discovered that recognize a CD45 antigen presented on HLA-A*01:01 and HLA-A*03:01, respectively. The FDA has cleared our IND applications for both TSC-102-A01 and TSC-102-A03, allowing us to initiate study start-up activities.

The CD45 antigen is expressed on all nucleated cells of hematopoietic origin. As with TSC-101, a specific HLA type is required to display the CD45 antigen on the cell surface. Donors who are negative for the HLA type are straightforward to identify and should be available to most patients who undergo HCT with haploidentical family members or MMUD identified through donor registries such as the NMDP.

Clinical Development Plan for Our Heme Malignancies Program

Background on Types of HCT

Patients with acute leukemias who undergo allogeneic HCT have heterogeneous outcomes that are primarily related to two main variables: (i) the intensity or doses of the conditioning regimen they receive prior to the stem cell infusion and (ii) the type of donor who provides the stem cells.

High-intensity conditioning regimens are called myeloablative conditioning and are associated with higher mortality rates. They are therefore reserved for young and relatively fit patients. Lower-intensity regimens are called reduced-intensity conditioning, or RIC, and are better tolerated, but are associated with higher relapse rates. Our heme malignancies TCR-T therapy product candidates are designed to substantially reduce relapse rates, and we are enrolling patients into our ongoing Phase 1 clinical trial who are eligible for RIC-based HCT with the goal of improving clinical outcomes for these patients.

There are different types of donors who are eligible for allogeneic HCT procedures. Donors who are siblings of the patient and are perfectly matched for eight out of eight HLA alleles are considered the highest priority donor type for patients undergoing allogeneic HCT, but these types of donors are available for less than a third of patients. For most patients, the choice is between an unrelated donor who is perfectly matched for eight out of eight HLA alleles, referred to as a matched unrelated donor, or MUD, or a family member such as a sibling or child who has a half-match with the patient, referred to as a haploidentical donor, or haplo. Historically, haplo donor transplantation was associated with much higher GvHD than MUD transplants, but a recent treatment regimen that uses chemotherapy given three days after stem cell infusion called post-transplantation cyclophosphamide, or PTCy, specifically kills immune cells that cause GvHD. As a result, haplo transplants with PTCy have recently achieved equivalent outcomes as MUD transplants and are rapidly increasing in usage in the U.S. and worldwide. Another recent advance is the recognition that transplants from 1-2 HLA mismatched unrelated donors (MMUD) have equivalent outcomes as fully HLA-matched MUD transplants when PTCy is used to prevent GvHD. The increasing use of alternative donors, such as MMUD and haplo donors for allo-transplants has not only greatly expanded donor availability, thereby enabling more patients to undergo transplant, but also makes it straightforward to identify donors negative for the HLA-A*02:01, HLA-A*01:01, or HLA-A*03:01 so that patients with those HLA-types could be treated with TSC-101, TSC-102-A01, or TSC-102-A03, respectively.

Phase 1 Clinical Trial

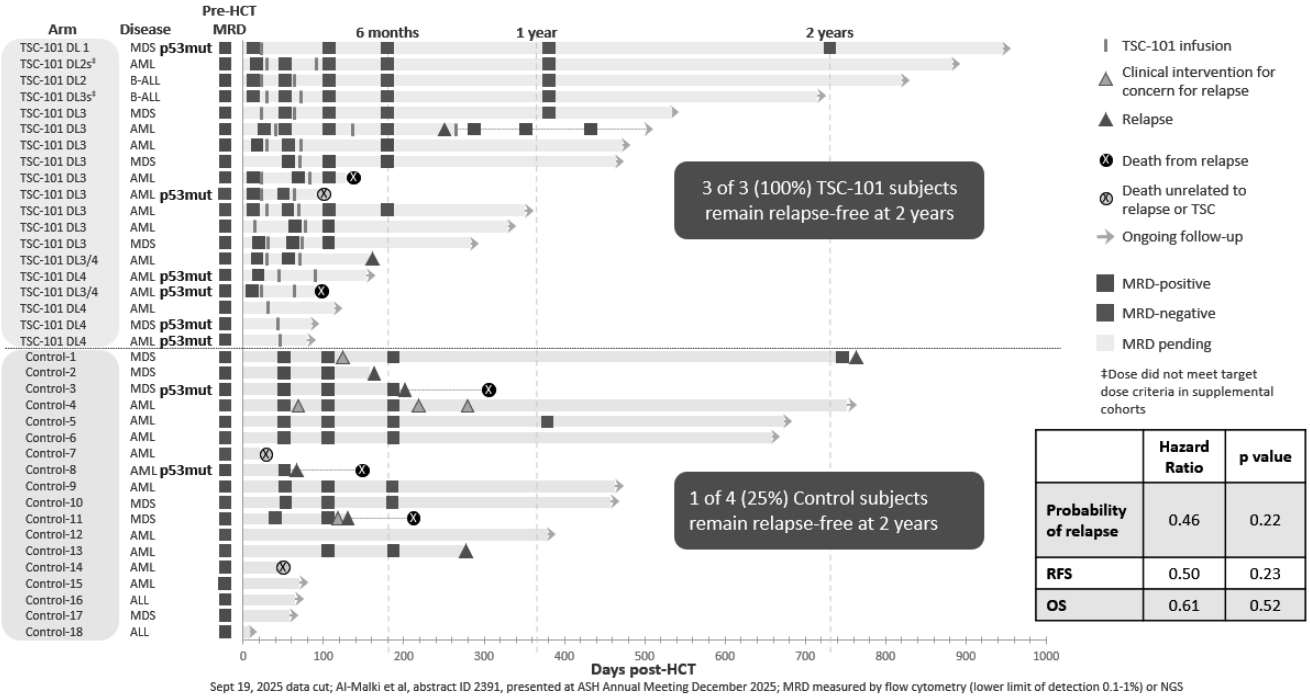
The clinical study for TSC-101 is well underway, within a Phase 1 clinical trial to investigate the safety and efficacy of TSC-101 in patients with AML, MDS, and ALL that are undergoing HCT following RIC. We are currently treating patients using a fixed dosing regimen (as compared to weight-based dosing) manufactured using our commercial-ready manufacturing process.

Our Phase 1 clinical trial is designed to include measurements of early surrogate markers of efficacy, such as donor chimerism, or the percentage of blood cells that are donor-derived, and whether patients continue to have detectable residual leukemia, referred to as minimal residual disease, or MRD, in their post-transplant bone marrow biopsy, both of which are predictors of relapse. We also included a genetically randomized control arm, comprising patients who do not meet the HLA or HA-2 genetic criteria and are treated with standard RIC-HCT alone. Comparisons of both safety and efficacy outcomes with this control arm will support transitioning the program to include a registrational trial required for a potential future biologics license application, or BLA, filing.

Clinical data

In December 2025, we reported updated results, dated as of September 19, 2025, from the ongoing ALLOHA™ Phase 1 trial, which we presented at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition. In that presentation, we reported that 42 patients had been enrolled in the trial and undergone HCT, with 23 in the TSC-101 treatment arm and 19 in the control arm. The key endpoints in the trial are safety and efficacy, with exploratory endpoints of donor chimerism and MRD.

As of the September 19, 2025 data cut, we have observed durable responses with 3 of 3 (100%) of patients 2-years post-HCT showing no evidence of disease, versus 1 of 4 (25%) in the control arm. In the treatment arm, 4 of 19 (21%) evaluable patients relapsed compared to 6 of 18 (33%) evaluable control-arm patients. Eight of 37 (22%) patients had TP53 mutations, with 6 cases in the treatment arm and 2 cases in the control arm. Of the 6 patients in the treatment arm, only 1 has relapsed. Both patients with TP53 mutations in the control arm have relapsed and subsequently succumbed to their disease. The first patient with a TP53 mutation to receive TSC-101 has now reached two years of follow-up and remains relapse-free. Relapse-free survival (HR=0.50; p=0.23) and overall survival (HR=0.61; p=0.52) favored the treatment arm.

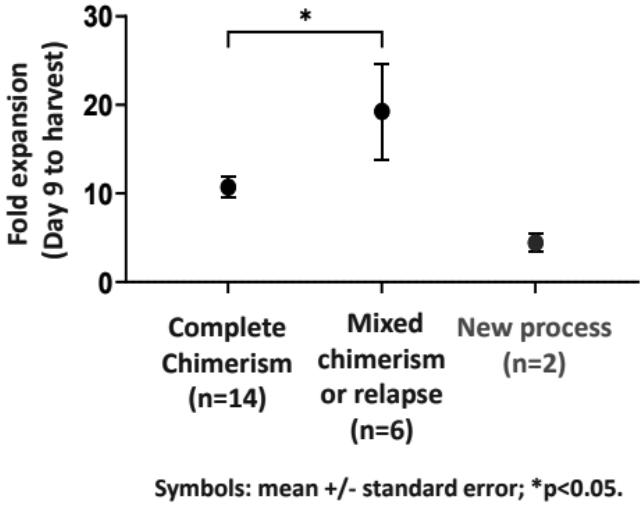


	Hazard Ratio	p value
Probability of relapse	0.46	0.22
RFS	0.50	0.23
OS	0.61	0.52

Sept 19, 2025 data cut; Al-Malki et al, abstract ID 2391, presented at ASH Annual Meeting December 2025; MRD measured by flow cytometry (lower limit of detection 0.1-1%) or NGS (lower limit of detection 0.05-0.1% in myeloid and 0.001-0.01% in lymphoid malignancies)

TSC-101 infusions were generally well-tolerated at all three dose levels with no dose-limiting toxicities. Observed adverse events were similar across the treatment and control arms and were generally consistent with post-HCT adverse events.

Mixed chimerism or relapses following TSC-101 infusions were found to be significantly associated with greater *ex vivo* expansion of TCR-T cells during the manufacturing process. A new commercial-ready process reduces the manufacturing time from 17 days to 12 days and has shown promising significant reduction in *ex vivo* expansion.



Anticipated timeline

In our Phase 1 clinical trial, we have now completed enrollment in Cohort C, where at least 10 patients will be treated with our commercial-ready manufacturing process at the highest dose level. We intend to share early data on these patients and subsequently initiate a registrational trial for TSC-101 using the commercial-ready manufacturing process, pending further feedback from regulatory authorities, in the second quarter of 2026. To expand our heme program, we recently filed investigational new drug (IND) applications with the U.S. Food and Drug Administration (FDA) for TSC-102-A01 and TSC-102-A03, TCR-T therapy product candidates targeting CD45 in patients who are HLA-A*01:01- and HLA-A*03:01-positive, respectively. The FDA has cleared our IND applications for TSC-102-A01 and TSC-102-A03, allowing us to initiate study start-up activities. We plan to initiate a Phase 1 study for both TSC-102 candidates in the second half of 2026.

Future market expansion opportunities

If TSC-101 demonstrates the ability to significantly reduce relapse rates after HCT, there could potentially be new opportunities to expand the curative potential of HCT combined with TSC products to greater numbers of patients. Currently, only about 5,600 patients with AML and MDS undergo allogeneic HCT per year in the U.S. out of approximately 35,000 patients diagnosed each year. There are two reasons for this relatively modest rate of transplant use. First, only patients who achieve a clinical complete remission (CR) are referred for HCT since the relapse rates of patients not in CR are considered too high to effectively use HCT. If HCT, combined with TSC-101, markedly reduces relapse rates, patients who do not achieve CR could possibly undergo HCT and benefit from its curative potential. This market expansion would require a separate clinical trial. Second, while RIC has enabled many more elderly and frail patients to undergo transplantation, the chemotherapy and radiation doses used for conditioning are still high and considered too toxic for most patients over the age of 65 or those with underlying comorbidities. This is because the conditioning regimen of HCT is considered the primary modality for eliminating residual leukemia cells and reducing doses further would result in greater relapse rates. If the relapse rates could be reduced by treatment with TSC-101 post HCT, however, a clinical trial could test the use of minimal intensity conditioning prior to HCT. If successful, this would further expand the curative potential of HCT combined with TSC-101 therapy to older, frailer patients. We could also expand the addressable market through the addition of TCRs for other HLA types, of which TSC-102-A01 and TSC-102-A03 are examples of this approach.

A final market expansion opportunity could occur from the use of TSC-101 as a chemotherapy and radiation-free conditioning regimen for non-malignant diseases such as sickle cell anemia which are currently treated with HCT. Since chemotherapy and radiation are associated with the risk of long-term toxicities such as cancer, heart damage, lung damage and infertility, cellular therapies such as TSC-101 could reduce those risks and increase the numbers of patients willing to undergo HCT for non-malignant diseases.

Our Solid Tumor Program

We are developing a portfolio of TCR-T therapy product candidates designed to be used in combination with each other to treat and eliminate solid tumors. Our solid tumor product candidates are designed to elicit an anti-tumor response in patients by targeting cancer-specific antigens in their tumor cells. Our TCR-T therapy product candidates include: (i) well-recognized cancer targets that have demonstrated anti-tumor activity in clinical trials as well as novel targets that were identified by our target discovery platform from the T cells of patients responding to immunotherapy and (ii) naturally occurring TCRs specific to a patient's HLA type that recognize these cancer-specific targets. Such targets are not only commonly shared among patients with the same cancer type, but also frequently expressed in multiple solid tumor types, enabling clinical development across multiple indications. Initial targets of interest include HPV16, MAGE-A4, and PRAME.

We have built a diverse collection of therapeutic TCRs that recognize cancer-specific targets to enable multiplex TCR-T therapy for patients with various types of solid tumors. We are currently engaged in preclinical development of an *in vivo* engineering platform to deliver off-the-shelf TCR-T therapy.

TCR-T Therapy Product Candidates for the Treatment of Solid Tumors

Immunotherapy has reshaped the treatment of solid tumors by demonstrating that tumor shrinkage, eradication, and long-term durable responses can be obtained by stimulating the patient's own immune system to attack their cancer cells. Immune checkpoint inhibitors, such as nivolumab or pembrolizumab, work by unleashing anti-cancer T cells that are already present in a patient's tumor, enabling those T cells to recognize and eliminate their cancer. For patients who respond to checkpoint inhibitors, these agents have been shown to be very effective. However, only a subset of patients responds to checkpoint inhibitors, highlighting the need for T cell-based therapies that can treat those patients who do not respond. Despite their efficacy in only a subset of patients, checkpoint inhibitors have annual sales of about $34 billion in the U.S.

One reason why patients may not respond to current immunotherapy treatment options is that they lack T cells with highly active TCRs that recognize the cancer-specific antigens in their tumors. By reprogramming the patient's own T cells to recognize these target antigens, we believe that we can expand the dramatic responses observed with checkpoint inhibitor therapy to the patients for whom these therapies have historically been ineffective. In addition, solid tumors are notoriously heterogeneous: not every cancer cell in a tumor expresses a given antigen. We believe that by targeting multiple antigens in a patient's tumor, we will be able to drive deep and durable responses. We have built a diverse collection of therapeutic TCRs to enable customized multiplex TCR-T therapy. We are currently engaged in preclinical development of an *in vivo* engineering platform to deliver off-the-shelf TCR-T therapy.

Development Plan for Our Solid Tumor Program

On November 3, 2025, following our alignment with the U.S. Food and Drug Administration (FDA) on the registrational path forward for the TSC-101 program, we made the strategic decision to prioritize clinical development of our heme program and pause further enrollment in our solid tumor Phase 1 trial (PLEXI-T™), while focusing our preclinical efforts on *in vivo* engineering for solid tumors. We treated seven patients at dose level 3 or higher with singleplex therapy and two patients with multiplex therapy in the PLEXI-T study. No dose-limiting toxicities were observed in these cohorts. Six of the seven patients treated with singleplex therapy received at least 6 billion cells over two infusions, administered 28 days apart. Of these patients, one (treated with the PRAME TCR) achieved a confirmed partial response, three achieved stable disease with varying degrees of tumor shrinkage (two with the PRAME TCR and one with the HPV-16 TCR), and the remaining two had progressive disease. Additionally, of the two patients that were treated with multiplexed therapy (HPV/PRAME and HPV/MAGE-A4), neither patient received the target dose of 4 billion cells of each TCR-T over two infusions, and both patients had evidence of disease progression. The inability to provide the target dose, coupled with the challenges associated with lymphodepletion and extended vein-to-vein times in the late-line disease setting, further reinforce our decision to focus on an *in vivo* engineering approach. We have now partnered with a third party specializing in the development of a lentiviral-based platform for *in vivo* engineering of T cells and believe this approach represents a promising, cost-efficient, and clinically tractable way to deliver off-the-shelf, multiplexed TCR-T therapies for solid tumors.

Our Autoimmune Program

Our primary focus is on the development of T cell therapies to treat cancer. However, T cells play a fundamental role in other disease areas. Many autoimmune disorders such as ankylosing spondylitis, ulcerative colitis and scleroderma are largely T cell-mediated, but with poorly defined instigating self-antigens. We believe our target discovery platform is well suited to identify self-antigens that cause T cell-driven autoimmune disorders. We are currently in early stages of identifying targets and developing potential treatment options for these disorders. We intend to build additional corporate value by opportunistically pursuing collaborations with strategic partners for applications of our platform outside our core focus areas.

License and Collaboration Agreements

Collaboration Agreement with Amgen

On May 8, 2023, we entered into a Research Collaboration and License Agreement with Amgen Inc. (Amgen), or the Amgen Agreement, to identify antigens recognized by T cells in patients with Crohn's disease utilizing our proprietary target discovery platform. Under the terms of the Amgen Agreement, Amgen will then evaluate a variety of modalities to create therapeutics based on targets discovered by us and will retain all global development and commercialization rights. Amgen made an upfront payment of $30.0 million to us, and we are eligible to earn success-based milestone payments of over $500 million based upon the achievement of certain development and commercial milestones, as well as tiered single-digit royalty payments on net sales of products developed from the collaboration, subject to reductions set forth in the Amgen Agreement.

Exclusive Patent License Agreement with BWH

On December 5, 2018, we entered into an Exclusive Patent License Agreement with The Brigham and Women's Hospital, Inc., or BWH, as amended on July 26, 2019 and further amended and restated on April 20, 2021, or, collectively, the BWH Agreement, pursuant to which we obtained an exclusive, sublicensable, worldwide license to practice under certain of BWH's patent rights for identifying T cell epitopes, which are relevant to our target discovery platform for identifying potential therapeutic products. The original 2018 BWH Agreement granted us the right to practice BWH's patent rights in a certain field of use, MHC Class I License Field. In connection with the amendment and restatement of the BWH Agreement in 2021, we expanded the field of use in which we are authorized to practice BWH's patent rights to include MHC Class II uses and applications in exchange for certain additional payments to BWH. We are obligated to use commercially reasonable efforts to develop and commercialize at least one product or process that practices the licensed patent rights and at least one therapeutic or diagnostic product or process directed to an epitope identified through practicing the licensed patent rights.

Upon execution of the amendment of the BWH Agreement dated April 20, 2021, we paid an additional one-time fee of $466,500. We are required to pay BWH up to an aggregate of $12.72 million upon the achievement of certain clinical, regulatory and sales milestones for therapeutic products and processes. We are obligated to pay a low double-digit percentage of all non-royalty income we receive under sublicenses of BWH's patent rights. We are also obligated to pay a low single-digit percentage of all non-royalty income we receive under agreements with third parties, or Collaborators, where we practice under BWH's patent rights in connection with the research or development of one or more therapeutic products or processes with or for such third party, or Collaboration Agreements. We are also obligated to pay tiered royalties in the high single-digit percentage range on annual net sales of products and processes that practice the licensed patent rights and in the low single-digit percentage range on annual net sales of therapeutic and diagnostic products and processes directed to an epitope identified through practicing the licensed patent rights (other than those sold by Collaborators), with the royalty percentage for such products and processes decreasing to lower than one-percent royalties if directed to epitopes identified through practicing the licensed patent rights after December 31, 2019. For therapeutic and diagnostic products and processes directed to an epitope identified through practicing the licensed patent rights and sold by a Collaborator, we are obligated to pay lower than one-percent royalties of the Collaborator's annual net sales of such products and processes. For products and processes sold by us, our affiliates or sublicensees, such royalties only apply to products and processes directed to epitopes in a defined field of use MHC Class I field identified prior to December 31, 2022, and products and processes based on epitopes in the MHC Class II field identified prior to September 30, 2023. For products or processes directed to epitopes identified under a Collaboration Agreement, such royalties apply regardless of when the epitopes were identified. For each applicable product or process, the royalty term continues until the tenth (10th) anniversary of the first commercial sale of such product or process. The royalty rates are also subject to reduction upon certain other events. Within 60 days of each anniversary of December 5th, we are obligated to pay BWH a non-refundable, mid-five-figure minimum annual royalty, which amount is creditable against royalties subsequently due on net sales of products and processes in such calendar year.

The BWH Agreement will terminate upon the later of (a) the last to expire or abandoned valid claim within the licensed patents, and (b) one year after the last sale for which a royalty is due. The current expected expiration date for the last-to-expire licensed patent right is June 8, 2038 (absent any adjustments or extensions of term). We also have the right to terminate the BWH Agreement in its entirety or on a country-by-country basis, for any reason upon 90 days' prior written notice to BWH. BWH may terminate the BWH

Agreement: (i) without notice if we fail to maintain insurance required by the BWH Agreement; (ii) upon notice within 60 days of our bankruptcy; (iii) upon notice within 60 days after notice by BWH of our default in the performance of any obligation under the BWH Agreement that is not cured within such 60-day period; (iv) if we fail to make any payments due under the BWH Agreement and do not cure such failure within 10 days after receiving BWH notice thereof; or (v) if we or any of our affiliates challenge the validity, enforceability or scope of any of the patent rights licensed to us under the BWH Agreement.

Non-Exclusive License Agreement with Provincial Health Services Authority

On October 15, 2020, we entered into a Non-Exclusive License Agreement with the Provincial Health Services Authority of British Columbia, or PHSA, and such agreement, the PHSA Agreement. Pursuant to the PHSA Agreement, we obtained a non-exclusive, perpetual, non-transferable, sublicensable, worldwide license to practice certain of PHSA's patent rights for identifying T cell epitopes, which epitopes are relevant to our platform for identifying potential TCR-T therapy product candidates. Any sublicenses we grant to PHSA's patent rights must also include a license of our own intellectual property; we are not permitted to sublicense PHSA's rights on a standalone basis.

Pursuant to the PHSA Agreement, we paid PHSA a one-time, non-refundable upfront fee of $500,000 as well as reimbursement for previously incurred patent prosecution costs of approximately $50,000. Starting on the first anniversary of the effective date of the PHSA Agreement and continuing for five years thereafter, we are required to pay PHSA a mid-five-figure annual license fee, of which the first installment has been paid. In addition, we are obligated to pay a mid-six-figure fee for each sublicense and each further sublicense granted by one of our sublicensees or a sublicensee of our sublicensee (through multiple tiers) of the rights granted to us under the PHSA Agreement.

The PHSA Agreement will terminate upon the last to expire patent licensed under the PHSA Agreement. We also have the right to terminate the PHSA Agreement at any time, but such termination will not be effective until the later of (a) October 16, 2023, and (b) the date we have paid PHSA total aggregate fees equal to the upfront fee plus five years of annual license fees totaling $750,000. PHSA may terminate the PHSA Agreement upon giving us two separate written notices at least 30 days apart if: (i) we or any of our affiliates challenge the validity, enforceability or scope of any of the patents licensed to us under the PHSA Agreement; (ii) we owe unpaid fees due under the PHSA Agreement in excess of $100,000; or (iii) we breach material terms of the PHSA Agreement regarding sublicense restrictions (such as failing to pay the sublicense fee or sublicensing PHSA technology on a standalone basis) or our obligation to indemnify PHSA for damages resulting from our research or commercialization of PHSA's patent rights and, in each case described above, such termination will be effective only if we fail to cure such breach after receiving PHSA's two separate notices.

Royalty Agreement

In connection with our incorporation in April 2018, we entered into a royalty agreement with one of our founders. We amended and restated this royalty agreement in June 2018, and our founder assigned his rights and obligations under the royalty agreement to one of his affiliated entities in January 2021. Pursuant to the royalty agreement, we are required to pay him a royalty of 1% of net sales (as defined in the royalty agreement) of any product sold by us or by any of our direct or indirect licensees for use in the treatment of any disease or disorder covered by a pending patent application or issued patent held or controlled by us as of the last date that the founder was providing services to us as a director or consultant under a written agreement. Royalties are payable with respect to each applicable product on a country-by-country and product-by-product basis, beginning on the first commercial sale of the first royalty-bearing product and ending on the later of (i) the date on which the exploitation of such royalty-bearing product is no longer covered by such patent in such country or (ii) the 15th anniversary of the first commercial sale of the first royalty-bearing product in such country. We may not assign our rights and obligations under the royalty agreement except in the event of a change in control relating to our company. The term of the royalty agreement continues until expiration of the last applicable royalty term.

Manufacturing

We have built in-house cell therapy manufacturing capabilities as one of the key components of our platform. The manufacturing of cell therapies requires the integration of several distinct components. Primary human blood cells are the source of T cells, along with a vector that delivers the desired genetic elements into these T cells. To provide an operationally flexible and cost-effective approach for our heme program, we have developed a manufacturing platform to genetically engineer T cells using a transposon/transposase system.

We have designed our heme program to use a transposon vector and corresponding transposase enzyme, which is derived from sfR fall armyworm, to deliver our TCRs into the genome of T cells. Our transposon/transposase system effectively inserts our TCRs and exogenous genes, such as CD8, at random locations in the genome. The transposon is delivered as a Nanoplasmid™ and has no antibiotic selection element, reducing the risk of inadvertent transmission of antibiotic resistance into T cells. The transposase is

delivered as mRNA. mRNA is transiently expressed in the cell, reducing exposure of cells to prolonged transposase activity, which could result in multiple transposition events where the transposon would be moved around the genome.

We have developed a manufacturing process currently producing product for our clinical program, using industry standard equipment and instrumentation. The equipment and instrumentation used in our manufacturing facility allows for functionally closed processes in a small footprint. For clinical product manufacturing, we use single-use consumables as well as process reagents that are available from well-established vendors who specialize in supplying clinical grade reagents for the cell and gene therapy industry. Our TCR-T therapy product candidates are released and characterized using well-developed analytical methods. The final product used in clinical studies is cryopreserved, simplifying logistics to support patient dosing. We have controls and safeguards throughout the entire process to ensure product identity, integrity, sterility, and chain of custody. A clearly defined and documented manufacturing process, performed by trained operators in an appropriately designed, commissioned, and operated manufacturing facility is critical for the manufacturing of safe, effective, and well-characterized cell therapies.

Our cell product manufacturing facility in Waltham, MA has been designed and built to support multiple programs through Phase 1 and Phase 2 clinical development. We believe internalizing our manufacturing process and product testing enables us to better control this key aspect of clinical development and reduces the risk of program delay due to third-party reliance. We continue to refine our manufacturing process to ensure it is commercially viable with focus on cost, consistency, and manufacturing success rate. We have engaged a CDMO with global capabilities to support increased capacity and potential commercial manufacturing.

Competition

We believe our diverse collection of therapeutic TCRs and our in-house cell therapy expertise constitute a meaningful competitive advantage in successfully developing novel and highly safe and effective treatments for cancer. However, the biopharmaceutical industry in general, and the cell therapy field in particular, is characterized by rapidly advancing and changing technologies, intense competition, and a strong emphasis on intellectual property. We face substantial and increasing competition from many different sources, including large and specialty biopharmaceutical companies, academic research institutions, governmental agencies, and public and private research institutions. Competitors may compete with us in hiring scientific and management personnel, establishing clinical study sites, recruiting patients to participate in clinical trials, and acquiring technologies complementary to, or necessary for, our programs.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of TCR-based or cell-based therapies for the treatment of cancer. We expect to compete with a number of other TCR-based companies, utilizing both cell therapy and other therapeutic modalities, such as Immatics N.V., Adaptimmune Therapeutics, Plc. (who sold their cell therapy assets to US WorldMeds, LLC in July 2025), Affini-T Therapeutics, Inc., Medigene AG (who initiated insolvency proceedings in April 2025), T-Knife GmbH, Immunocore Holdings, Plc., and 3T Biosciences Inc. We may also face competition from companies focused on other T cell therapies (e.g., TIL, CAR-T, gammadelta T cells) such as Iovance Biotherapeutics, Inc., Instil Bio, Inc., Kite Pharma, Inc., a subsidiary of Gilead, Inc. (including Yescarta, which is approved for the treatment for large B cell lymphoma or follicular lymphoma, two types of non-Hodgkin lymphoma), Juno Therapeutics, Inc., a subsidiary of Bristol-Myers Squibb, Inc., Regeneron Pharmaceuticals, Inc., through their acquisition of 2seventy Bio, Inc.'s research pipeline, AstraZeneca plc, through their acquisition of Gracell Biotechnologies, Inc., Legend Biotech Corporation, Autolus Therapeutics plc, Sana Biotechnology, Inc., Lyell Immunopharma, Inc., Allogene Therapeutics, Inc., Century Therapeutics, Inc., Arcellx, Inc., and Adicet Bio, Inc. There are also companies utilizing other cell-based approaches that may be competitive to our product candidates. For example, companies such as Takeda Pharmaceutical Company, Ltd. (who announced the discontinuation of all cell therapy initiatives in October 2025), Celyad, S.A., ImmunityBio, Inc., Celularity, Inc., Fate Therapeutics, Inc., and Nkarta, Inc. are developing therapies that target and/or engineer natural killer, or NK, cells. In addition, for our lead program, TSC-101, we may face competition from BlueSphere Bio, IN8bio, Inc., Orca Biosystems, Inc., Fred Hutchinson Cancer Center partnered with Promicell Therapeutics Inc., and Marker Therapeutics, Inc., who are also developing cell therapies in the post-HCT setting. The named companies are not fully inclusive of all possible competitive threats.

Furthermore, we also face competition more broadly across the oncology market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation, and drug therapy, including chemotherapy, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, immunotherapy, cell-based therapy, and targeted therapy, or a combination of any such treatments. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our TCR-T therapy product candidates, if any are approved, may compete with these existing drugs and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our TCR-T therapy product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. As a result, obtaining market acceptance of, and gaining a significant share of the market for, and commanding a certain price for any of our TCR-T therapy product candidates that we successfully introduce to the market may pose challenges. In addition, many companies are developing new oncology therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through preclinical and clinical development.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive, are more accessible, or receive a more favorable label than our TCR-T therapy product candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our TCR-T therapy product candidates, if approved, are likely to be their efficacy, safety, convenience, accessibility, price, and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Our success depends in part on our ability to obtain, maintain and protect our proprietary technology and intellectual property and proprietary rights and to operate our business without infringing, misappropriating and otherwise violating the intellectual property and proprietary rights of third parties. We rely on a combination of patent applications, trademarks, trade secrets, and other intellectual property rights and measures to protect the intellectual property rights that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position. We also seek to protect our proprietary rights by entering into confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to our proprietary information. The steps we have taken to protect our trade secrets, trademarks, patent applications and other intellectual property and proprietary rights may not be adequate, and third parties could infringe, misappropriate or misuse our intellectual property. If this were to occur, it could harm our reputation and adversely affect our business, competitive position, financial condition or results of operations.

As of the date hereof, our patent portfolio includes a patent family exclusively licensed from BWH, including 2 granted U.S. patents, a pending U.S. non-provisional patent application, and multiple foreign granted patents and non-provisional patent applications, relating to methods and compositions for identifying target antigens specific to T cells. In addition, we have filed applications in multiple patent families including multiple pending U.S. provisional patent applications, multiple granted foreign patents, and more than 200 pending international and foreign patent applications. The claims of these patent applications are directed toward various aspects of our therapy candidates and research programs, including compositions of matter and uses thereof directed to SARS-CoV-2 immunodominant antigens, anti-SARS-CoV-2 TCRs, anti-SARS-CoV-2 vaccines, anti-HA-2 TCRs (including the TSC-101 TCR-T therapy product candidate), anti-CD45 TCRs (including the TSC-102 TCR-T therapy product candidate), anti-HPV TCRs (including the TSC-200 TCR-T therapy product candidate), anti-MAGE-C2 TCRs (including the TSC-201 TCR-T therapy product candidate), anti-MAGE-A4 TCRs (including the TSC-202 TCR-T therapy product candidate), anti-PRAME TCRs (including the TSC-203 TCR-T therapy product candidate), and anti-MAGE-A1 TCRs (including the TSC-204 TCR-T therapy product candidate), as well as platform technologies including a phospholipid scrambling reporter-based T cell antigen screening platform and certain screening methods thereof, and a TCR multiplexing platform and certain therapeutic methods thereof. These patent applications, if issued, are expected to expire on various dates from 2038 through 2046, in each case without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid.

Heme Malignancies Program Product Patent Families

We have filed multiple patent families encompassing pending U.S. and foreign patent applications covering aspects of our heme malignancies programs including claims to the composition-of-matter and uses thereof of TSC-101, and other anti-HA-2 TCRs, anti-CD45 TCRs, and related T cell therapies. We expect the issued Australian and Singaporean patents, as well as any additional patents within these families, if issued, to expire no earlier than 2041 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

Solid Tumor Program Product Patent Families

We have filed multiple patent families encompassing pending U.S. and foreign patent applications covering aspects of our solid tumor programs including claims to the composition-of-matter of anti-HPV, anti-MAGE-C2, anti-MAGE-A4, anti-PRAME, anti-MAGE-A1 TCRs, and related T cell therapies. We expect the issued Australian patents, as well as any additional patents within these families, if issued, to expire no earlier than 2042 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

Infectious Disease Product Patent Families

We have filed multiple patent families encompassing pending U.S. and foreign patent applications covering aspects of our infectious disease programs including claims to the composition-of-matter of SARS-CoV-2 immunodominant antigens, anti-SARS-CoV-2 TCRs, and the composition-of-matter of certain SARS-CoV-2 vaccines. We expect the issued Australian and Democratic Republic of the Congo patents, as well as any additional patents within these families, if issued, to expire no earlier than 2041 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid). Certain of these pending patent applications are jointly owned by us and AHS Hospital Corporation, or AHS. AHS has exclusively licensed their interest in such patent applications to us.

Platform Technology

We have filed a patent family encompassing pending U.S. and foreign patent applications covering aspects of our reporter-based T cell antigen screening platform. We expect any claims within this family, if issued, to expire no earlier than 2041 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

In addition, we have filed several patent families encompassing pending U.S. and foreign patent applications covering certain multiplexed TCR compositions and certain therapeutic methods thereof. We expect any claims within these families, if issued, to expire no earlier than 2043 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid).

Our pending patent applications may not result in issued patents and we can give no assurance that any patents that might issue in the future will protect our products or provide us with any competitive advantage. Moreover, U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we generally intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. For more information regarding the risks related to our intellectual property, please see “Item 1A. Risk Factors—Risks Related to Our Intellectual Property” in this Annual Report.

Third-Party Intellectual Property Rights

For certain aspects of our business, we rely on certain technology and intellectual property rights that we in-license from third parties. We have an exclusive patent license from BWH to a patent family directed to aspects of a granzyme B (GzB)-based antigen screening technology platform, as well as compositions-of-matter and certain screening methods thereof (consisting of two granted U.S. patents, one pending U.S. patent application, a granted patent in each of Australia, France, Germany, Great Britain, Netherlands, Switzerland, two granted patents in Japan, and six foreign patent applications pending in Australia, Canada, China, Europe, Hong Kong, and Japan). Any patents issuing from the U.S. and foreign patent applications are expected to expire no earlier than 2038 (without taking into account any possible patent term adjustments or extensions and assuming that appropriate maintenance and governmental fees are paid). We also have a non-exclusive, perpetual, non-transferable patent license from PHSA to a patent family directed to granzyme-based antigen screening methods consisting of an issued U.S. patent that is expected to expire on August 4, 2035 (assuming that appropriate maintenance and governmental fees are paid) and issued Canadian patent that is expected to expire March 25, 2035 (assuming that appropriate maintenance and governmental fees are paid).

As of the date hereof, we own or have rights to U.S. and foreign trademark registrations and applications that cover certain aspects of our business.

Government Regulation

FDA Regulation and Marketing Approval

In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or FDCA, and biologics under the Public Health Service Act, the regulations promulgated under both laws and other federal, state, and local statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions and non-approval of product candidates. These sanctions could include, among other things, the imposition by the FDA of a clinical hold on trials, the FDA’s refusal to approve pending applications or related supplements, withdrawal of an approval, untitled or warning letters, product recalls, product seizures,

total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties, or criminal prosecution. Such actions by government agencies could also require us to expend a large amount of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, approval, manufacture, distribution and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of our products. Our drugs must be approved by the FDA as biologics through the BLA approval process applicable to gene therapy product candidates before they may be legally marketed in the U.S.

Within the FDA, the FDA's Center for Biologics Evaluation and Research, or CBER, regulates gene therapy products and has published guidance documents with respect to the development of these types of products. The FDA also has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy INDs.

The process required by the FDA before a biologic may be marketed in the U.S. generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practice, or GLP, or other applicable regulations;
- submission of an IND application, which allows clinical trials to begin unless the FDA objects within 30 days;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use or uses conducted in accordance with FDA regulations and Good Clinical Practices, or GCP, which are international ethical and scientific quality standards meant to ensure that the rights, safety and well-being of trial participants are protected, and that the integrity of the data is maintained;
- preparation and submission to the FDA of a BLA;
- submission of a user fee for FDA review of the BLA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of pre-approval inspection of manufacturing facilities and clinical trial sites at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements, and if applicable, the FDA's current Good Tissue Practice, or cGTP, requirements, and of selected clinical trial sites to assess compliance with GCP requirements; and
- FDA approval of a BLA which must occur before a biologic can be marketed or sold.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND application.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with, or cGMP, requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop 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 drug candidate does not undergo unacceptable deterioration over its shelf life.

IND Application and Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Prior to commencing the first clinical trial, an initial IND application, which contains the results of preclinical testing along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol, must be submitted to the FDA. The IND application 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 drug product or the conduct of the clinical trial and imposes a clinical hold. A clinical hold may also be imposed at any time while the IND application is in effect. In such a case, the IND application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin or re-commence. Accordingly, submission of an IND application may or may not result in the FDA allowing clinical trials to commence or continue.

In addition to the submission of an IND application to the FDA before initiation of a clinical trial in the U.S., certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the National Institutes for Health, or NIH, Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an Institutional Biosafety Committee (IBC), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND application. If a foreign clinical trial is not conducted under an IND application, the sponsor may submit data from the clinical trial to the FDA in support of a BLA or IND application so long as the clinical trial is conducted in compliance with GCP, and the FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary.

A separate submission to the existing IND application must be made for each successive clinical trial to be conducted during product development. Further, an independent Institutional Review Board, or IRB, for each site at which the clinical trial will be conducted must review and approve the clinical trial before it commences at that site. Informed written consent must also be obtained from each trial subject. Regulatory authorities including the FDA, or IRB, or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access to certain data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Human clinical trials for BLA approval typically involve a three-phase process, although some phases may overlap, be combined, or in some cases, be deemed unnecessary to establish safety and efficacy. Phase 1, the initial clinical evaluation, generally involves of administering the drug and testing for safety and tolerated dosages, and in some indications, such as rare disease, generates preliminary evidence of efficacy in humans. Phase 2 generally involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. Phase 3 clinical trials generally consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit-to-risk index of the investigational drug in relationship to the disease treated. In March 2022, the FDA released a final guidance, "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 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. Expansion cohort trials can potentially bring efficiency to drug development and reduce developmental costs and time.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The results of preclinical and human clinical testing are submitted to the FDA in the form of a BLA for approval to commence commercial sales. Our clinical trials may not be completed

successfully within any specified period, or at all. Government regulation may delay or prevent marketing of product candidates or new drugs for a considerable period of time and impose costly procedures upon our activities.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved up to a maximum of two years. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The Biologics License Application Approval Process

In order to obtain approval to market a drug in the U.S., a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. The application includes all relevant data available from pertinent non-clinical or preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators that meet GCP requirements.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND application, at the End-of-Phase 1 or 2, and before a Biologics License Application, or BLA, is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development.

The results of product development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product for its intended indication. The FDA reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept a BLA for filing. In this event, the BLA must be resubmitted with the additional requested information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA has 60 days from its receipt of a BLA to conduct an initial review to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA reviews a BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA has agreed to specific performance goals on the review of BLA's. Specifically, under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, as amended, the FDA has ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission. After the FDA completes its substantive review of a BLA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the BLA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, non-clinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application or the timing of any such approval, if ever. If or when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA may issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and, if so, 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 a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. For a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with current Good Tissue Practice, or cGTP. These are FDA regulations

that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through appropriate screening and testing. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 or post-approval trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency. See "Post-Marketing Requirements" below.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy, or REMS, from manufacturers to ensure that the benefits of a drug outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the BLA submission. The need for a REMS is determined as part of the review of the BLA. Based on statutory standards, elements of a REMS may include "Dear Doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases distribution and use restrictions, referred to as elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. These elements are negotiated as part of the BLA approval, and in some cases the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or use, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, including safety labeling or imposition of a REMS, the requirement to conduct post-market studies or clinical trials or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, a portion of a product's U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND application (falling after issuance of the patent) and the submission date of a BLA, plus the time between the submission date of a BLA and the approval of that application, provided that the sponsor acted with diligence. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Market Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-approved reference biological product. Bio-similarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product be biosimilar to the reference product, and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biological product is granted four- and 12-year exclusivity periods from the time of first licensure of the product. FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until 12 years after the date of first licensure of the reference product. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. "First licensure" typically means the initial date the particular product at issue was approved in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously approved product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

In addition, under the Orphan Drug Act, the FDA may designate a biological product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the U.S., or more in cases in which there is no reasonable expectation that the cost of developing and making a biologic product available in the U.S. for treatment of the disease or condition will be recovered from sales of the product). Orphan product designation must be requested before submitting a BLA. After FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by FDA. Orphan product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, meaning that the FDA may not approve any other applications to market the same drug or biologic product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the party holding the exclusivity fails to assure the availability of sufficient quantities of the drug to meet the needs of patients with the disease or condition for which the drug was designated. Competitors, however, may receive approval of different products for the same indication than that for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan medicinal product status in the EU has similar, but not identical, benefits.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months to existing exclusivity periods for all formulations, dosage forms, and indications of the biologic. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, the FDA incentivizes the development of drugs and biological products that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the U.S. or affects more than 200,000 in the U.S. and for which there is no reasonable expectation that the cost of developing and making in the U.S. a drug or biological product for such disease or condition will be received from sales in the U.S. of such drug or biological product. The sponsor of a product 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 or biological product application after the date of approval of the rare pediatric disease drug or biological product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its BLA. 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 statutory provisions, the FDA may not award a PRV for an approved rare pediatric disease product application after September 30, 2029, although the FDA's authority to do so could be extended by Congress in the future.

Expedited Development and Review Programs

The FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, the sponsor of a biologic product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND application. Biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track BLA before the application is complete, a process known as rolling review.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as regenerative medicine advanced therapy, or RMAT, designation, priority review and accelerated approval. To qualify for RMAT designation, the product candidate must be a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21 of the Code of Federal Regulations; is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. A gene therapy product may meet the definition of a regenerative medicine therapy for purposes of RMAT designation. A BLA for a product candidate that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

A product candidate including one that received Fast Track or RMAT designation is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition compared to available therapies. The FDA aims to complete its review of priority review applications within six months of the filing date, compared to 10 months for standard review.

Additionally, a biologic product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to 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, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials intended for 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. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Additionally, under FDORA, a platform technology incorporated within or utilized by a biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a biological product approved under a BLA; (2) preliminary evidence submitted by the sponsor of the licensed biological product, or a sponsor that has been granted a right of reference to data submitted in the application for such biological product, demonstrates that the platform

technology has the potential to be incorporated in, or utilized by, more than one biological product without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the biological product development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a biological product that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA for a biological product that uses or incorporates the platform technology. Designated platform technology status does not ensure that a biological product will be developed more quickly or receive FDA approval. In addition, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling, or off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may, in their independent professional medical judgment, prescribe legally available drugs for off-label uses, manufacturers typically may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, a part of the FDCA. Additionally, under FDORA, sponsors of approved biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

In the U.S., once a product is approved, its manufacturing is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs 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 cGMP and other laws. Additionally, manufacturers and other parties involved in the supply chain for prescription drug products must also comply with product tracking and racing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such product or may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, the manufacturer and/or holder of an approved BLA are subject to annual product and establishment fees. These fees are typically increased annually.

The FDA also may require post-marketing testing, also known as Phase 4 testing, to monitor the effects of an approved product or place conditions on an approval via a REMS that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, withdrawal of approval, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government

requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Coverage and Reimbursement

Sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors, including government healthcare program administrative authorities, managed care organizations, private health insurers, and other entities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, our products, once approved, may not obtain market acceptance unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products.

In the U.S., no uniform policy of coverage and reimbursement for drug or biological products exists. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved. Moreover, a third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

The containment of healthcare costs has become a priority of federal, state, and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for drug products and medical services, examining the medical necessity, and reviewing the cost effectiveness of drug products and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

The American Recovery and Reinvestment Act of 2009 provided funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates, once approved. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be significantly lower.

Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the U.S., among other things, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA,

including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (HHS) (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General and other state and local government agencies. Our current and future business activities, including for example, sales, marketing, and scientific/educational grant programs must comply with healthcare regulatory laws, as applicable, which may include the Federal Anti-Kickback Statute, the Federal False Claims Act, as amended, the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, as amended, physician payment transparency laws, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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 Federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, in cash or in kind, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the Federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal False Claims Act. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, and the potential for additional legal or regulatory change in this area, it is possible that our future business activities, including our sales and marketing practices and/or our future relationships with physicians and the medical community might be challenged under anti-kickback laws, which could harm us.

Federal false claims and false statement laws, including the civil False Claims Act, prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. For example, pharmaceutical companies have been found liable under the Federal Civil False Claims Act in connection with their off-label promotion of drugs. Penalties for a civil False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the Federal Civil False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

Additionally, HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing, or covering up a material fact or making any material false, fictitious, or fraudulent 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.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. For example, federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs. In addition, as discussed below, a similar federal requirement under the Physician Payments Sunshine Act, requires certain manufacturers to track and report to the federal government certain payments provided to physicians, certain other licensed health care practitioners and teaching hospitals made in the previous calendar year, as well as certain ownership and investment interests held by physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other licensed healthcare practitioners, and their immediate family members. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information on certain types of individuals and organizations. 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. In addition, there may be other federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

The failure to comply with regulatory requirements subjects us to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, refusal to allow us to enter into supply contracts, including government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the law and program requirements to which we will or may become subject because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs.

Changes in law or the interpretation of existing law could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (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.

Healthcare Legislative Reform

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts 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; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted since the ACA was enacted.

- The Budget Control Act of 2011, which, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. Subsequent legislation extended the 2% reduction which remains in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025; however legislation has been introduced in the U.S. Congress that would, if enacted, reverse these payment reductions. In addition to provider payment cuts under Medicare, the American Rescue Plan Act of 2021 also eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed 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 a federal level, President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 entitled "Lowering Prescription Drug Costs for Americans." President Trump may issue new executive orders designed to impact drug pricing. A number of these and other proposed measures may require authorization through additional legislation to become effective. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022 (IRA) includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 which began in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. 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 until January 1, 2032 the implementation of the HHS rebate rule that would have limited 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 orphan designation and for which the only approved indication is for that disease or condition. Under the One Big Beautiful Bill Act of 2025, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The outcome of these challenges on the IRA, and the effects of the IRA on our business and the healthcare industry in general are not yet known.

On April 15, 2025, the Trump administration published Executive Order 14273, "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the federal government to take measures to reduce drug prices, including eliminating the so-called "pill penalty" under the Inflation Reduction Act that creates a distinction between small molecule and large molecule products for purposes of determining when a drug may be eligible for drug price negotiation. On May 12, 2025, the Trump administration published Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which generally, among other things, directs the federal government to establish and communicate most-favored-nation (MFN) price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations. Further, the Executive Order directs the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. It also states that the Administration will take additional aggressive action (for example, examining whether marketing approvals should be modified or rescinded or opening the door for individual drug importation waivers) should manufacturers fail to offer American consumers the MFN lowest price. It also directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Notably, a similar "Most Favored Nation" pricing rule enacted under the first Trump administration was subject to an injunction resulting from judicial challenges to the rule, which was formally rescinded by the former Biden Administration in August 2021.

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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards (PDABs) and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits (UPLs) on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

European Union Drug Review and Approval

Clinical Trial Approval

In the EU, an applicant for authorization of a clinical trial must obtain prior approval from the national competent authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the relevant independent ethics committee has issued a favorable opinion. In April 2014, the EU adopted the Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. It overhauls the system of approvals for clinical trials in the EU. Specifically, the Clinical Trials Regulation, which is directly applicable in all EU Member States (meaning that no national implementing legislation in each EU Member State is required), aims at simplifying and streamlining the approval of clinical trials in the EU. For instance, it provides for a streamlined application procedure via a single-entry point (instead of submitting applications separately to each national competent authority and ethics committee in the Member States in which the trial will be conducted) and strictly defined deadlines for the assessment of clinical trial applications. The Clinical Trials Regulation also makes it more efficient for EU Member States to evaluate and authorize applications together, via the Clinical Trials Information System. The transitory provisions of the Clinical Trials Regulation provide that, by January 31, 2025, all ongoing clinical trials must have transitioned to the Clinical Trials Regulation.

Marketing Authorization

In the EU, medicinal products can only be commercialized after obtaining a marketing authorization. There are two types of marketing authorizations: (1) the centralized authorization, which is issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, a body of the EMA, and which is valid throughout the entire territory of the European Economic Area, or EEA (comprising the EU Member States plus Norway, Iceland and Liechtenstein); and (2) national marketing authorizations, which are issued by the competent authorities of the Member States and only authorize marketing in that Member State's national territory and not the EEA as a whole.

The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy medicinal products (i.e., gene-therapy, somatic cell-therapy, and tissue-engineered medicines) and medicinal products containing a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune disorders and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU. The EMA is responsible for the scientific evaluation of marketing authorization applications in the centralized procedure. The maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days from receipt of a valid application, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an application considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

National marketing authorizations are for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in a Member State of the EU, this marketing authorization can be recognized in another Member State through the mutual recognition procedure. If the product has not received a national marketing authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the Member States in which an authorization is sought, one of which is selected by the applicant as the Reference Member State, or RMS. If the RMS proposes to authorize the product, and the other Member States do not raise objections, the product is granted a national marketing authorization in all the Member States where the authorization was sought.

Under the above-described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EU make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

Regulatory exclusivity

In the EU, innovative products authorized for marketing (i.e., reference products) may 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. The ten-year market exclusivity period can be extended to a maximum of 11 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. Even if an innovative medicinal product gains the prescribed period of data exclusivity, however, another company may market another version of the product if such company obtained marketing authorization based on a marketing authorization application with a complete and independent data package of pharmaceutical tests, preclinical tests, and clinical trials.

Orphan designation and exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the U.S. Under Regulation (EC) 141/2000, a medicinal product may be designated as an orphan product if the following criteria are fulfilled: (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) 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 (iii) 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, as defined in Regulation (EC) 847/2000. 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 therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity period 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. Otherwise, during the period of market exclusivity, a marketing authorization may only be granted in the EU to a "similar medicinal product" to the authorized orphan product for the same therapeutic indication if:

- a second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective, or otherwise clinically superior;
- the marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or
- the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal 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.

PRIME designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage product development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (i.e., there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicine will bring a major therapeutic advantage) and they must show potential to benefit patients with unmet medical needs based on early clinical data. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's CHMP or Committee for Advanced Therapies are appointed early in PRIME

scheme facilitating increased understanding of the product at the EMA's committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

All of the aforementioned EU rules are generally applicable in the EEA.

Reform of the Regulatory Framework in the European Union

The European Commission 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). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval, and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law.

Regulatory Framework in the United Kingdom

At present, the UK has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). The regulatory regime in the UK therefore largely aligns with current EU regulations, however it is possible that these regimes will diverge in the future now that the UK's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, the EU Clinical Trials Regulation does not apply in the UK and the current UK clinical trials legislation is based on the now repealed Clinical Trials Directive 2001/20/EC. However, on December 12, 2024, the UK government introduced a legislative proposal – the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024 – that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK and increase the transparency of clinical trials conducted in the UK. This includes a notification scheme to enable lower-risk clinical trials to be automatically approved by the MHRA, where the risk is similar to that of standard medical care (although such trials would still require ethics committee approval). Such regulations are expected to come into force in early 2026. Notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new framework put in place by the MHRA on January 1, 2024, the MHRA may take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for UK marketing authorizations.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, and the medicines aspects of the Windsor Framework have applied since January 1, 2025. This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA is now responsible for approving all medicinal products destined for the UK market (Great Britain and Northern Ireland), and the EMA no longer has any role in approving medicinal products destined for Northern Ireland under the EU centralized procedure. 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, the new arrangements require all medicines placed on the UK market to be labeled "UK only", indicating they are not for sale in the EU.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to

hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Human Capital

As of February 27, 2026, we had 142 full-time employees and 0 part-time employees, 29 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 112 employees are engaged in research and development activities and 30 are engaged in finance, business development and other general and administrative functions. None of our employees are represented by labor unions or covered by collective bargaining agreements, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset, and we aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical trials, our pipeline, our platform technologies, business and operations, and also protect the long-term interests of our securityholders.

Our success also depends on our ability to attract, engage and retain a diverse group of employees. Our efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value innovation, passion, data-driven decision making, persistence and honesty, and are building a diverse environment where our employees can thrive and be inspired to make exceptional contributions to bring novel and more effective therapies to cancer patients.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, motivating and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards, in order to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives. We are committed to providing a competitive and comprehensive benefits package to our employees. Our benefits package provides a balance of protection along with the flexibility to meet the individual health and wellness needs of our employees. We plan to continue to refine our efforts related to optimizing our use of human capital as we grow, including improvements in the way we hire, develop, motivate and retain employees.

Facilities

Our corporate headquarters is located at 830 Winter Street in Waltham, Massachusetts. The facility at 830 Winter Street is 51,100 square feet consisting of GMP clean room, laboratory, warehouse and office space, with a lease expiration of October 2029. We also lease a facility at 880 Winter Street which is 113,487 square feet of office and laboratory space with a lease termination date of December 2032.

We believe that these facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Available Information

Our website address is https://www.tscan.com/. The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we have filed or may file with the Securities and Exchange Commission, or SEC, and any reference to our website address is intended to be an inactive textual reference only. We will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC maintains an Internet site, http://www.sec.gov, containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

In addition, we routinely post on the "Investors and Media" page of our website investor and scientific presentations, SEC filings, press releases, public conference calls and webcasts and other statements about our business and results of operations, some of which may contain information that may be deemed material to investors. Accordingly, investors should monitor these portions of our website, in addition to following our press releases, SEC filings, public conference calls and webcasts, as well as our social media channels (LinkedIn and X). This list of channels may be updated from time to time on our investor relations website and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

A copy of our Corporate Governance Guidelines, and Code of Conduct are posted on our website, https://www.tscan.com and are available in print to any person who requests copies by contacting us by calling (857) 399-9500 or by writing to TScan Therapeutics, Inc., 830 Winter Street, Waltham, Massachusetts 02451, Attention: Zoran Zdraveski.

Item 1A. Risk Factors

Our business involves a high degree of risk. You should carefully consider the material and other risks and uncertainties described and summarized below, as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Special Note Regarding Forward-Looking Statements," as well as our other filings with the SEC, before you make an investment decision. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K. The risks described below are not the only risks that we face. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

RISK FACTORS

Risks Related to Our Business and Industry

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 biotechnology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates and have initiated clinical trials for certain of our product candidates. We have no products licensed for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through equity issuances, borrowings under secured loan agreements and upfront payments under our existing or previous collaborations.

We have incurred significant net losses in each period since our inception in April 2018. For the years ended December 31, 2025, 2024, and 2023, we reported net losses of $129.8 million, $127.5 million, and $89.2 million, respectively. As of December 31, 2025, we had an accumulated deficit of $504.9 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:

- continue our research and development efforts to identify and develop product candidates and submit additional IND applications for such product candidates;
- conduct preclinical studies and commence and complete clinical trials for our current and future product candidates based on our proprietary platform;
- develop processes suitable for manufacturing and clinical development;
- continue to develop and expand our manufacturing capabilities;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- build commercial infrastructure to support sales and marketing for our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional personnel; and
- continue to operate as a public company.

Because of the numerous risks and uncertainties associated with biotechnology product research and development, we are unable to accurately predict the timing or amount of the increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development expenses and other expenditures to develop, seek regulatory approval for, and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors 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 our stockholders' equity and working capital.

Our business depends upon the success of our proprietary platform.

Our success depends on our ability to use our proprietary platform (i) to discover the natural targets of clinically relevant TCRs, (ii) to discover highly active TCRs for known targets, (iii) to genetically engineer patient- or donor-derived T cells safely and reproducibly, (iv) to obtain regulatory approval for product candidates derived from our proprietary platform and related technologies, and (v) to then commercialize our product candidates that address one or more indications. All of our product candidates will require significant additional clinical and non-clinical development, review and approval by the FDA or other regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Some of our product candidates are currently being evaluated in humans and may never become commercialized. Moreover, our current product candidates leverage the same or similar technology and use the same or similar manufacturing processes. As a result, an issue with one product candidate could adversely impact our ability to successfully develop and commercialize other product candidates, particularly ones within the same clinical program.

In addition, the success of our proprietary platform in discovering novel targets for TCR-T therapy product candidates is dependent on us obtaining tumor samples from cancer patients who actively respond to cancer immunotherapies. If our ability to obtain a significant amount of such tumor samples in a timely manner is compromised due to unforeseen circumstances, we may not be successful in discovering novel targets and creating new product candidates based on such targets.

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

We are a clinical-stage biotechnology company with a limited operating history. We commenced operations in April 2018, and our operations to date have been limited to organizing and staffing our Company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and initiating clinical trials, entering into licenses and collaborations, establishing capabilities to manufacture our product candidates, and establishing arrangements for component materials for such manufacturing. Although we have initiated clinical trials for certain of our product candidates, we have not yet demonstrated our ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture clinical or 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 about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

We have never generated any revenue from sales of our TCR-T therapy product candidates and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from sales of any of our product candidates. We do not expect to generate significant revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Although we have initiated clinical trials for certain of our product candidates, we have not yet demonstrated an ability to successfully complete clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization to enable us to generate any revenue from product sales. Our other product candidates are in various stages of preclinical development and, as such, we face significant translational risk as we work to advance these product candidates to the clinical stage. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- our ability to develop processes suitable for clinical manufacturing and to obtain related chemistry, manufacturing, and controls (CMC) regulatory approvals;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to continue to complete IND-enabling studies and to continue to successfully submit INDs or comparable applications;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, potency, purity and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues, including adverse events, experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates to treat patients;
- our ability and the ability of our third-party contractors to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, to remain in good standing with regulatory authorities and to

develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practice (cGMP);

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the U.S. and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if licensed; and
- our ability to establish, obtain, maintain, protect and enforce intellectual property and proprietary rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates, if approved. If we are unable to raise this necessary capital when needed, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.

Since our inception, we have financed our operations through equity issuances, upfront payments under our collaborations and through our debt financings. The development of biotechnology product candidates is capital intensive and we expect our expenses to increase substantially during the next few years. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

As of December 31, 2025, we had $152.4 million in cash and cash equivalents. We believe that our existing cash and cash equivalents will enable us to fund our current operating plan into the second half of 2027. Accordingly, our existing cash and cash equivalents will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We may also need to raise additional funds sooner if we choose to pursue additional indications for our product candidates or otherwise expand more rapidly than we presently anticipate.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, costs and results of our drug discovery, preclinical or clinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities and our ability to scale them up or out;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost, timing and outcome of regulatory review of our product candidates, including the potential for regulatory authorities to require that we conduct more studies and trials than those that we currently expect to conduct and the costs of post-marketing studies or risk evaluation and mitigation strategies that could be required by regulatory authorities;
- potential changes in the regulatory environment and enforcement rules;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining, obtaining, protecting and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims;
- our ability to establish new and maintain existing licensing or collaboration arrangements and the progress of the development efforts of third parties with whom we may enter into such arrangements;
- the impact of any public health crises or other external disruptions on our business, results of operations, development plans (including any supply related matters) and financial position;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the costs associated with being a public company; and
- the cost associated with commercializing our product candidates, if they receive marketing approval.

Identifying potential product candidates and conducting preclinical studies 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. In addition, our product candidates, if approved, may not achieve product sales or commercial success. We do not expect to have any products commercially available for sale for many years, if at all. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, limit, reduce or eliminate our research and development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of management from day-to-day activities and distract from our research and development efforts. We may also seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our intellectual property or product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through collaboration arrangements, public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other strategic alliances and licensing arrangements or any combination of these approaches. However, there can be no assurance that we will be able to raise capital on commercially reasonable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholder ownership interest will be diluted, and the terms may include liquidation preferences or other rights, powers or preferences that may adversely affect rights of our stockholders. To the extent that debt financing is available, and we choose to raise additional capital in the form of debt, such debt financing may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital

expenditures or declaring dividends. If we raise additional capital pursuant to collaborations, licensing arrangements or other strategic partnerships, such agreements may require us to relinquish rights to our technologies or product candidates.

If we are unable to raise additional funds through equity or debt financings, or through collaborations, licensing arrangements or strategic partnerships or other sources when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts.

Global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts could make it more difficult for us to access financing and could adversely affect our business and operations.

Our ability to raise capital is subject to the risk of adverse changes in the market value of our stock. Periods of macroeconomic weakness or recession and heightened market volatility caused by adverse geopolitical developments could increase these risks, potentially resulting in adverse impacts on our ability to raise further capital on favorable terms. The impact of geopolitical tension, such as a deterioration in the bilateral relationship between the U.S. and China or in the ongoing conflicts between Russia and Ukraine, and in the Middle East, including resulting sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries could also lead to disruption, instability and volatility in global trade patterns, which may in turn impact our ability to source necessary reagents, raw materials and other inputs for our research and development operations.

In addition, political developments impacting government spending and international trade, including changes in trade agreements, potential government shutdowns, trade disputes and tariffs, including tariffs that have been or may in the future be imposed by the U.S. or other countries and future legislation or actions taken by the U.S. or other countries that restrict trade, and protectionist or retaliatory measures taken by the U.S. or other countries, may negatively impact markets and cause weaker macroeconomic conditions. For example, in 2025, the U.S. imposed substantial tariffs on imports from its trading partners, including, without limitation, Canada, Mexico, the EU and China. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. While certain tariffs were subsequently suspended, modified, or temporarily reduced, and the U.S. Supreme Court ruling in February 2026 invalidated many of the tariffs imposed by the Trump administration, the Trump administration immediately imposed new tariffs based on different statutory authority. The impact of tariffs has already been seen, and we expect will continue to be seen, in global markets. In addition, the Trump administration has expressed an intent to impose tariffs on pharmaceutical imports, with the stated policy objective of reshoring pharmaceutical manufacturing to the United States. Among other means, such tariffs may be imposed by the United States under Section 232 of the Trade Expansion Act of 1962, as amended, pursuant to which the U.S. Department of Commerce recently initiated an investigation to determine the effects of importing pharmaceuticals and pharmaceutical ingredients on national security. Historically, tariffs have led to increased trade and political tensions. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of any political instability and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section. We are continuing to monitor global capital markets and assessing the potential impact of these factors on our business.

The U.S. Congress and the Trump administration have made and may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

Since the start of the Trump administration in 2025, there have been significant changes to U.S. trade, healthcare, tax, immigration and government regulatory policy. For example, the U.S. government has imposed substantial tariffs on most countries throughout the world and, despite the February 2026 U.S. Supreme Court ruling invalidating many of the tariffs imposed in 2025, has further threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any future administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may impact our liquidity, limit our ability to

grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, respond to business challenges or opportunities, develop new products, retain or expand our current levels of personnel, support our programs, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements, including clinical manufacturing capacity;
- support our discovery and preclinical development activities, and clinical trials for our product candidates;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. If we are unable to obtain adequate financing or financing on terms satisfactory to us, we could face significant limitations on our ability to invest in our operations and otherwise suffer harm to our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Although we are not a borrower or party to any financial instruments with any financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or

- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a supplier may determine that it will no longer deal with us as a customer. In addition, a supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any supplier bankruptcy or insolvency, or any breach or default by a supplier, or the loss of any significant supplier relationships, could result in material losses to us and may material adverse impacts on our business.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

On December 20, 2024 (the SVB Loan Effective Date), we entered into a Loan and Security Agreement (SVB Loan Agreement) with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (SVB), pursuant to which, SVB will extend up to $52.5 million in a term loan facility, of which $32.5 million was fully funded at the SVB Loan Effective Date. A second tranche of $20.0 million may be funded at SVB's sole discretion on or prior to June 30, 2026. Our obligations under the SVB Loan Agreement, are secured by a first-priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions and will be guaranteed by each of our future direct or indirect subsidiaries, subject to certain exceptions. The SVB Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our and our subsidiaries' ability to, among other things, dispose of assets, make changes to its business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, grant liens on its assets, pay dividends or other distributions, repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain thresholds and exceptions. The SVB Loan Agreement does not require us to comply with a financial maintenance covenant. Upon the occurrence of an event of default, a default interest rate of an additional 3% may be applied to the outstanding loan balance at the sole discretion of SVB and SVB may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the SVB Loan Agreement and under applicable law. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We have recently reduced the size of our organization, and we may encounter difficulties in managing this development and our strategic prioritization, which could disrupt our operations. In addition, we may not achieve the anticipated benefits and savings from the workforce reduction.

On November 3, 2025, the Company announced a prioritization strategy and pursuant to this strategy, the Company also implemented a workforce reduction of approximately 30%, or 66 roles. The workforce reduction that will accompany our prioritization strategy will result in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. The restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. In addition, we may not achieve anticipated benefits from the workforce reduction. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, further loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition and workforce reduction and additional cost containment measures, our expenses may be more than expected and we may not be able to implement our

business strategy. As a result, our future financial performance and our ability to commercialize our future product candidates successfully could be negatively affected.

Risks Related to the Development of Our Product Candidates

Our approach to the discovery and development of product candidates based on our proprietary platform represents a novel approach to cancer treatment, which creates significant challenges for us.

Our future success depends on the successful development of our product candidates, which target heme malignancies and solid tumors utilizing TCR-T therapy product candidates. Advancing our product candidates creates significant challenges for us, including:

- educating medical personnel about the administration of TCR-T therapy product candidates on a stand-alone basis or in combination with built-in immune and tumor modulators;
- educating medical personnel regarding the potential side effect profile related to our product candidates, such as the potential adverse side effects related to cytokine release syndrome, graft vs host disease (GvHD), neurotoxicity or autoimmune or rheumatologic disorders, which are the most common adverse side effects associated with engineered T cell therapies;
- administering chemotherapy to patients in advance of administering our product candidates, which may increase the risk of adverse side effects;
- sourcing clinical and, if licensed, commercial, supplies for the materials used to manufacture and process our product candidates;
- manufacturing TCR-T therapy product candidates efficiently and consistently without the use of viral vectors using our T-Integrate technology;
- developing a complete shipment lifecycle and supply chain, including efficiently managing the shipment of patient cells from and to clinical sites, minimizing potential contamination to the cell product and effectively scaling manufacturing capacity to meet demand;
- developing processes suitable for clinical manufacturing and obtaining related CMC regulatory approvals;
- managing costs of inputs and other supplies while scaling production;
- using medicines to manage adverse side effects of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the potency of our product candidates;
- using medicines to manage adverse side effects of chemotherapy and/or allogeneic stem cell transplantation, used prior to the administration of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the potency of our product candidates;
- obtaining and maintaining regulatory approval from the FDA or comparable foreign regulatory authority for our product candidates; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

In developing our product candidates, we have not exhaustively explored different options in the design of the TCR construct and in the method for manufacturing TCR-T therapies. We may find that our existing TCR-T therapy product candidates and manufacturing process may be substantially improved with future design or process changes, necessitating development of new or additional TCR constructs and further clinical testing, which may delay the commercial launch of our product candidates. For example:

- We have made several TCR constructs and used preclinical studies to select product candidates to advance into clinical trials. The preclinical studies are limited in their ability to predict behavior in patients. As we gain experience working with TCR constructs, we may decide to select other TCR constructs for clinical development.
- The process by which patient cells are converted into a TCR-T therapy product candidate has many steps that can influence quality and activity.
- Our efforts to develop an *in vivo* engineering platform for TCR-T therapies for solid tumors are at a very early stage, and it may take substantial time and investment for us to develop this novel capability, and we may not ultimately be successful in doing so.

We have explored a subset of variables and expect to continue to improve and optimize the manufacturing process. Depending upon the nature of the process changes, we may be compelled to perform bridging studies and/or to re-start clinical development, causing delays in time to market and potentially introducing a risk of failure if new processes do not perform as expected.

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

We are early in our development efforts. We have initiated clinical trials for a number of our product candidates, and other product candidates are still in preclinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend significantly on the successful development and eventual commercialization of one or more of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful development of a process suitable for clinical manufacturing;
- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of marketing approvals and licensures from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or expanding our manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of our product candidates following licensure; and
- effectively competing with other therapies including other cancer therapies.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business.

Although many of our personnel have extensive experience in clinical development and manufacturing at other companies, we have limited direct experience as a company in conducting clinical trials and managing a manufacturing facility for our product candidates.

Although many of our personnel have extensive experience in clinical development and manufacturing at other companies, we have limited experience as a company in conducting clinical trials at TScan. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies or clinical trials will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs) and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control.

Although we have expanded our existing cell manufacturing facility, we have limited direct experience as a company in expanding or managing a manufacturing facility. In part because of this lack of experience, we cannot be certain that any further expansion of our existing manufacturing facility will be completed on time, if at all, or if the planned clinical trials will begin or be completed on time, if at all. In part because of our inexperience, we may have unacceptable or inconsistent product quality success rates and yields, and we may be unable to maintain adequate quality control, quality assurance and qualified personnel. In addition, when we switch from manufacturing in our own facility to manufacturing in a different facility (for example, at an external CDMO) for one or more of our product candidates or make changes to our manufacturing process, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Failure to successfully further expand our existing manufacturing capabilities could adversely affect our process and clinical development timelines, regulatory approvals, and the commercial viability of our product candidates.

Our business is highly dependent on our current product candidates, and we must complete IND-enabling studies and clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates.

There is no guarantee that any of our product candidates will proceed through preclinical or clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned or, if at all.

There is no guarantee that the results obtained in current and planned preclinical studies or clinical trials of our current or future product candidates will be sufficient to obtain regulatory approval or marketing authorization for such product candidates. Negative results in the development of our lead product candidates may also impact our ability to obtain regulatory approval for our other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying proprietary platform, manufacturing process and development process is the same for all of our product candidates. Accordingly, a failure in any one of our programs may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidates, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular current or future product candidate, we may relinquish valuable rights to those product candidates through collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates.

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency and purity profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency and purity necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, potency and purity of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety, potency or purity results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

We cannot be certain that our ongoing and future preclinical study and clinical trial results will be sufficient to support regulatory approval of our product candidates. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Failure or delay can occur at any time during the clinical trial process.

We may experience delays in obtaining the FDA's authorization to initiate clinical trials under future IND applications, completing ongoing preclinical studies of our other product candidates, and initiating or completing our planned preclinical studies and clinical trials. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board (IRB) approval at each clinical trial site;
- recruiting or retaining an adequate number of suitable patients to participate in a clinical trial;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from the approved clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other product candidates;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- any public health crises may hinder our development or commercialization activities;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- our current or future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

For example, we are planning a registrational trial for TSC-101, and based on feedback from regulatory authorities, we may need to modify our clinical trial design or may be delayed in initiating such trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the data safety monitoring board for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our business could be adversely affected by the effects of health epidemics in regions where we, our partners or other third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.

Public health crises such as pandemics, epidemics, or similar outbreaks could adversely impact our business. For example, our materials suppliers could be disrupted by conditions related to epidemics, possibly resulting in disruption to our supply chain. If our suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. Even when such public health crises are largely resolved, the lingering effects of such crises may continue to adversely affect our business operations, and the extent of the impact on our development and regulatory efforts and the future value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time.

We may rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our product candidates, if licensed.

We have established facilities and engaged third-party contract manufacturers to manufacture our current product candidates. We rely on outside vendors to manufacture supplies for our manufacturing process, and we expect to rely on outside vendors to help us manufacture our product candidates for registration-enabling additional clinical trials as well as commercial sales. We have not yet manufactured or processed any product candidates on a commercial scale and may not be able to do so. We plan to optimize the existing manufacturing process to support product commercialization. The process modifications we intend to introduce will require regulatory approval of our product candidates, which could delay the commercialization of the products. We cannot be sure that such changes in the process will result in therapies that are efficacious and viable for commercial sale. In addition, changes in the manufacturing process may result in the need to conduct additional bridging clinical trials to demonstrate product comparability.

The facilities used by us or any third-party contract manufacturers to manufacture and commercialize our product candidates must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit a Biologics License Application (BLA) to the FDA or other foreign regulatory authorities to support commercialization. We may not control the manufacturing process of, and may be completely dependent on, third-party contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. We have limited control over the ability of any third-party contract manufacturers we engage to maintain adequate quality control, quality assurance and qualified personnel. Even with oversight, the third party may not be able to meet proper quality standards or its contractual obligations. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if licensed.

We, and any third-party contract manufacturers we engage to support our clinical trials, may experience manufacturing difficulties due to limited manufacturing experience, resource constraints or as a result of labor disputes, geopolitical and economic tensions with China, including as a result of the escalation of tariffs or other trade restrictions under the Trump administration, or unstable political environments. The pharmaceutical industry in general, and our suppliers or other third parties on which we rely, may depend on China-based suppliers for certain raw materials, products and services, or other activities. If we or our suppliers are unable to depend on these China-based suppliers or service providers, we may not be able to engage a backup or alternative supplier in a timely manner or at all. This, in turn, could materially and adversely affect our or our suppliers' ability to manufacture or supply products and product candidates which could materially and adversely affect our business. If we or any third-party contract manufacturers we engage were to encounter any of these difficulties, our ability to manufacture sufficient product supply for our preclinical studies and clinical trials, or to provide products for patients once approved, would be jeopardized.

Many of the materials and regents we expect to use in our processes are single or sole source, and/or have limited stability and as such supply disruptions could materially impact our ability to develop or manufacture products. In addition, certain cell processing equipment, consumables and tubing used in our current manufacturing process are sourced from a single supplier, or are otherwise available from a limited number of suppliers. Any interruption in the supply by those single source suppliers could impact our ability to continue development of any and all of our product candidates on the anticipated timelines or at all. We may be unable to obtain these materials and products for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, or labor shortages or disputes. Regional or single-source dependencies may in some cases accentuate these risks.

We cannot guarantee that our product candidates will show any functionality in the solid tumor microenvironment.

We cannot guarantee that our solid tumor product candidates will show any functionality in the solid tumor microenvironment. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. Our TCR-T-based product candidates may not be able to access the solid tumor, and even if they do, they may not be able to exert anti-tumor effects in a hostile solid tumor microenvironment. As a result, we have recently decided to focus on developing an *in vivo* engineering platform for TCR-T product candidates for solid tumors, and our efforts are at a very early stage. Therefore, we do not yet know whether this platform will yield viable product candidates with the potential to demonstrate potency in solid tumors. If we are unable to make our product candidates function in solid tumors, our development plans and business may be significantly harmed.

Since the number of patients that we plan to dose in our initial clinical trials may be small, the results from such clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial clinical trials. In addition, patients who are undergoing allogeneic HCT are very sick and may pass away from complications of their standard clinical transplantation and treatments thus making it difficult to ascertain the beneficial effects of the added T cell therapy. Further, toxicities of the T cell therapy may be difficult to distinguish from the toxicity of the transplantation itself.

Allogeneic HCT is a high-risk procedure that may result in complications or adverse events for patients in our clinical trials including those unrelated to the use of our product candidates.

Stem cell transplantation can cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many therapies are used to prepare or treat patients undergoing allogeneic HCT, patients in our clinical trials or patients that use any of our product candidates may be subject to many of the risks that are currently inherent to this procedure. In particular, stem cell transplant involves certain known potential post-procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. For example, autoimmune cytopenia is a known and severe frequent complication of the transplant procedure in certain patients, that can result in death. If these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical trial's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our hematology product candidates, we would follow the clinical trial protocol's requirements, which call for our data safety monitoring committee to review all available clinical data in making a recommendation regarding the trial's continuation.

We may not be able to file IND applications or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We have initiated clinical trials for some of our product candidates and we expect to submit additional IND applications for our current programs. However, we may not be able to file such IND application on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND

application will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing IND applications.

In addition, we are planning to develop treatments consisting of a combination of TCR-Ts, which we refer to as multiplex TCR-T. Our plan is to assess the safety and preliminary efficacy of multiplex TCR-T early in the clinical development of our product candidates. While our experience with our T-Plex IND shows that the FDA may clear an IND application, which allows us to combine our product candidates with each other in a multiplex TCR-T, we must still provide safety data for each individual product candidate or each variation or combination of a multiplex TCR-T. Any such requirements could result in material delays in the development timelines of our multiplex TCR-T therapy product candidates.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including IRBs, to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Because of the design of the dose escalation of our planned Phase 1 clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our therapies specifically or may be due to an illness from which the clinical trial subject is suffering.

For example, there could be an increased risk of GvHD with our TCR-T therapy product candidates in the post-HCT setting. GvHD is a common toxicity in patients undergoing allogeneic HCT, the focus of our heme malignancies program. GvHD occurs because donor T cells, which are part of the standard stem cell product, misrecognize antigens in the patient as foreign and attack tissues and organs that express those antigens. GvHD may be worsened by our TCR-T therapy product candidates because they are derived from donor T cells. While the engineered T cells express a new TCR that is specific for the intended target antigen and is not expected to cause GvHD, those T cells may have low levels of endogenous TCR that have the potential to misrecognize patient antigens as foreign and worsen GvHD.

In solid tumor patients, autoimmunity may occur after TCR-T treatment. TCR-T therapies are generated from a patient's own T cells isolated from their peripheral blood. There is a risk that this process will expand a patient's own T cell that has autoreactivity, or that may recognize healthy cells, and upon re-infusion may trigger an autoimmune reaction resulting in damage to normal tissues and potentially even death.

Autoimmune reaction triggered by an interaction between a patient's naturally occurring antibodies and engineered T cells is a theoretical safety risk of product candidates we develop using our proprietary platform. If a patient's self-generated antibodies were directed to a target expressed on the surface of cells in normal tissue (autoantibodies), engineered T cells would be directed to attack these same tissues, potentially resulting in off-tumor effects. These autoantibodies may be present whether or not the patient has an active autoimmune disorder. In our clinical testing, we plan to take steps to minimize the likelihood that this occurs, for example by excluding patients with a history of a severe autoimmune disorder from our trials. There is no guarantee, however, that we will be able to implement interventions to address the risk of autoimmune reactions if and when they occur.

In addition, immunogenicity, which is the reaction between a patient's immune system and a foreign protein outside of the autoimmune context, is an additional theoretical safety risk of product candidates we develop using our proprietary platform. Patients' immune systems may recognize the TCR construct on the TCR-T product as a foreign protein and fight against it, potentially rendering it ineffective, or even provoking an allergic/anaphylactoid response or other adverse side effects. The immunogenic potential of novel therapeutics like TCR-T therapies is difficult to predict. There is no guarantee that we will be able to implement interventions to address the risk of observation of immunogenic reactions if and when they occur.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities, or local regulatory authorities such as IRBs, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or

managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand the side effect profile of our product candidates for both our planned clinical trials and upon any commercialization of any product candidates, if licensed. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may significantly harm our reputation as well as business, financial condition and prospects.

Our product candidates may target healthy cells expressing target antigens leading to potentially fatal adverse effects.

Our product candidates target specific antigens that are also potentially expressed on healthy cells. Our product candidates may target healthy cells, leading to serious and potentially fatal adverse effects. In our planned clinical trials of our product candidates, we plan to use a dose escalation model to closely monitor the effect of our product candidates on vital organs and other potential side effects. Even though we intend to closely monitor the side effects of our product candidates in both preclinical studies and clinical trials, we cannot guarantee that products will not target and kill healthy cells.

Our product candidates may have serious and potentially fatal cross-reactivity to other peptides or protein sequences within the body.

Our product candidates may recognize and bind to a peptide unrelated to the target antigen to which it is designed to bind. If this peptide is expressed within normal tissues, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse effects. Detection of any cross-reactivity may halt or delay any ongoing clinical trials for any of our TCR-T therapy product candidates and prevent or delay regulatory approval. Unknown cross-reactivity of the TCR-T binding domain to related proteins could also occur. We have also developed a preclinical screening process to identify cross-reactivity of T cell binders. Any cross-reactivity that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization.

The vectors used to manufacture our TCR-T therapy product candidates may incorrectly modify the genetic material of a patient's T cells, potentially triggering the development of a new cancer or other adverse events.

Our TCR-T therapy product candidates are manufactured by using a vector to insert genetic information encoding the TCR construct into the patient's T cells. The TCR construct is then integrated into the natural TCR complex and transported to the surface of the patient's T cells. Because the vector modifies the genetic information of the T cell, there is a risk that modification will occur in the wrong place in the T cell's genetic code, leading to vector-related insertional oncogenesis, and causing the T cell to become cancerous. If the cancerous T cell is then administered to the patient with the TCR-T therapy product candidates, the cancerous T cell could trigger the development of a new cancer in the patient. We use non-viral transposon/transposase to insert genetic information into T cells. The risk of insertional oncogenesis remains a concern for gene therapy and we cannot guarantee that it will not occur in any of our ongoing or planned preclinical studies or clinical trials. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of vectors used to carry the genetic material. The FDA has stated that vectors possess characteristics that may pose high risks of delayed adverse events. Non-viral transposon/transposase systems have limited clinical history, and their safety profile is still to be determined. If any such adverse events occur, further advancement of our preclinical studies or clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their approved protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the clinical trial protocol, particularly those who meet the requisite genetic criteria;
- for our heme malignancies program, the ability to find a donor who must be mismatched with the patient either for the HLA type or the antigen type to ensure that the engineered T cell therapy does not recognize donor-derived blood cells;
- any impact of public health crises on clinical trial initiation and enrollment;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical trial sites;

- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- risk that patients enrolled in clinical trials will drop out of the clinical trial or pass away from disease-related complications or complications from their standard clinical therapy before they can experience benefits of the engineered T cell therapy;
- the need to obtain sufficient T cells from the patient or allogeneic donor in order for the engineered T cell product to be manufactured; and
- our ability to produce sufficient TCR-T product to meet the dosing requirements of the clinical studies.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates 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 chemotherapy and HCT, rather than enroll patients in any future clinical trial. Additionally, because some of our clinical trials are expected to be in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

Delays in completing patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Research and development of biotechnology products is inherently risky. We may not be successful in our efforts to use and enhance our target discovery platform and TCR technologies to create a pipeline of product candidates and develop commercially successful products, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited.

We are at an early stage of development and our target discovery platform has not yet led, and may never lead, to approved or commercially successful products. All of our current product candidates are being developed by leveraging the same or similar underlying proprietary platform, manufacturing process and development program. As a result, an issue with one product candidate or failure of any one program to obtain regulatory approval could lead to a failure of our entire pipeline of product candidates.

Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates may require substantial additional funding and are prone to the risks of failure inherent in biotechnology product development.

Investment in biotechnology product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our research methodology, including our screening technology, may not successfully identify additional product candidates;
- our pursuit of difficult-to-drug targets may make it challenging to design potential product candidates;
- results of clinical trials conducted by others on similar indications or on compounds with similar mechanisms of action could result in our having to conduct additional or cost prohibitive clinical trials, which could delay development and possibly make commercialization prohibitively expensive;

- we may encounter product manufacturing difficulties that limit yield, produce undesirable characteristics, that increase the cost of goods, cause delays, or make the product candidates unmarketable;
- our product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If we are unable to identify suitable compounds for preclinical and clinical development, we will not be able to obtain revenues from the sale of drugs in future periods, which likely would result in significant harm to our business prospects and financial position.

The market opportunities for our product candidates may be relatively small. In addition, our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first-line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful (refractory disease) or the cancer returns after a disease-free interval (relapsed disease), subsequent lines of therapy may be required to manage the disease and/or disease-related side-effects. We expect to initially seek approval for use of our TCR-T therapy product candidates to treat patients with heme malignancies, including acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) who are undergoing allogeneic HCT. While HCT provides a potentially curable option for patients with intermediate and high-risk disease, disease relapse remains the main cause of treatment failure and constitutes a significant unmet medical need. For our solid tumor product candidates, we expect to initially seek approval in patients with a history of relapsed disease or refractory disease. For those product candidates that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval in earlier lines of therapy, as appropriate, but there is no guarantee that our product candidates would be licensed for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. Consequently, the potentially addressable patient population for our product candidates may be extremely limited or may not be amenable to treatment with our product candidates.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line or type of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected.

Our product candidates rely on the use of protein binding domains, or binders, to target specific cancers, which we may develop, or which may be developed by third parties. We are limited in our ability to apply our product candidates to a wider range of potential target cancers by our ability to develop, partner for or acquire these binders on commercially reasonable terms.

TCR-T therapies require the use of antigen-specific protein binding domains (binders) which guide the TCR-Ts and bind to the antigens on the surface of a tumor to target specific types of cancers. Our ability to develop and commercialize our product candidates will depend on our ability to develop these binders or partner for such binders on commercially reasonable terms for use in clinical trials as well as the availability of such binders for use in commercialized products, if licensed. We cannot ensure that we will have a steady supply of binders that we can utilize in combination with the TCR construct to develop our product candidates. If we are unable to enter into such collaborations on commercially reasonable terms or fail to realize the benefits of any such collaboration, we may be limited to using antibody fragments that we are able to independently develop which may limit the ability of our product candidates to target and kill cancer cells.

The failure to enter into a successful collaboration or to develop our own binders may delay our development timelines, increase our costs and jeopardize our ability to develop future product candidates as a commercially viable drug, which could result in delays in product development and harm our business.

We currently have no marketing and sales organization and have no experience as a company in marketing products. If we are unable to establish marketing and sales capabilities or to enter into agreements with third parties to market and sell our product candidates, if licensed, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We may also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. or overseas.

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

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other TCR-T therapies;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other adoptive cell therapies, TCR-T therapies and public perception of other adoptive cell therapies and TCR-T therapies;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such clinical trials to demonstrate that these therapies are safe and effective may limit market

acceptance of our product candidates. If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other TCR-T therapy approaches, serious adverse events or deaths in other clinical trials involving engineered TCR, or other T cell products or with our use of licensed TCR-T therapy candidates, even if not ultimately attributable to our product candidates, could negatively impact our business.

Even if our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our product candidates, are more cost effective or render our product candidates obsolete.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs (including tariffs that have been or may in the future be imposed by the U.S. or other countries), trade barriers (including further legislation or actions taken by the U.S. or other countries that restrict trade), price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results. Our potential competitors include larger biotechnology and pharmaceutical companies with greater resources than us, academic institutions, governmental agencies, public and private research institutions and early stage or smaller companies. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Further, our competitors may have more financial resources, greater access to capital and diversified product offerings and revenue sources, which may give our competitors an advantage over us. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are safety, potency, purity, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, by genetically engineering T cell therapies, we face significant competition in the T cell immunotherapy space from many companies. For additional information regarding our competition, see "Item 1. Business – Competition" in this Annual Report on Form 10-K. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Moreover, the development and manufacturing costs associated with engineered T cell therapies may make it difficult to compete with alternative products that may be simpler and cheaper to develop and manufacture.

Our internal computer systems, or those used by our third-party CROs, our clinical sites, or other contractors or consultants, may fail or suffer cybersecurity incidents, data breaches or other unauthorized or improper access, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, our clinical sites, and other contractors and consultants are vulnerable, and like companies in our industry, we have experienced a variety of disruptions and data privacy and information security threats and incidents. These cyberattacks may include cybersecurity incidents, data breaches, attacks by hackers and other malicious third parties (including the deployment of computer viruses, malware, ransomware, denial-of-service attacks, social engineering fraud (including phishing attacks), and other events that affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, fires, terrorism, war, telecommunications or electrical interruptions or failures, employee error or malfeasance or other malicious or inadvertent disruptions, including inadvertent or intentional wrongful actions by insider employees and vendors. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on Ukraine, including its government, companies, institutions and people, as well on the financial and communications infrastructure of other countries, companies and individuals therein. Additionally, the increased usage of computers operated on home networks may make our or our partners' systems more susceptible to cybersecurity incidents or data breaches. If any such material system failure, cybersecurity incident, or data breach, were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from ongoing or completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, similar events relating to the computer systems of our third party vendors or manufacturers could also have a material adverse effect on our business, financial condition, results of operations and prospects. Bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the potential or current use of artificial intelligence models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a cybersecurity incident, data breach, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world.

As we become more dependent on information technologies to conduct our operations, cybersecurity incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks and to the confidentiality, availability and integrity of our data, and these risks apply both to us and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners or collaborators may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal data on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to cybersecurity incidents or data breaches, computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investments to protect against cybersecurity incidents or data breaches or to mitigate the impact of any such cybersecurity incidents or data breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or cybersecurity incident or data breach were to result

in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Cybersecurity incidents, loss of data or modification of information, and other disruptions could compromise information related to our business or prevent us from accessing critical information, result in a significant disruption of our activities and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store information, including personal information, intellectual property and proprietary business information that we own or control or have an obligation to protect. For example, we collect and store research and development information, employee data, commercial information, customer information and business and financial information. We and our service providers, including security and infrastructure vendors, manage and maintain our data using a combination of on-site systems and cloud-based data centers. We face a number of risks related to protecting critical information, including inappropriate use or disclosure, unauthorized access or acquisition, or inappropriate modification of, critical information. We also face the risk of being unable to access our critical information or technology systems due to actual or threats of ransomware, unauthorized encryption, or other malicious activity. We face the risk of being unable to adequately monitor, audit and modify our controls over our critical information. These risks extend to third-party service providers and subcontractors we use to assist us in managing our information or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of our critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information.

Although we take reasonable measures to protect critical information and other data from unauthorized access, acquisition, use or disclosure, our information technology and infrastructure and that of our service providers handling and storing information on our behalf may be vulnerable to a variety of disruptions, including cybersecurity incidents, data breaches, attacks by hackers and other malicious third parties (including the deployment of computer viruses, malware, ransomware, denial-of-service attacks, social engineering (including phishing attacks), and other events that affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, fires, terrorism, war, telecommunications or electrical interruptions or failures, employee error or malfeasance or other malicious or inadvertent disruptions. In particular, the risk of a cybersecurity incident, data breach or disruption, particularly through cyber-attacks or cyber intrusion, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures that are effective against all such security threats. Because the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates or terrorist organizations, we and our service providers and other partners may be unable to anticipate these techniques or implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of third parties that collect, process and store sensitive information on our behalf. Any unauthorized access or acquisition, cybersecurity incident, data breach, or other loss, of information could result in legal claims or proceedings, and liability under federal, state or foreign laws regarding the privacy and protection of information, including personal information, and could disrupt our operations and harm our reputation. In addition, notice of cybersecurity incidents or data breaches may be required to affected individuals, regulators, credit reporting agencies or the media. Any such publication or notice could harm our reputation and our ability to compete. The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Manufacturing

Manufacturing and administering our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our TCR-T therapy product candidates for clinical trials or, if approved, for commercial purposes, could be delayed or stopped.

The process of manufacturing and administering our product candidates is complex and highly regulated. The manufacture of our product candidates involves complex processes, including the manufacture of a transposon containing the genetic information for our TCR construct, a transposase used to insert the transposon genetic information into the T cell genome, and manufacturing operations to ensure the safety, integrity, strength, sterility, purity, and quality of the final product. As a result of the complexities entailed in this process, our manufacturing and supply costs may be higher than those of more traditional manufacturing processes and the manufacturing process may be less reliable and more difficult to reproduce. Additionally, the number of facilities that are capable of harvesting cells for the manufacture of our product candidates and other cell therapy products and product candidates is limited. As the number of cell therapy products and product candidates increases, the limited number of facilities capable of harvesting cells could result in delays in the manufacture and administration of our product candidates.

We currently rely on our internal manufacturing facility for clinical manufacturing, and any disruption to this facility could impact our ability to advance our clinical trials. We currently rely on third parties for the manufacture of our non-viral vector and other components of our manufacturing process, and we have engaged a global third-party manufacturer to support the manufacture of products for our clinical trials. These third-party manufacturers may incorporate their own proprietary processes into our components. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our product candidates. In addition, we are currently reliant on a single manufacturer for our transposon and transposase components, and many of the critical raw materials and reagents used in the process are single or sole source. These third-party providers may not be able to provide adequate resources, capacity to meet our needs, timely delivery of material, or may change internal processes or specifications that adversely affect our process or product candidates.

Our manufacturing process is and will be susceptible to product loss or failure due to logistical issues, manufacturing issues associated with the differences in patients' white blood cells, interruptions in the manufacturing process or supply chain, contamination, equipment or reagent failure, process design flaws, operator error, power failures, supplier error and variability in patient characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, product rejection, or other supply disruptions. If for any reason we lose a patient's white blood cells, such material gets contaminated or processing steps fail at any point, the manufacturing process of the TCR-T therapy product candidate will need to be restarted, if possible, and the resulting delay may adversely affect a patient's outcome. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates or critical raw materials or reagents are made or administered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

As our product candidates progress through preclinical studies and clinical trials towards licensure and commercialization, it is expected that various aspects of the manufacturing and administration process will be altered in an effort to optimize processes and results, for example, our efforts to develop an *in vivo* engineering platform for our solid tumor program. We have already identified some improvements to our manufacturing and administration processes, but these changes may not achieve the intended objectives, and could cause our product candidates to perform inadequately affecting the results of ongoing or future clinical trials. In addition, any changes may require amendments to be made to regulatory applications or necessitate development of new or additional TCR constructs and further clinical testing, which may further delay the timeframes under which modified manufacturing processes can be used for any of our product candidates.

Developing a commercially viable process is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out or scale-up, process reproducibility, stability issues, lot consistency, facility suitability or capacity, staffing, and availability of reagents or raw materials. Competitors have had difficulty reliably producing T cell therapies in the commercial setting. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once approved. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment.

Although many of our personnel have experience in clinical manufacturing at other companies, we have limited experience as a company managing manufacturing for our product candidates, which will be costly, time-consuming, and which may not be successful.

We have limited experience as a company in managing a manufacturing facility or manufacturing suite, and may never be successful in managing our own manufacturing suite, manufacturing facility or manufacturing capability. We will need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development, and eventual commercialization, if licensed, of our product candidates. If we fail to recruit the required personnel, manage our growth effectively, have inadequate facility design or construction, or fail to select the correct location, the development and production of our product candidates could be curtailed or delayed. Although we have established a manufacturing facility, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, design or construction flaws, labor shortages, supply disruptions, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

In addition, the FDA, the European Medicines Agency (EMA), and other foreign regulatory authorities may require us to submit samples of any lot of any licensed product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls, or inability to manufacture product

in the future. Lot failures or product recalls could cause us to delay or forgo product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process or quality control testing could restrict our ability to meet market demand for our product candidates.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and facility, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

We may have difficulty validating our manufacturing process as we manufacture TCR-T therapy product candidates from an increasingly diverse patient population for our clinical trials.

As we develop our clinical products, we may encounter unforeseen difficulties due to quality, quantity, supply timing, or variability issues with donor starting materials and may not be able to develop a robust process or incur additional costs or delays in developing a robust process due to starting material variation or supply.

Although we believe our current manufacturing process is scalable for commercialization, we may encounter challenges in validating our process due to the heterogeneity of the product starting material. While we anticipate that during the early phases of our clinical trials we will be able to adapt our process to account for these differences resulting in a more robust process, we cannot guarantee that issues relating to the heterogeneity of the starting material will not impact our ability to manufacture our product candidates for clinical or commercial distribution.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA to the FDA or similar licensure applications to comparable foreign regulatory authorities. A BLA, or similar licensing application, must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity, and potency for each desired indication and must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and licensure may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval at each clinical trial site by an IRB or ethics committee;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs, including current Good Tissue Practice (cGTPs), and applying them on a subject-by-subject basis for use in clinical trials.

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety, efficacy, potency and purity profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the data monitoring committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Securing regulatory approval also requires the submission of information about the biologic manufacturing process and inspection of manufacturing facilities by the relevant regulatory authority. The FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities, whether run by us or our third-party CDMOs. In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

The research, testing, manufacturing, labeling, licensure, sale, marketing and distribution of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the U.S. or in any foreign countries until they receive the requisite licensure from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory authorities can delay, limit or deny licensure of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority that any of our product candidates are safe, potent and pure;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for licensure;
- the FDA's or the applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities or those of third-party manufacturers upon which we rely;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for licensure;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain licensure of our product candidates in the U.S. or elsewhere; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, some of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Of the large number of biological products in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Even if we eventually complete clinical testing and receive licensure from the FDA or applicable foreign regulatory authorities for any of our product candidates, the FDA or the applicable foreign regulatory agency may grant licensure contingent on the performance of costly additional clinical trials which may be required after licensure. The FDA or the applicable foreign regulatory agency also may license our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not license our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such product candidates.

In addition, even if the trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional

resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

We may seek orphan drug status for some of our current or future product 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.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug 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 U.S., or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for some or all of our current or future product 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 U.S. may be limited if we seek licensure 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 product candidates, we may never receive such designations.

We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Breakthrough Therapy designation by the 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 plan to seek a Breakthrough Therapy designation for our current product candidates and may seek Breakthrough Therapy designation for some or all of our 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 the 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. Biologics designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including Accelerated Approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the 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 licensure compared to candidate products considered for licensure under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the 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 future product candidates for the treatment of various cancers, 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 current or future product candidates, may not lead to a faster development or regulatory review or approval process, 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. We plan to seek Fast Track designation for our current product candidates and may seek Fast Track designation for certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed 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 licensure 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 Accelerated Approval from the FDA for any of our current or future product candidates. Accelerated Approval, even if granted, for any of our current or future 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 approval of our current product candidates or future product candidates using the FDA's Accelerated Approval pathway. A product may be eligible for Accelerated Approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving Accelerated Approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving Accelerated Approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive Accelerated Approval, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving Accelerated Approval does not provide assurance of ultimate FDA approval.

A Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval and we may be unable to obtain or maintain the benefits associated with such designation.

We have obtained and may continue to seek an RMAT designation for some of our product candidates. In May 2024, we announced that the FDA granted RMAT designation for TSC-100 and TSC-101 for the treatment of patients with AML, ALL, and MDS undergoing HCT with reduced intensity conditioning. An RMAT is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act. The RMAT program is intended to facilitate efficient development and expedite review of RMATs which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and where preliminary clinical evidence indicates the product has the potential to address unmet medical needs for such disease or condition. A BLA for an RMAT may be eligible for priority review if it meets the criteria for priority review, or for accelerated approval based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation include all the benefits of the Fast Track and Breakthrough Therapy designation programs, including early interactions with the FDA, which could include interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. An RMAT that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for RMAT designation and seek RMAT designation for such product candidate, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development, review or approval process compared to product candidates considered for approval under non-expedited FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for RMAT designation, the FDA may later decide that the product candidate no longer meets the conditions for qualification.

We may seek designation for our target discovery platform as a designated platform technology, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

We may seek designation for our target discovery platform as a designated platform technology. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), a platform technology incorporated within or utilized by a biological product is eligible for designation as a designated platform technology if (1) the platform technology is incorporated in, or utilized by, a biological product approved under a BLA; (2) preliminary evidence submitted by the sponsor of the licensed biological product, or a sponsor that has been granted a right of reference to data submitted in the application for such biological product, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one biological product without an adverse effect on quality, manufacturing, or safety; and (3) data or information submitted by the applicable person indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the biological product development or manufacturing process and to the review process. A sponsor may request the FDA to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission of an IND application for a biological product that incorporates or utilizes the platform technology that is the subject of the request. If so designated, the FDA may expedite the development and review of any subsequent original BLA for a biological product that uses or incorporates the platform technology. Even if we believe our target discovery platform technology meets the criteria for such designation, the FDA may disagree and instead determine not to grant such designation. In addition, the receipt of such designation for a platform technology does not ensure that a biological product will be developed more quickly or receive FDA approval. Moreover, the FDA may revoke a designation if the FDA determines that a designated platform technology no longer meets the criteria for such designation.

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

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

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

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety, potency and purity of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to license our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, cGTPs and good clinical practices (GCPs) for any clinical trials that we conduct post-licensure. Manufacturers and manufacturers' 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 and applicable product tracking and tracing requirements. Later discovery of previously

unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our manufacturing processes (or those of third parties we engage), or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- under FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a product, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- 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 revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes. This decision may result in more lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action. 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.

The third-party payer or insurance coverage and reimbursement status of newly-approved products are uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. For more information, please see "Item 1. Business – Government Regulation – Coverage and Reimbursement" in this Annual Report on Form 10-K.

In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which

medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as cell therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicaid and Medicare Services (CMS), an agency within the U.S. Department of Health and Human Services (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 products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the U.S. and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (ASP) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our product candidates compared to standard of care drugs, including lower-priced biosimilar versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. For more information on healthcare laws and regulations that may impact us, please see "Item 1. Business – Government Regulation – Healthcare Legislative Reform" in this Annual Report on Form 10-K.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our product candidates;
- our ability to obtain coverage and reimbursement approval for a product candidate;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Regulatory requirements in the U.S. and abroad governing cell therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.

Regulatory requirements in the U.S. and abroad governing cell therapy products have changed frequently and may continue to change in the future. The FDA has established an office, called the Office of Therapeutic Products within its Center for Biologics Evaluation and Research to meet its growing cell and gene therapy workload. The FDA also established the Cellular, Tissue and Gene Therapies Advisory Committee to advise its review. Under guidelines issued by the National Institutes of Health (NIH) certain gene therapy clinical trials are subject to review and oversight by an institutional biosafety committee (IBC) a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before such a clinical trial can begin, the institution's institutional review board (IRB) and its IBC assess the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell and gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including staffing, government budget and funding levels, the FDA's ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. 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. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, in some instances have had to furlough critical FDA, SEC and other government employees and stop critical activities.

Disruptions at the FDA and other agencies, including substantial leadership departures and changes, personnel cuts and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved, which would harm our business. Changes and cuts in FDA staffing also could result in delays in the FDA's responsiveness or in its ability to review, or consistency in reviewing, regulatory submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. If a prolonged government shutdown or substantial leadership, personnel, and policy changes occur, 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, in our operations as a public company, 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. Such changes could significantly impact the ability of the FDA to timely review and take action on our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to the extent and nature of how the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. This uncertainty could present new challenges and/or opportunities as we navigate development of our product candidates. Additionally, the Trump administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new product candidates. Any delay in obtaining, or our inability to obtain, applicable regulatory approvals would delay or prevent development and commercialization of our product candidates and could materially adversely impact our business and prospects.

We are subject to the obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980 (Bayh-Dole Act). As a result, the U.S. government may have rights in certain inventions developed under these government-funded programs, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights."

Any exercise of the march-in rights by the U.S. government could harm our competitive position, business, financial condition, results of operations and prospects. In December 2023, the Biden administration released a proposed framework specifying for the first time that price can be a factor in considering whether an invention is sufficiently available to the public. The proposed framework could potentially enable march-in rights to be used as a tool to regulate drug pricing. The potential inclusion of price as a factor in a march-in determination is expected to draw extensive criticism and challenge, and the ultimate impact is currently unknown. If the U.S. government exercises such march-in rights, we may receive compensation deemed reasonable by the U.S. government, which may be less than what we might be able to obtain in the open market. IP generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory authorities, provide true, complete and accurate information to the FDA and other similar foreign regulatory authorities, comply with manufacturing standards we have established,

comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. For more information, please see "Item 1. Business – Government Regulation – Anti-Kickback and False Claims Laws and Other Regulatory Matters" in this Annual Report on Form 10-K.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations.

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

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

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to induce or reward improper performance generally is governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 (Bribery Act) in the UK. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU. 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.

We are currently subject to, and may in the future become subject to additional, federal, state and foreign laws and regulations, industry guidelines, and contractual requirements, imposing obligations on how we collect, store, use and process personal information. Our actual or perceived failure to comply with such obligations could harm our business.

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations and mandatory industry standards relating to privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the U.S., various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act (CCPA) established new privacy rights for California residents and introduced new on covered companies that process personal information of California residents. Among other things, the CCPA requires covered companies to provide certain disclosures to California residents and provide such residents with new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The amendments introduced by the California Privacy Rights Act (CPRA) significantly modified the CCPA by expanding residents' rights with respect to certain personal information and created a new state agency to oversee implementation and enforcement efforts, among other changes. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches. This private right of action may increase the likelihood of, and risks associated with, data breach litigation, including class action litigation.

Similar laws have been passed in numerous other states and a number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition, laws in all 50 U.S. states require businesses to provide notice to individuals if certain of their personal information has been disclosed as a result of a qualifying data breach. There are also states that are specifically regulating health information. For example, the state of Washington has enacted a comprehensive health privacy law that regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

Moreover, U.S. regulators and legislators are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. Department of Justice regulations that went into effect April 8, 2025 prohibit data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer, marketing or other processing of personal data. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area (EEA), including personal health data, is subject to the EU General Data Protection Regulation 2016/679 (EU GDPR), and with regards individuals based in the UK, the EU GDPR in such form as incorporated into the laws of the UK (UK GDPR, together with EU GDPR referred to as "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 having a legal basis or condition for processing personal data, stricter requirements relating to the processing of sensitive data (such as health data), where required by GDPR 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, requirements to conduct data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20

million (£17.5 million in UK) 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. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be 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.

The GDPR provides that EEA Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between EEA Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition.

Significantly, the GDPR imposes strict rules on the transfer of personal data out of the EEA and UK to other regions outside the EEA/UK, or third countries, that have not been deemed to offer "adequate" privacy protections by the competent data protection authorities, including the U.S. in certain circumstances, unless a derogation exists or adequate international transfer safeguards are put in place, such as, for example, the European Commission approved Standard Contractual Clauses (the EU SCCs) and the UK International Data Transfer Agreement/Addendum (the UK IDTA). Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments on the transfers made pursuant to the EU SCCs and UK IDTA, on a case-by-case basis, to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred personal data as provided in the EEA and UK, and may be required to adopt supplementary measures if this standard is not met. Further, the EU and the U.S. have adopted its adequacy decision for the EU-U.S. Data Privacy Framework (Framework), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the U.S. are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the U.S. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA to the U.S. in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

Although the UK is regarded as one of the third countries under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. In December 2025, the European Commission adopted a decision to extend the validity of the UK adequacy decision for six years until December 2031, determining that the UK continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the UK's adoption of the Data (Use and Access) Act 2025 on 19 June 2025.. The Data (Use and Access) Act 2025 may have the effect of further altering the similarities between the UK and EEA data protection regime. The competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country and therefore we do not expect to operate in a uniform legal landscape in the EEA.

The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. For more information, please see "Item 1. Business – Government Regulation – Coverage and Reimbursement" in this Annual Report on Form 10-K.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, government authorities and third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our product candidates may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the U.S. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products, product candidates and technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success will depend in large part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection and other intellectual property and proprietary rights in the U.S. and other countries with respect to our technology and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business, as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

Given the early stage of development of our product candidates, our patent portfolio is similarly at an early stage. If we do not obtain meaningful patent coverage for our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, competitors may be able to erode or negate any competitive advantage we may have, which would likely harm our business and ability to achieve profitability. To establish our proprietary position, we have filed provisional patent applications and corresponding Patent Cooperation Treaty (PCT), national, and regional applications related to our novel product candidates that are important to our business, and we have exclusively licensed a patent family from the Brigham and Women's Hospital, Inc. (BWH); we may in the future also license or purchase issued patents or pending patent applications filed by others. U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. If we are unable to secure or maintain patent protection with respect to our antibody technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

If the scope of the patent protection we or our existing and potential licensors obtain, if any, is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited and may not adequately protect our business or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our owned or exclusively licensed pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property now or in the future, we cannot provide any assurances that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Furthermore, patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new product candidates, any patents that we may obtain in the future protecting such candidates might expire before or shortly after commercialization of such candidates, if any. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Even if they are unchallenged, our issued patents or pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors or other third parties from designing around our patent claims to circumvent any patents that may issue by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent claims. If any patent protection that we may obtain in the future from the patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Similar risks apply to patents or patent applications that we have in-licensed or may in the future in-license.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions and are subject of much litigation. No consistent policy governing the scope of claims allowable in the field of binding protein therapeutics, including antibodies and T cell receptors, has emerged in the U.S. The scope of patent protection in jurisdictions outside of the U.S. is also uncertain. Changes in either the patent laws or in their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, obtain, maintain, protect and enforce our intellectual property and other proprietary rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of any patents that we may obtain in the future and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we do not intend to pursue, and may not obtain, patent protection in all potentially relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor’s or other third party’s patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, corporate collaborators, external academic scientific collaborators, CROs,

contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patent rights and patent applications or were the first to file for patent protection on the inventions claimed in our pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even where patent applications we currently own or that we license now or in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade or circumvent our patent rights by developing new alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and patents we may obtain in the future may be challenged, invalidated, narrowed or held to be enforceable, including in the courts or patent offices in the U.S. and abroad, or circumvented. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent 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, but which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging any patent rights we have or may obtain in the future or the patent rights of others, including based on priority of invention or other features of patentability, in the U.S. Patent and Trademark Office (USPTO) or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, any patent rights we have or may obtain in the future, allow third parties to use or commercialize our technology or product candidates and compete directly with us, without payment to us (as they can now), or extinguish our ability to manufacture or commercialize product candidates without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. 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 material adverse effect on the price of our common stock.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, any patents we have or may obtain in the future protecting such candidates might expire before or shortly after commercialization of such candidates, if any. As a result, our intellectual property may never provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, any patents or patent applications that we own or may own or in-license in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in any such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, thereby enabling our competitors to market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of any patents that we own or may own or in-license in the future in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We could be unsuccessful in obtaining meaningful patent protection on one or more components of our platform technology.

We believe that an important factor in our competitive position is our screening technology platform to identify future product candidates and therapeutic targets. Our screening platform is based in part on technology processes that are (or will be) publicly disclosed in patents and patent applications owned by or licensed to us. Even if such patents and patent applications provide broad protection, it may be difficult or impossible to detect whether a competitor is practicing the proprietary methods claimed in such patents or patent applications in order to discover their own product candidates and therapeutic targets. In such cases, any existing patents, or patents that may issue from patent applications, owned by or licensed to us would not provide us protection to prevent such activity. Additionally, a competitor may also practice such methods in a jurisdiction where we have no relevant patent protection. Our competitive position could be weakened by competitors or other third parties practicing the methods claimed in these patent applications in a manner we do not detect or in jurisdictions in which we or our licensors do not obtain any relevant patent protection.

If we fail to comply with any of our obligations under existing or future agreements pursuant to which we license intellectual property rights or technology, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights or technology that are material to our business and could interfere with our ability to operate our business.

We are a party to technology licenses, including in-license agreements with BWH and PHSA, and we may enter into additional licenses in the future. Such licenses do, and may in the future, impose commercial, contingent payment, royalty, insurance, indemnification, and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we could lose valuable rights under our collaboration agreements and our ability to develop product candidates could be impaired. Additionally, should any such license agreement be terminated for any reason, there may be a limited number of replacement licensors, and a significant amount of time may be required to transition to a replacement licensor.

Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of third-party licenses, pursuant to which we have acquired rights from the applicable licensors. Our rights with respect to such intellectual property may terminate, in whole or in part, if we fail to meet applicable requirements or milestones relating to development and commercialization. We may also lose our rights to develop and commercialize our product candidates under such agreements if we fail to pay required milestones or royalties. In the event of an early termination of our license agreements, all rights licensed and developed by us under these agreements may be extinguished, which may have an adverse effect on our business, financial condition, results of operations and prospects.

We rely on certain of our licensors to prepare, file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them and may continue to do so in the future. We have limited or no control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited or no control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that any licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

These agreements may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, a third party may in the future bring claims that our performance under our license agreements, including our sponsoring of clinical trials, interferes with such third party's rights under its agreement with one of our licensors. If any such claim were successful, it may adversely affect our rights and ability to advance our product candidates as clinical candidates or subject us to liability for monetary damages, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We are currently, and expect in the future to be, party to material license or collaboration agreements, which may impose numerous obligations and restrictions on us.

We are currently, and expect in the future to be, party to material license or collaboration agreements. These agreements typically impose numerous obligations and restrictions on us, such as various diligence, commercialization, insurance and payment obligations, among others, in order to maintain such licenses. Any of these restrictions or obligations could delay or otherwise negatively impact a transaction that we may wish to enter into. In addition, any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Licensing of intellectual property is of high importance to our business and involves complex legal, business and scientific issues. Disputes may also arise between us and our licensors regarding intellectual property subject to a license or collaboration agreement, including:

- the scope of rights granted under the license or collaboration agreement and other interpretation-related issues;
- whether, and the extent to which, our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing or collaboration agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- the calculation and existence of certain payment obligations under the license or collaboration agreement;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions, know-how and other intellectual property and proprietary rights resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, and our success will depend in part on the ability of our licensors to adequately obtain, maintain, protect and enforce patent protection for our licensed intellectual property, especially with respect to patent rights which we exclusively in-license. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We rely on certain of our licensors to prepare, file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them and may continue to do so in the future. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that any licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

Furthermore, certain of our licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. For example, a portion of our intellectual property portfolio is non-exclusively licensed to us and may be used by our licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. Thus, patent rights licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our proprietary position may depend upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition-of-matter patents are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the active pharmaceutical ingredient used. We currently have a limited number of issued patents, but our pending owned U.S. and international patent applications include claims directed to certain compositions-of-matter and certain methods of use of our product candidates. We cannot be certain that claims in any issued patent, or patent that may issue from our pending owned or in-licensed patent applications, will cover the composition-of-matter of any of our current or future product candidates. If we are unsuccessful in obtaining issued patents that cover the composition-of-matter of any of our current or future product candidates, competitors may be able to erode or negate any competitive advantage we may have and our business, financial condition, results of operations and prospects could be materially harmed.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. 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 would otherwise have been the case.

We rely upon a combination of patent rights, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors or other third parties to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We, or any partners, collaborators, licensees or licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or any partners, collaborators, licensees or licensors fail to establish, maintain or protect such patent rights and other intellectual property rights, such rights may be reduced or eliminated. If any partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patent applications, any patents that may issue from such patent applications may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, results of operations and prospects.

Currently, our patents and patent applications are directed to our TCR-T therapy product candidates and accompanying technologies. We seek or plan to seek patent protection for our proprietary platform and product candidates by filing and prosecuting patent applications in the U.S. and other countries as appropriate. Our patent portfolio also includes patent families exclusively licensed from BWH, which include issued and pending U.S. and foreign non-provisional patent applications. Any patents that have issued or may issue from any non-provisional patent applications claiming priority to these provisional patent applications would be expected to expire on various dates from 2038 through 2046, in each case without taking into account any possible patent term adjustments or extensions.

We anticipate additional patent applications will be filed both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- whether and when any patents will issue;
- the degree and range of protection that any patents that may issue will afford us against competitors;
- whether any of our intellectual property will provide any competitive advantage;
- whether any patents that may issue may be challenged, invalidated, modified, revoked, circumvented or found to be unenforceable;
- whether or not others will obtain patents claiming inventions similar to those covered by our patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings, which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO or patent offices in foreign countries.

Method-of-use patents protect the use of a product for the specified method. If we obtain any of these types of patents, they would not prevent a competitor from making and marketing a product that is identical to one of our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may induce or contribute to the infringement of method-of-use patents, the practice is common, and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. 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. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Various post-grant review proceedings, such as *inter partes* review and post-grant review, are available for any interested third party to challenge the patentability of claims in any patents issued to us or our licensors. While these post-grant review

proceedings have been used less frequently to invalidate biotech patents, they have been successful regarding other technologies, and these relatively new procedures are still changing, and those changes might affect future results. No assurance can be given that, if challenged, any patents that we or our licensors may obtain would be declared by a court to be valid or enforceable or that, even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe any such patent. We may analyze patents or patent applications of our competitors that we believe are relevant and conclude that our activities do not infringe any valid claims of those patents or patent applications, but our conclusions may be erroneous or our competitors may obtain patents with issued claims, including in patents we consider to be unrelated, that block our efforts or that our product candidates or our activities infringe. Others may independently develop products that have the same effect as our product candidates without infringing any patents we may obtain or any of our other intellectual property rights, or they may design around the claims of any patents that we may obtain.

Recent and future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents we may obtain. In March 2013, under the Leahy-Smith America Invents Act (America Invents Act) the U.S. moved from a "first to invent" to a "first-to-file" system. Under a "first-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 included a number of other significant changes to U.S. patent law, including provisions that have affected the way patent applications are prosecuted, redefined prior art and established a new post-grant review system. The effects of these changes are still 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-to-file" provisions, only became effective in March 2013. Moreover, the courts have yet to address many of these provisions. Overall, the America Invents Act and its implementation have increased the uncertainties and costs surrounding the prosecution of our patent applications and any enforcement or defense of any patents that we may obtain, which could have a material adverse effect on our business and financial condition.

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

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of any patents that we may obtain;
- the active biological ingredients in our current product candidates may eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- there may be prior public disclosures that could invalidate any patents that we or our licensors may obtain;
- the inventors of our owned or in-licensed patent applications may become involved with competitors, develop products or processes that design around any patents that we may obtain, or become adverse to us or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed 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 any patents that may issue from these patent applications to be held invalid or unenforceable;
- we have engaged and may continue to engage in scientific collaborations, and such collaborators may develop adjacent or competing products to ours that are outside the scope of any patents that we may obtain;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by any patent rights we may obtain, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect our proprietary know-how, information, technology and other proprietary information that is not 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 we have not sought to protect through patent applications. For example, significant elements of our product candidates, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. 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 generally 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 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. 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. Despite these measures, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not 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 to the same extent or in the same manner as the laws of the U.S. Courts outside the U.S. are sometimes less willing to protect trade secrets. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. 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. If we are unable to prevent unauthorized disclosure of our material 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, operating results and financial condition. For more information, see "Risks Related to Our Intellectual Property – We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world."

Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product candidate discovery and development efforts.

Our commercial success depends in part on our avoiding infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates or identifying potential product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Because of the large number of patents and patent applications in our fields, there is a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

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

- infringement, misappropriation and other violation of 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, misappropriation or other violation which we may have to pay if a court decides that the product candidate or technology at issue infringes on, misappropriates or otherwise violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates or using our proprietary technologies; and
- redesigning our product candidates or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors or other third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the U.S. is not considered an act of infringement. If any of our product candidates is licensed by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates, if licensed, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing", a heightened standard of proof. As a result, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any third-party patent were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, or aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holder of any such patent may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patent, or until such patent expires or it is finally determined to be held invalid or unenforceable. In any case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. 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 material adverse effect on the price of our common stock. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have certain patent rights directed to certain TCR constructs, we may not be able to obtain intellectual property to broad T cell or TCR constructs.

Our product candidates may also require specific formulations to work effectively and efficiently and rights to these formulations may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any formulations, compositions, methods of use, processes or other third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may eventually become involved in lawsuits to protect or enforce our intellectual property and proprietary rights, including any patents that we or our licensors may obtain in the future, which could be expensive, time-consuming and unsuccessful.

In the future, competitors or other third parties may infringe any patents that we or our licensors may obtain. To counter any such future infringement or unauthorized use, we may eventually be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our licensors' patents are invalid or unenforceable. In addition, in a patent infringement proceeding, a court may decide that one or more patents that we may obtain in the future is not valid or is unenforceable, in whole or in part, construe the patent's claims narrowly or may refuse to stop the other party from using the technology at issue on the grounds that such patents, if any, do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of such patents, if any, at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Asserting any patent rights we may obtain in the future, and defending challenges to our rights, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and we may find it impractical or undesirable to enforce our intellectual property against some third parties.

Post-grant, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the validity or priority of inventions with respect to our or our licensors' patent applications or any patents that may issue therefrom. An unfavorable outcome could result in a loss of any patent rights we may have. 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 or proceeding. 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 material adverse effect on the price of our common stock. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Some of our patent applications may be allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that cause withdrawal of the allowance of a patent application. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO or foreign patent agency to review the application in view of the new material. In that circumstance, the USPTO or the other agency may not re-allow an application in view of the new material. Further, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the USPTO and foreign patent agencies at several stages over the lifetime of the patents and/or patent applications. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary and other similar provisions during the patent application process and following the issuance of a patent. We also may be dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors and other third parties might be able to enter the market without infringing our or our licensors' patents and patent applications, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we obtain any patents covering our product candidates, they could nonetheless be found invalid or unenforceable if challenged in court or the USPTO.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Our owned or in-licensed patents, and any of our owned or in-licensed patent applications that may issue in the future, may be challenged at the USPTO or foreign patent offices in re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions

(such as opposition proceedings). Such proceedings could result in the revocation of or amendment to such patents in such a way that they no longer cover our product candidates or technologies. If we or one of our licensing partners initiates legal proceedings against a third party to enforce a patent that we may obtain in the future covering one of our product candidates, the defendant could counterclaim that such patent is invalid and/or unenforceable. In patent litigation in the U.S., counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to any patents we may obtain in the future in such a way that they would no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of any patent protection we may eventually obtain on our product candidates and technologies. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects and our ability to commercialize or license our technology and product candidates.

Changes to patent law and its interpretation in the U.S. and in foreign jurisdictions could diminish the value of patents in general and may impact the validity, scope or enforceability of our patent rights, thereby impairing our ability to protect our product candidates and technologies.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly any patents that may issue from our pending patent applications. Changes in either the patent laws or in their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property and proprietary rights and, more generally, may affect the value of our intellectual property and proprietary rights. The U.S. continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, various courts, including the U.S. Supreme Court, have rendered decisions that have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our pending patent applications. Similarly, any adverse changes in the laws and regulations governing patents in other jurisdictions could have an adverse effect on our ability to obtain and effectively enforce our patent rights and have a material adverse effect on our business and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws in the U.S., and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in some or all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the U.S. These products may compete with our product candidates and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents. We will need to decide whether, and in which jurisdictions, to pursue protection for the various inventions in our portfolio prior to applicable filing deadlines.

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 biotechnology products and biotechnology, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights, including any infringement of any patents we may obtain in the future in such countries, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any 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 patent applications at risk of not issuing, any patent rights at risk of being invalidated or interpreted narrowly 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 establish 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.

We may be subject to claims challenging the inventorship or ownership of our patent rights and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our intellectual property as an inventor or co-inventor. It is our policy to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, such agreements may not be honored and may not effectively assign intellectual property rights to us. For instance, 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 current or former employees, consultants, and contractors, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Moreover, there may be circumstances where we are unable to negotiate for such ownership rights.

Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to inventions or other intellectual property, such a dispute could be expensive and time consuming. If we are unsuccessful in defending such claims, in addition to paying monetary damages, unless we are able to obtain a license, which might not be available on commercially reasonable terms or at all, we could lose valuable rights in intellectual property, such as the exclusive ownership of, or right to use, intellectual property that we regard as our own or that is important to our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and certain customers, licensors or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed trade secrets or other confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.

We have received, and will continue to receive, confidential and proprietary information from third parties. In addition, we have employed and expect to continue to employ individuals who were previously employed at university or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. Although we try to ensure that our employees, consultants, advisors and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, our employees, advisors, consultants or independent contractors have deliberately, inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information of these former employers, competitors or other third parties, or to claims that we have improperly used or obtained such trade secrets. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management and employees. If we are not successful in defending such claims, in addition to paying monetary damages, we could lose access or exclusive access to valuable intellectual property rights and face increased competition to our business. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

We may be subject to claims, and damages resulting from claims, that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information belonging to these former

employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates or potential products, which could have an adverse effect on our business, results of operations, financial condition and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration, conditions and specifics of any FDA marketing approval of any of our current or future product candidates that we may receive, one or more U.S. patents that we may obtain in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) and one or more of our foreign patent rights may be eligible for patent term extension under similar legislation, for example, in the EU. In the U.S., the Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, we may not be granted an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to the expiration of relevant patents, or otherwise fail to satisfy other applicable requirements. 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 term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors or other third parties may obtain approval to market competing products following expiration of any patents that we may obtain in the future, and our business, financial condition, results of operations, and prospects could be materially harmed.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on both registered and common law protection for our trademarks for use in connection with our product candidates and services in various countries. These trademarks may not afford adequate protection. Our trademark applications may be provisionally or ultimately refused by the USPTO or the trademark agencies of other countries, or such applications may be challenged by others. We also may not have the financial resources to enforce the rights under these trademarks, which may enable others to use the trademarks and dilute their value. Our trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing the trademarks of others. In such a case, we may not be able to protect or derive any value from such trademarks or may be required to cease using a conflicting mark entirely. The value of our trademarks may also be diminished by our own actions, such as failing to impose appropriate quality control when licensing our trademarks. Any of the foregoing could impair the value of, or ability to use, our trademarks, reduce our ability to compete effectively, and have an adverse effect on our business.

Certain of our in-licensed patent rights are, and our future owned and in-licensed patent rights may be, subject to a reservation of rights by one or more third parties, including government march-in rights with regards to certain patents, that may limit our ability to exclude third parties from commercializing product candidates similar or identical to ours.

Certain of our in-licensed patent rights may be subject to a reservation of rights by one or more third parties. Pursuant to the Bayh-Dole Act, the U.S. government has march-in rights with regards to government-funded technology. For example, the U.S. government has certain rights, including march-in rights, to patent rights and technology funded by the U.S. government and licensed to us from BWH. When new technologies are developed with government funding, in order to secure ownership of such patent rights, the recipient of such funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. Any failure to timely elect title to such inventions may provide the U.S. government with the right to, at any time, take title to such inventions. Additionally, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf. If the government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal

regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Risks Related to Our Reliance on Third Parties

We rely on third parties to help us conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CDMOs and strategic partners to help us conduct our preclinical studies and clinical trials under agreements with us. We have and expect to have to negotiate budgets and contracts with CROs, trial sites and CDMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations, including cGTP regulations, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. 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 drug 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 clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We have in the past and may in the future form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We have in the past and may in the future form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency and purity and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property or proprietary rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers;
- there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our collaboration agreements may grant our collaborators exclusive rights under certain of our intellectual property and may therefore preclude us from entering into collaborations with others relating to the same or similar compounds, therapeutic targets, indications or diseases. For example, the Amgen Agreement, to identify antigens recognized by T cells in patients with Crohn's disease, grants Amgen options to evaluate a variety of modalities to create therapeutics based on targets discovered by us, and Amgen will retain all global development and commercialization rights. In addition, if a collaboration agreement is terminated, in whole or in part, we may be unable to continue the development and commercialization of the applicable product candidates, and even if we are able to do so, such efforts may be delayed and result in additional costs.

We may in the future determine to partner with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our discovery platform and our business, prospects, financial condition and results of operations may be materially and adversely affected.

We have engaged a global third-party manufacturer to manufacture products for our clinical trials. In the future, we may rely on the use of manufacturing suites in third-party GMP facilities or third parties to manufacture our product candidates. Our business could be harmed if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels, prices, or timing.

We have manufacturing capacity at our facilities in Waltham, Massachusetts, but we have not yet manufactured our product candidates on a commercial scale and may not be able to do so for any of our product candidates.

We are using third parties as part of our manufacturing process to support our clinical trials for our product candidates, and we may also use them for product candidates in the future. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA must inspect any manufacturers for current cGMP and cGTP compliance as part of our marketing application;
- a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates;
- our manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our third-party suppliers or collaborators from whom we receive our antibodies used in combination with our product candidates may be unable to timely manufacture or provide the applicable antibody or produce the quantity and quality required to meet our clinical and commercial needs;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our product, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, cGTP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters;
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel; and
- our contract manufacturers may be adversely affected by the geopolitical and economic tensions with China, the ongoing conflicts between Russia and Ukraine, political unrest in countries where we or our partners operate, earthquakes, flooding, fires, and other natural or man-made disasters, equipment failures, labor shortages, power failures, and numerous other factors.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our Company until deficiencies are remedied.

The manufacture of cellular-based drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of such products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, intermediates, or raw materials, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot provide assurance that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

We may fail to manage the logistics of collecting and shipping patient material to our manufacturing site (or that of any third party we engage) and shipping the product candidate back to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to patient material as it moves to the manufacturing facility, through the manufacturing process and back to the patient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

Our product candidates rely on the availability of specialty materials, which may not be available to us on acceptable terms or at all.

Our product candidates require specialty materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. We may not be able to contract with suppliers on acceptable terms or at all. In addition, a number of our suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biotechnology firms or may divert their resources towards hospitals rather than us. Our suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We may experience delays in receiving key materials to support clinical or commercial manufacturing.

In addition, some of our raw materials are currently sourced from a single supplier, or a small number of suppliers. We also use certain biologic materials that are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and potentially modify the manufacturing process if we change suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Accordingly, if we no longer have access to these suppliers, we may experience delays in our clinical or commercial manufacturing which could harm our business or results of operations.

Our manufacturing process needs to comply with FDA or other regulatory agency regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our product candidates either at our own facility or at a third party's facility, we will need to comply with the FDA's or other regulatory agencies' cGMP regulations and guidelines, including cGTPs. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our TCR-T therapy product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our TCR-T therapy product candidates, including leading to significant delays in the availability of our TCR-T therapy product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of

approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

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

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

Risks Related to Employee Matters and Managing Growth

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. In addition, on November 3, 2025, we announced a prioritization strategy that reduced our workforce by approximately 30%, which may adversely impact our ability to retain or recruit key personnel.

We conduct our operations at our facility in Waltham, Massachusetts. This region is headquarters to many other biotechnology companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations, including as a result of the change in the U.S. presidential administration, impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

As of February 27, 2026, we had 142 full-time employees and 0 part-time employees. As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates 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 certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, and clinical trial management. There can be no assurance that the services of independent organizations, advisors and consultants 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 or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent 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, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

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

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain 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, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies 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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986 (IRC), as amended, if a corporation undergoes an "ownership change" (generally defined as one or more shareholders or groups of shareholders who own at least 5 percent of the corporation's equity increasing their equity ownership in the aggregate by a greater than 50 percentage point change (by value) over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our public offerings, our most recent private placements and other transactions that have occurred over the past three years, we have experienced, such an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership or other transactions. As of December 31, 2025, we had U.S. federal net operating loss carryforwards of $174.7 million and U.S. federal research and development tax credit carryforwards of $21.8 million that expire through 2045 and which could be limited if we experience an "ownership change." Under the current law, federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such net operating loss carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020. State net operating loss carryforwards and other tax attributes may be similarly limited. Any such limitations may result in increased tax liabilities that could adversely affect our business, results of operations, financial position and cash flows.

Risks Related to Our Common Stock and Our Status as a Public Company

We do not know whether an active trading market will continue to develop or be sustained for our common stock and, as a result, it may be difficult for our stockholders to sell their shares of our common stock.

Our common stock began trading on the Nasdaq Global Market in July 2021. Prior to July 2021, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price of our common stock, or at all.

The price of our common stock is volatile and fluctuates substantially, which could result in substantial losses for our stockholders.

Our stock price has been, and is likely to continue to be, volatile. The stock market in general, and the market for smaller biotechnology companies in particular, have experienced extreme price volatility and volume fluctuations that have often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- delays in the commencement, enrollment and the ultimate completion of clinical trials;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory actions with respect to our product candidates;
- regulatory or legal developments in the U.S. and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development or commercialization goals or regulatory approval milestones in the timeframe we announce;
- changes in hospital or emergency care partner practices;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- developments or disputes concerning intellectual property or proprietary rights;
- our ability to obtain, maintain, protect and enforce our intellectual property and proprietary rights;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry, including conditions resulting from ongoing conflicts between Russia and Ukraine;

- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- financing or other corporate transactions, or inability to obtain additional funding;
- trading activity by a limited number of stockholders who together beneficially own a substantial amount of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements, as applicable;
- the size of our market float; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biotechnology companies. Stock prices of many biotechnology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Substantial amounts of our outstanding shares may be sold into the market. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. Shares held by directors, executive officers and their affiliates will be subject to volume limitations or other restrictions under Rule 144 under the Securities Act of 1933, as amended (Securities Act) and various vesting agreements.

Certain of our stockholders have rights, subject to some conditions above, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We also have registered shares of common stock that we have issued and may issue under our employee equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

The concentration of our stock ownership will likely limit our stockholders' ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

As of February 27, 2026, our executive officers, directors, and entities affiliated with such persons beneficially owned, in the aggregate, approximately 28% of our outstanding voting stock and approximately 33% of our outstanding common stock. As a result, these stockholders, acting together, have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders, oppose them. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you or other stockholders may feel are in your or their best interest as one of our stockholders. This concentration of ownership might also have the effect of delaying or preventing a change of control of our Company that other stockholders may view as beneficial.

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

We are an "emerging growth company" as defined in the JOBS Act and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- not being required to disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation; and
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes."

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to take advantage of this extended transition period.

We cannot predict if investors will find our common stock less attractive because we will rely on 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) December 31, 2026; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our voting and non-voting common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, as amended (Sarbanes-Oxley Act) and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on 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.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC, and the Nasdaq Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.

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

We are 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 "emerging growth company" under JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to the Sarbanes-Oxley Act. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) December 31, 2026; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our voting and non-voting common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. 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 financial statement restatements and require us to incur the expense of remediation.

We will have broad discretion in the use of our cash and cash equivalents and may not use them effectively.

We will have broad discretion in the application of our cash and cash equivalents, including working capital and other general corporate purposes, and our stockholders may disagree with how we spend or invest these proceeds. We may spend our funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our stockholders.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

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

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, including the nature of the data obtained from such clinical trials, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit patients for preclinical studies and clinical trials, and any delays caused by difficulties in such recruitment efforts;
- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;

- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future drugs that compete with our product candidates;
- the changing and volatile U.S., European and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

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

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our Company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation or our amended and restated bylaws, which may inhibit the ability of an acquiror to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our Company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for stockholders to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the U.S. is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation provides further that the federal district courts of the U.S. is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choices of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the exclusive-forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

General Risk Factors

Changes in tax legislation could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local and non-U.S. taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department and other taxing authorities. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to the U.S. federal tax law. Changes to tax laws or tax rulings (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the IRC, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed outside the U.S. will be capitalized and amortized. The OBBBA provides that for taxable years beginning after December 31, 2024, expenses that are incurred for research and development performed in the U.S. may, at the taxpayer's election, be immediately deducted or capitalized and amortized. In addition, the OBBBA provides that for taxable years beginning after December 31, 2021 and before January 1, 2025, certain eligible taxpayers generally may elect to retroactively deduct expenses for research and development performed in the U.S. in such taxable years by filing amended tax returns for such taxable years, and all other taxpayers that are not eligible to make such an election and that amortized expenses for research and development performed in the U.S. in such taxable years generally may elect to accelerate and deduct the remaining unamortized amounts of such research and development expenses (i) in the first taxable year beginning after December 31, 2024, or (ii) ratably over the two-taxable year period beginning with the first taxable year beginning after December 31, 2024. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Rising inflation rates may result in increased operating costs and reduced liquidity, and affect our ability to access credit.

Increased inflation may result in increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the U.S. Federal Reserve System has repeatedly raised, and may continue to raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CDMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Item 1B. Unresolved Staff Comments

Not Applicable

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the importance of safeguarding the security of our computer systems, software, networks, and other technology assets. We have implemented processes for identifying, assessing, and mitigating cybersecurity risks and we have implemented a cybersecurity risk management program that is informed by recognized industry standards and frameworks and incorporates elements of the same, including elements of the National Institute of Standards and Technology (NIST) Cybersecurity Framework.

Our cybersecurity risk management program incorporates a number of components, including, but not limited to, information security policies and operating procedures, periodic information security risk assessments and other vulnerability analyses, and ongoing monitoring of critical risks from cybersecurity threats using automated tools. Additionally, we have implemented a process to conduct cybersecurity awareness training for employees during onboarding and thereafter.

We maintain a Cybersecurity Incident Response Plan, or CIRP, which is designed to guide our response to cyber incidents, including to mitigate and contain any potential cybersecurity incidents that could affect our systems, network, or data. The CIRP identifies the individuals responsible for developing, maintaining, and following procedures related to cybersecurity incident response, including escalation protocols. We also engage external third-party consultants to provide services, such as penetration testing, which is conducted on an annual basis, along with ongoing vulnerability scans. These consultants also perform annual assessments of our cybersecurity program, which involve, among other things, review of our IT security measures and processes for alignment with the NIST Cybersecurity Framework and provision of threat intelligence regarding emerging risks to our information systems.

As part of our cybersecurity risk management program, we maintain processes around third-party vendor risk management, including a framework for managing third-party information security risks. This framework, which applies to select third parties who have access to our systems and/or process our information, includes processes for assessing and reviewing the cybersecurity practices of such third-parties, including a review of available security audit reporting and certifications and inclusion of security requirements in contracts, as appropriate.

We have not been materially affected by cybersecurity threats. We may, from time to time, experience threats to and security incidents related to our data systems but we do not believe they are reasonably likely to materially affect our business strategy, results of operations or financial condition. For more information, please see the risk factors entitled "Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer cybersecurity incidents, data breaches or other

unauthorized or improper access, which could result in a material disruption of the development programs of our product candidates" and "Cybersecurity incidents, loss of data or modification of information, and other disruptions could compromise information related to our business or prevent us from accessing critical information, result in a significant disruption of our activities and expose us to liability, which could adversely affect our business and our reputation" in Item 1A- Risk Factors in this Annual Report on Form 10-K.

Governance

Our Head of Information Technology and Security, or Head of IT, has primary responsibility for day-to-day management of our cybersecurity risk management program, including leading a dedicated team of information technology professionals to monitor cybersecurity risks on behalf of TScan.

This team is responsible for assessing potential vulnerabilities and exposures to cybersecurity threats, implementing controls and measures designed to mitigate these risks, and regularly monitoring and updating these policies, to adapt to evolving threats. If an incident arises, the Head of IT notifies our Chief Legal and Compliance Officer, and Chief Financial Officer, who will raise issues to those charged with governance, as appropriate.

Our board of directors, as a whole and through its committees, is responsible for our overall enterprise risk management program, which incorporates as an element our cybersecurity risk management program. Our audit committee, a subcommittee of our board of directors, has been delegated responsibility for oversight of cybersecurity risk management, which includes reviewing our cybersecurity and other information, technology risks, controls and procedures, including our plans to mitigate and respond to cybersecurity risks. The Head of IT, alongside the Chief Legal and Compliance Officer, and Chief Financial Officer, provide quarterly reports to the audit committee covering cybersecurity and other information technology risks affecting us. These reports may include reviewing our current infrastructure and the status of key cybersecurity initiatives, including the status of ongoing mitigation efforts, providing insights into the latest cybersecurity threats, and discussing any recent security incidents impacting our peer companies. Periodically, or in the event of a critical cybersecurity incident, the Chief Legal and Compliance Officer, and Chief Financial Officer will provide our full board of directors with findings and recommendations from these reports.

Item 2. Properties

Our corporate headquarters is located at 830 Winter Street in Waltham, Massachusetts. The facility at 830 Winter Street is 51,100 square feet of laboratory space, with a lease expiration of October 2029. We also lease a facility at 880 Winter Street which is 113,487 square feet of office and laboratory space with a lease termination date of December 2032. We believe our facilities are sufficient to meet our current needs for the foreseeable future.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

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 has been publicly traded on The Nasdaq Global Market under the symbol “TCRX” since July 16, 2021. Prior to that time, there was no public market for our common stock.

Holders

As of February 27, 2026, there were approximately 70 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the foreseeable future.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans is incorporated herein by reference to Item 12, *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*, of this Annual Report on Form 10-K

Recent Sale of Unregistered Equity Securities

During the year ended December 31, 2025, we did not issue or sell any unregistered securities.

Use of Proceeds

In July 2021, our Registration Statement on Form S-1 (No. 333-225491) was declared effective by the SEC pursuant to which we issued and sold an aggregate of 6,666,667 shares of voting common stock at a public offering price of $15.00 per share for aggregate net cash proceeds of $89.6 million, after deducting $7.0 million underwriting discounts and commissions, and $3.4 million in offering costs borne by us. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates. The sale and issuance of 6,666,667 shares closed on July 20, 2021. Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company LLC and Barclays Capital Inc. acted as joint book-running managers for the offering. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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

Overview

We are a fully integrated clinical-stage biotechnology company focused on developing a robust pipeline of T cell receptor (TCR)-engineered T cell, or TCR-T, therapies for the treatment of patients with cancer. Our lead product candidate, TSC-101, is in development for the treatment of patients with acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) who are undergoing allogeneic hematopoietic cell transplantation (HCT). The product is designed to eliminate residual disease and promote complete donor chimerism, thereby preventing relapse. TSC-101 targets HA-2, an antigen that is present on all blood cells, malignant or benign, in patients with the HLA type A*02:01. We are currently conducting a Phase 1 clinical study of TSC-101 (the ALLOHA™ trial, NCT05473910) and during the fourth quarter of 2025, following a productive End-of-Phase meeting with the U.S. Food and Drug Administration (FDA), we reached agreement on a registrational path forward for the TSC-101 program as a potential treatment for patients with AML and MDS. The pivotal study will mirror our ongoing Phase 1 ALLOHA study, using a biologically-assigned (genetically randomized) control arm to support relapse-free survival as the primary endpoint.

We are further expanding our hematologic (heme) malignancies program with the addition of TCRs targeting other HLA types. TSC-102-A01 and TSC-102-A03 are allogeneic, donor-derived TCR-T therapy candidates targeting epitopes derived from CD45. Like TSC-101, these candidates are designed to eliminate residual cancer cells and prevent relapse in patients undergoing HCT. TSC-102-A01 and TSC-102-A03 are designed for patients with HLA types A*01:01 and A*03:01, respectively.

We are also developing multiple TCR-T therapy product candidates for the treatment of solid tumors. One of the challenges of treating solid tumors is that they are heterogeneous – not every tumor cell expresses a given target. To address this challenge, we are developing what we refer to as multiplex TCR-T therapy, in which we treat a patient with more than one TCR-T therapy product candidate at a time. We are designing these multiplex therapies to be a simultaneous administration of up to three highly active TCR-Ts that are customized for each patient based on which targets are expressed in their tumors. On November 3, 2025, following our alignment with the U.S. Food and Drug Administration (FDA) on the registrational path forward for the TSC-101 program, we made the strategic decision to prioritize clinical development of our heme program and pause further enrollment in our solid tumor Phase 1 trial (PLEXI-T™), while focusing our preclinical efforts on *in vivo* engineering for solid tumors. We believe an *in vivo* approach represents a promising and more cost-efficient way to deliver off-the-shelf, multiplexed TCR-T therapy for solid tumors.

While primarily focused on oncology, we believe our target discovery platform is well suited to identify targets that cause T cell-driven autoimmune disorders. We have identified a set of indications in which T cells play a key role and are currently identifying targets and developing potential treatment options for these disorders. Initial indications include ankylosing spondylitis, ulcerative colitis and scleroderma. In addition, the Company is continuing to discover targets for Crohn's disease in partnership with Amgen.

Since our inception in 2018, we have devoted our efforts to raising capital, obtaining financing, filing, prosecuting and maintaining intellectual property rights, organizing and staffing our Company and incurring research and development costs related to the identification of novel targets for TCRs and development of TCR-T therapy product candidates to target and eliminate cancer cells. We do not have any therapies approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from sales of capital stock, revenue received under our collaboration agreements, as well as debt facilities.

Components of Results of Operations

Revenue

To date, our revenue has primarily been derived from our collaboration and licensing agreements, which have been in the scope of ASC 606, *Revenue from Contracts with Customers*. We have not generated any revenue from the sale of therapies to date, nor do we expect to generate revenues therefrom in the near future, if at all. If our development efforts for our product candidates are successful and result in regulatory approval or if we enter into additional license or collaboration agreements with third parties, we may generate additional revenue in the future from sales of our therapies, payments from license or collaboration agreements that we may enter into with third parties, or any combination thereof. However, there can be no assurance as to when we will generate such

revenue, if at all. We expect that our revenue for at least the next several years will be derived primarily from collaborations and licenses that we may enter into in the future, if any.

Collaboration Revenue

Amgen

On May 8, 2023, the Company entered into a Collaboration Agreement with Amgen Inc. (the Amgen Agreement) to identify antigens recognized by T cells in patients with Crohn's disease in accordance with a research plan. Under the terms of the Agreement, Amgen will retain all global development and commercialization rights.

The collaboration included an upfront fee of $30.0 million. We have identified performance obligations for research and development activities, the license, data reporting and participation in joint steering and research committees, which were determined to be a single combined performance obligation due to the services and licenses being highly interrelated. During the years ended December 31, 2025 and 2024, we recognized $10.3 million and $2.8 million, respectively, of revenue associated with the Amgen Agreement. The research term of the Amgen Agreement is expected to be approximately 3 years.

See Note 9, Collaboration and License Agreements, to our audited financial statements included elsewhere in this Annual Report.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research activities, including our therapeutic discovery efforts, preclinical and clinical trials, and the development of our proprietary platform technologies and product candidates. We expense research and development costs as incurred, which include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation, and other related costs for those employees involved in research and development efforts;
- expenses incurred in connection with our research programs, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of raw materials, developing and scaling our manufacturing process, and manufacturing our product candidates for use in our research and preclinical studies, including under agreements with third parties, such as consultants, contractors, and contract development and manufacturing organizations, or CDMOs;
- laboratory supplies and research materials;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered. Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Our direct external research and development expenses consist of costs that include fees, reimbursed materials, direct material costs, and other costs paid to consultants, contractors, CDMOs and CROs in connection with our development and manufacturing activities. We do not allocate employee costs, general laboratory supplies, and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform technology and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in preclinical and earlier stages of clinical development, primarily due to increased size and duration of later stage clinical trials. At this time, we cannot

accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with therapeutic development and commercialization, including the following:

- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and progress of preclinical and clinical development activities for each program;
- our ability to raise additional funds necessary to complete preclinical and clinical development of and commercialize our product candidates;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of raw materials for use in the manufacture of our product candidates;
- our ability to consistently manufacture our product candidates for use in clinical trials;
- our ability to establish and operate a manufacturing facility, or secure manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- competition with other products and therapies; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of these product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates or in establishing market acceptance for any product candidates that may be approved.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel expenses, including stock-based compensation, for our personnel in executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional fees paid for accounting, auditing, consulting, and tax services; insurance costs; travel expenses; and facility costs not otherwise included in research and development expenses.

Restructuring Charges

On November 3, 2025, following our alignment with the U.S. Food and Drug Administration (FDA) on the registrational path forward for the TSC-101 program, we made the strategic decision to prioritize clinical development of our heme program and pause further enrollment in our solid tumor Phase 1 trial, while focusing our preclinical efforts on in vivo engineering for solid tumors and target discovery in autoimmunity. Pursuant to this strategy, we also implemented a workforce reduction of approximately 30%, or 66 roles. As part of this strategic restructuring, we incurred expenses of approximately $2.0 million for severance-related benefits and other costs, of which $1.6 million is included in research and development expenses and $0.4 million is included in general and administrative expenses in the accompanying consolidated statements of operations. The strategic prioritization is expected to produce annual cost savings of $45.0 million in 2026 and 2027. These expected savings are based on our current operating plan and may vary depending on the timing and scope of our development activities and other operational factors.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our earned research and development tax credits, due to the uncertainty of realizing a benefit from those items. As of December 31, 2025, we had federal and state net operating loss carryforwards of $174.7 million and $186.6 million, respectively, which may be used to offset future taxable income, if any. The state amounts expire at various dates through 2045. The federal net operating losses generated in and after 2018 can be carried forward indefinitely. As of December 31, 2025, we had federal and state tax credit carryforwards of $21.8 million and $13.0 million, which expire at various dates through 2045 and 2040, respectively. Due to the degree of uncertainty related to the ultimate use of the deferred tax assets, we have fully reserved these tax benefits, as the determination of the realization of the deferred tax benefits was not determined to be more likely than not.

Results of Operations

Years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Revenue			
Collaboration and license revenue	$ 10,325	$ 2,816	$ 7,509
Operating expenses:			
Research and development	114,150	107,350	6,800
General and administrative	31,988	30,287	1,701
Total operating expenses	146,138	137,637	8,501
Loss from operations	(135,813)	(134,821)	(992)
Other (expense) income:			
Interest and other income, net	8,816	12,065	(3,249)
Interest expense	(2,769)	(3,653)	884
Loss on extinguishment of debt	-	(1,090)	1,090
Total other income	6,047	7,322	(1,275)
Net Loss	$ (129,766)	$ (127,499)	$ (2,267)

Revenue

Revenue for the years ended December 31, 2025 and 2024 was $10.3 million and $2.8 million, respectively. The increase was primarily due to the timing of research activities performed pursuant to our collaboration agreement with Amgen which commenced in May 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Laboratory supplies, research materials and studies	$ 35,157	$ 31,468	$ 3,689
Personnel expenses	33,904	31,742	2,162
Facility-related and other	20,068	16,669	3,399
Clinical studies	16,847	19,245	(2,398)
Stock-based compensation	5,964	4,846	1,118
Depreciation expense	2,210	3,380	(1,170)
Total research and development expenses	$ 114,150	$ 107,350	$ 6,800

Research and development expenses increased $6.8 million and was primarily attributable to a $3.7 million increase in laboratory supplies, research materials and studies expenses driven by timing of manufacturing activities. There was also a $3.4 million increase in facility-related expenses due to the commencement of rent payments for the 830 Winter Street expansion space in December 2024, as well as a $2.2 million increase in personnel expenses which was primarily incurred prior to our enacted strategy in November 2025 to prioritize the clinical development of our heme program. Clinical expenses decreased by $2.4 million due to timing of ongoing trial activities, and depreciation expense decreased by $1.2 million as certain assets became fully depreciated. Research and development expenses included non-cash stock compensation expense of $6.0 million and $4.8 million for the years ended December 31, 2025 and 2024, respectively.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Personnel expenses	$ 11,415	$ 10,900	$ 515
Legal and professional fees	7,217	7,380	(163)
Facility-related and other	6,958	6,576	382
Stock-based compensation	5,742	4,703	1,039
Depreciation expense	656	728	(72)
Total general and administrative expenses	$ 31,988	$ 30,287	$ 1,701

General and administrative expenses increased by $1.7 million and was primarily due to a $0.5 million increase in personnel expenses. There was also a $0.4 million increase in facility-related and other expenses, a $0.2 million decrease in legal and professional fees, and a $0.1 million decrease in depreciation expense. General and administrative expenses included non-cash stock compensation expense of $5.7 million and $4.7 million for the years ended December 31, 2025 and 2024, respectively.

Other (Expense) Income

Other income decreased $1.3 million primarily due to a $3.2 million decrease in interest income attributable to lower cash balances available for investment. This decrease was offset by a $1.1 million non-recurring charge for loss on extinguishment of debt in 2024 related to the K2HV Loan Agreement repayment and a $0.9 million decrease in interest expense due to more favorable rates in 2025 under the SVB Loan Agreement.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenue from product sales and have incurred net losses and negative cash flows from our operations. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Under the terms of the Amgen Agreement, we received an upfront

payment of $30.0 million in July 2023. In addition, we are eligible to earn success-based milestone payments of over $500 million, based upon the achievement of certain clinical development and commercial milestones, as well as tiered single-digit royalty payments on net sales of products developed from the collaboration, subject to reductions set forth in the Amgen Agreement.

On June 1, 2023, we completed an underwritten public offering of (a) 23,287,134 shares of the Company's Voting Common Stock, inclusive of the underwriters' 30-day option to purchase 297,660 additional shares of Voting Common Stock, at a price of $2.00 per share, and (b) the Pre-Funded Warrants to purchase up to 47,010,526 shares of the Voting Common Stock, with a purchase price of $1.9999 per warrant and an exercise price of $0.0001 per warrant. The Company received aggregate net proceeds from the offering of $134.7 million after deducting underwriting discounts, commissions and other offering expenses.

On April 24, 2024, we completed an underwritten public offering resulting in the issuance and sale of (a) 4,958,068 shares of Voting Common Stock, including the partial exercise of the underwriters' option to purchase 2,485,487 additional shares of Voting Common Stock, at the closing market price on April 16, 2024, of $7.13 per share, and (b) Pre-Funded Warrants to purchase up to 18,577,419 shares of the Voting Common Stock, with a purchase price of $7.1299 per warrant and an exercise price of $0.0001 per warrant. We received aggregate net proceeds of approximately $161.4 million after deducting underwriting discounts, commissions and other estimated offering expenses.

Pursuant to the K2HV Loan Agreement dated September 9, 2022, K2HV extended an initial convertible term loan of $30.0 million to the Company in accordance with the K2HV Loan Agreement. On November 20, 2024, K2HV converted $15.0 million outstanding principal under the loan in exchange for 3,134,796 shares of our voting common stock. On December 20, 2024, we entered into a loan agreement with SVB (the SVB Loan Agreement), terminated the K2HV Loan Agreement and repaid all remaining outstanding loan obligations to K2HV. The SVB Loan Agreement provides for term loans up to an aggregate principal amount of $52.5 million, of which $32.5 million was provided on the closing date. We have the option to draw a second tranche of $20.0 million at the lender's sole discretion on or prior to June 30, 2026. See "Notes to Consolidated Financial Statements" and "Item 1A. Risk factors—The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility" for additional details regarding the SVB Loan Agreement.

On December 27, 2024, we completed a registered direct offering with an existing investor for the issuance of Pre-Funded Warrants to purchase up to 7,500,000 shares of the Company's Voting Common Stock with an exercise price of $0.0001 per warrant. The Pre-Funded Warrants were issued at a purchase price of $4.00 per warrant, resulting in gross proceeds of approximately $30.0 million, before deducting offering expenses of $0.2 million.

As of December 31, 2025, we had cash and cash equivalents of $152.4 million, excluding restricted cash of $5.0 million.

Funding requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our research programs into preclinical and clinical development. The timing and amount of our operating expenditures will depend largely on:

- the identification of additional research programs and product candidates;
- the scope, progress, results and costs of research and development for our current and future product candidates, including our current and planned clinical trials, and ongoing preclinical development for our current and future product candidates;
- the costs, timing and outcome of regulatory review of any product candidates we may develop;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate a clinical trial;
- our decision to develop and expand our manufacturing capabilities;
- our decision to invest in facilities to enable growth;
- investing in next-generation T cell engineering capabilities;
- changes in laws or regulations applicable to any product candidates we may develop, including but not limited to clinical trial requirements for approvals;
- the cost and timing of obtaining materials to produce adequate supply for any preclinical or clinical development of any product candidate we may develop;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any product candidate we may develop for which we obtain marketing approval;

- the legal costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims;
- additions or departures of key scientific or management personnel;
- our ability to establish and maintain collaborations on favorable terms, if at all, as well as the costs and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; and
- the costs of continuing to operate as a public company.

We believe that our existing cash and cash equivalents will enable us to fund our planned operating expenses and capital expenditure requirements into the second half of 2027. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have not yet received regulatory approval for or commercialized any of our product candidates and do not expect to generate revenue from product sales for several years, if at all. We do not expect to generate any product revenue unless and until we (1) complete development of any of our product candidates; (2) obtain applicable regulatory approvals; and (3) successfully commercialize or enter into collaborative agreements for our product candidates. We do not know with certainty when, or if, any of these items will ultimately occur. We expect to incur continuing significant losses for the foreseeable future and our losses to increase as we ramp up our preclinical and clinical development programs. We may encounter unforeseen expenses, difficulties, complications, delays and other currently unknown factors that could adversely affect our business.

While we remain an emerging growth company and a smaller reporting company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, as we continue to evolve as a business, we will incur increased costs related to legal and financial compliance.

We will require additional capital to develop our product candidates and fund our operations into the foreseeable future. We anticipate that we will eventually need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of various computerized information systems;
- impact of health crises and other external disruptions on our clinical development or operations; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions, in addition to those contained in our SVB Loan Agreement. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. If we are unable to raise capital when needed it could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds as required, we may need to delay, reduce, or terminate some or all development programs and clinical trials. We may also be required to sell or license our rights to product candidates in certain territories or indications that we would otherwise prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to address our liquidity needs, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates. See Part 2, Item 1A. “Risk Factors” of this Annual Report for additional risks associated with our substantial capital requirements.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Net cash used in operating activities	$ (135,319)	$ (110,822)	$ (24,497)
Net cash provided by (used in) investing activities	109,372	(52,613)	161,985
Net cash provided by (used in) financing activities	(336)	208,765	(209,101)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (26,283)	$ 45,330	$ (71,613)

Operating Activities

During the year ended December 31, 2025, net cash used in operating activities of $135.3 million was primarily driven by our net loss of $129.8 million, partially offset by non-cash charges of $12.6 million related to depreciation expense, accretion of marketable securities, stock-based compensation, and non-cash interest expense related to note payable. During 2025, working capital changes resulted in a use of $18.2 million. The change in working capital was primarily driven by revenue recognition related to the Amgen Agreement and changes in accrued expenses.

During the year ended December 31, 2024, net cash used in operating activities of $110.8 million was primarily driven by our net loss of $127.5 million, partially offset by non-cash charges of $11.6 million related to depreciation expense, accretion of marketable securities, stock-based compensation, non-cash interest expense related to note payable, and loss on extinguishment of debt. During 2024, working capital changes contributed $5.1 million to our cash flows. The change in working capital was primarily driven by the timing of payments to our vendors.

Investing Activities

During the year ended December 31, 2025, net cash provided by investing activities was $109.4 million, primarily related to the purchases and maturities of marketable securities, and the purchases of property and equipment.

During the year ended December 31, 2024, net cash used in investing activities was $52.6 million, primarily related to the purchases and maturities of marketable securities, and the purchases of property and equipment.

Financing Activities

During the year ended December 31, 2025, net cash used in financing activities was $0.3 million, consisting of cash paid for debt issuance and financing costs previously accrued, offset by proceeds from the issuance of common stock under the employee stock purchase plan.

During the year ended December 31, 2024, net cash provided by financing activities was $208.8 million, consisting of net proceeds of $161.4 million from our follow-on public offering in April 2024, cash proceeds of $32.5 million from borrowings under SVB Loan Agreement, cash proceeds of $30.0 million from our direct offering in December 2024, $1.7 million of proceeds from the exercise of stock options, and $0.3 million of proceeds from the issuance of common stock under 2021 ESPP. These proceeds are partially offset by $17.1 million of repayments of the K2HV Loan Agreement.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or 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. 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 making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition

To date, our revenues have primarily consisted of consideration related to the Novartis Agreement and the Amgen Agreement, which we are accounting for under ASC 606. In accordance with ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the assessment of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as we satisfy each performance obligation.

As part of the accounting for arrangements under ASC 606, we must use significant judgment to determine the performance obligations based on the determination under step (ii) above. We also use judgment to determine whether milestones or other variable consideration, except for royalties and sales-based milestones, should be included in the transaction price as described below. We recognize revenue based on those amounts when, or as, the performance obligations under the contract are satisfied.

We utilize judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. The measure of progress, and the resulting periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the arrangement, which are subject to review by the joint steering committee, or JSC. Such a change could have a material impact on the amount of revenue we record in future periods. We concluded that the transfer of control to the customer for the performance obligation occurs over the time period that the research and development services are provided by us. We recognize revenue for the performance obligation as those services are provided using an input method, based on the cumulative costs incurred compared to the total estimated costs expected to be incurred to satisfy the performance obligation. The cost-to-cost method is, in management's judgment, the best measure of progress towards satisfying the performance condition.

At the inception of each arrangement that includes research, development or regulatory milestone payments, we evaluate whether the milestones are considered likely to be met and estimate the amount to be considered for inclusion in the transaction price using the most-likely-amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone value is included in the transaction price. For milestone payments due upon events that are not within our control, such as regulatory approvals, we are not able to assert that it is likely that the regulatory approval will be granted and that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur until those approvals are received. In making this assessment, we evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur.

We reevaluate the transaction price and our total estimated costs expected to be incurred at the end of each reporting period and as uncertain events, such as changes to the expected timing and cost of certain research, development and manufacturing activities that we are responsible for, are resolved or other changes in circumstances occur. If necessary, we will adjust our estimate of the transaction price or our estimates of the total costs expected to be incurred. To date, we have not had any significant changes in our estimates.

Accrued research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

- Vendors in connection with discovery and preclinical development activities;
- CROs in connection with preclinical and clinical studies and testing; and
- CDMOs in connection with the process development and scale up activities and the production of materials.

We record the expense and accrual related to contract research and manufacturing based on our estimates of the services received and efforts expended considering a number of factors, including our knowledge of the progress towards completion of the research, development, and manufacturing activities; invoicing to date under contracts; communication from the contract research organizations, contract development and manufacturing organizations and other companies of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts and purchase orders. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of 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. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Recently Issued Accounting Pronouncements

A description of recently adopted or issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private 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 the IPO is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

The 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 financial statements is found in Item 15, *Exhibits and Financial Statement Schedules*, of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial Officer), has evaluated the effectiveness of our disclosure controls and procedures as of period end. 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, means controls and other procedures of a company 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 information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. generally accepted accounting principles or "GAAP". Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of our company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, the end of our fiscal year. Management based its assessment on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that our internal controls over financial reporting were effective as of December 31, 2025 and provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with GAAP. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our report was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the Securities and Exchange Commission for "emerging growth companies" that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. The design of any disclosure controls and procedures 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. Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

Item 9B. Other Information

None of our directors or "officers," as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the three months ended December 31, 2025.

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, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated by reference.

We have adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees as required by Nasdaq governance rules and as defined by applicable SEC rules. Stockholders may locate a copy of our Code of Business Conduct and Ethics on our website at www.tscan.com.

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 and is incorporated 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 and is incorporated 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 and is incorporated by reference.

Item 14. Principal Accountant Fees and Services.

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 and is incorporated by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

- For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.
- 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.
- Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of TScan Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 20, 2021).
3.2	Amended and Restated Bylaws of TScan Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on July 20, 2021).
4.1	Registration Rights Agreement made as of January 15, 2021 by and between the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
4.2	Amended and Restated Nominating Agreement, dated April 22, 2021, by and among the Registrant, Baker Brothers Life Sciences, L.P. and 667, L.P. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
4.3	Description of the Registrant's securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 9, 2022).
4.4	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 Securities and Exchange Commission on May 31, 2023).
4.5	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 Securities and Exchange Commission on April 17, 2024).
4.6	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 Securities and Exchange Commission on December 26, 2024).
10.1	Lease, by and between TScan Therapeutics, Inc. and BXP Waltham Woods LLC, dated November 29, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 2, 2021).
10.2#	2018 Stock Option Plan, as amended and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.3#	Amended and Restated TScan Therapeutics, Inc. 2021 Equity Incentive Plan and form of agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 14, 2024).
10.4#	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.5†	Amended and Restated Exclusive Patent License Agreement by and between the Registrant and The Brigham and Women's Hospital, Inc. dated April 20, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.6†	Collaboration Agreement by and between the Registrant and Amgen, Inc., dated as of May 8, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 10, 2023).
10.7	Lease by and between PPF OFF 828-830 Winter Street LLC and the Registrant, dated August 13, 2019 (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).

10.8	First Amendment to Lease by and between PPF OFF 828-830 Winter Street LLC and the Registrant, dated November 8, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 9, 2023).
10.9	Second Amendment to Lease by and between PPF OFF 828-830 Winter Street LLC and the Registrant, dated October 28, 2024 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 5, 2025).
10.10†	Collaboration and License Agreement by and between the Registrant and Novartis Institutes for Biomedical Research, dated as of March 27, 2020 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.11†	Non-Exclusive License Agreement by and between the Registrant and Provincial Health Services Authority, dated as of October 15, 2020 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.12	Amended and Restated Royalty Agreement, dated as of June 12, 2018 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.13#	Employment Agreement, dated May 25, 2023, by and between the Registrant and Gavin MacBeath, Ph.D (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 6, 2024).
10.14#	Form of Management Cash Incentive Plan (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 23, 2021).
10.15#	Employment Agreement, dated July 28, 2021, by and between the Registrant and Zoran Zdraveski (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 6, 2024).
10.16#	Employment Agreement, dated January 29, 2024, by and between the Registrant and Jason A. Amello (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 13, 2024).
10.17#	Employment Agreement, dated April 4, 2024, by and between the Registrant and Chrystal Louis (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 12, 2024).
10.18#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 23, 2021).
10.19	Loan and Security Agreement, dated September 9, 2022, by and among TScan Therapeutics, Inc., K2 HealthVentures LLC and Ankura Trust Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 12, 2022).
10.20†	Loan and Security Agreement, dated December 20, 2024, by and among TScan Therapeutics, Inc. and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 23, 2024).
19*	Insider Trader Policy.
21*	List of Subsidiaries of Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
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#	Compensation Recovery Policy (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2024).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Furnished herewith
# Indicates a management contract or any compensatory plan, contract or arrangement.
† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

TScan Therapeutics, Inc.

Date: March 4, 2026 By: /s/ Gavin MacBeath
Gavin MacBeath, Ph.D.
Chief Executive Officer (Principal Executive Officer)

Date: March 4, 2026 By: /s/ Jason A. Amello
Jason A. Amello
Chief Financial Officer (Principal Financial Officer)

Each person whose individual signature appears below hereby authorizes and appoints Gavin MacBeath and Jason A. Amello, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on March 4, 2026.

Signature	Title	Date
/s/ Gavin MacBeath Gavin MacBeath, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2026
/s/ Jason A. Amello Jason A. Amello	Chief Financial Officer (Principal Financial Officer)	March 4, 2026
/s/ Leiden Dworak Leiden Dworak	Vice President, Finance (Principal Accounting Officer)	March 4, 2026
/s/ Garry Nicholson Garry Nicholson	Director	March 4, 2026
/s/ Stephen Biggar Stephen Biggar, M.D., Ph.D.	Director	March 4, 2026
/s/ Katina Dorton Katina Dorton, J.D., M.B.A.	Director	March 4, 2026
/s/ Gabriela Gruia Gabriela Gruia, M.D.	Director	March 4, 2026
/s/ Barbara Klencke Barbara Klencke, M.D.	Director	March 4, 2026
/s/ R. Keith Woods R. Keith Woods	Director	March 4, 2026

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INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and Board of Directors of TScan Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TScan Therapeutics, Inc. and subsidiary (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the 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.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 Company'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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 4, 2026

We have served as the Company’s auditor since 2020.

TScan Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 152,406	$ 178,689
Marketable securities	-	111,421
Prepaid expenses and other current assets	4,802	2,612
Total current assets	157,208	292,722
Property and equipment, net	8,706	7,242
Right-of-use assets	57,743	64,357
Restricted cash	5,031	5,031
Long-term deposit and other assets	101	1,766
Total assets	$ 228,789	$ 371,118
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,241	$ 4,278
Accrued expenses and other current liabilities	7,668	15,410
Operating lease liability, current portion	7,167	4,570
Deferred revenue, current portion	2,619	11,698
Total current liabilities	18,695	35,956
Deferred revenue, net of current portion	-	1,246
Operating lease liability, net of current portion	54,437	60,739
Long-term debt and accrued interest	32,534	32,072
Other long term liabilities	-	135
Total liabilities	105,666	130,148
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2025 and 2024	-	-
Voting common stock, $0.0001 par value; 300,000,000 shares authorized; 52,625,035 and 52,314,039 shares issued and outstanding at December 31, 2025 and 2024, respectively	5	5
Non-voting common stock, $0.0001 par value; 10,000,000 shares authorized; 4,276,588 shares issued and outstanding at December 31, 2025 and 2024	1	1
Additional paid-in capital	627,979	616,009
Accumulated other comprehensive income	-	51
Accumulated deficit	(504,862)	(375,096)
Total stockholders' equity	123,123	240,970
Total liabilities and stockholders' equity	$ 228,789	$ 371,118

The accompanying notes are an integral part of these consolidated financial statements

TScan Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	**2024**
Revenue		
Collaboration and license revenue	$ 10,325	$ 2,816
Operating expenses:		
Research and development	114,150	107,350
General and administrative	31,988	30,287
Total operating expenses	146,138	137,637
Loss from operations	(135,813)	(134,821)
Other (expense) income:		
Interest and other income, net	8,816	12,065
Interest expense	(2,769)	(3,653)
Loss on extinguishment of debt	-	(1,090)
Total other income	6,047	7,322
Net loss	$ (129,766)	$ (127,499)
Net loss per share, basic and diluted	$ (1.00)	$ (1.14)
Weighted average common shares outstanding—basic and diluted	129,777,415	111,990,417
Comprehensive loss:		
Net loss	$ (129,766)	$ (127,499)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	(51)	51
Comprehensive loss	$ (129,817)	$ (127,448)

The accompanying notes are an integral part of these consolidated financial statements

TScan Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share data and issuance costs)

	Voting Common Stock		Non-voting Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at January 1, 2024	43,552,941	$ 4	4,276,588	$ 1	$ 398,459	$ -	$ (247,597)	$ 150,867
Exercise of stock options	586,081	-	-	-	1,717	-	-	1,717
Issuance of common stock under employee stock purchase plan	82,153	-	-	-	333	-	-	333
Issuance of common stock, net of offering costs	4,958,068	1	-	-	33,130	-	-	33,131
Issuance of pre-funded warrants, net of offering costs	-	-	-	-	158,071	-	-	158,071
Conversion of convertible debt	3,134,796	-	-	-	14,750	-	-	14,750
Stock-based compensation expense	-	-	-	-	9,549	-	-	9,549
Net loss	-	-	-	-	-	-	(127,499)	(127,499)
Unrealized gain on available-for-sale securities	-	-	-	-	-	51	-	51
Balances at December 31, 2024	52,314,039	$ 5	4,276,588	$ 1	$ 616,009	$ 51	$ (375,096)	$ 240,970
Issuance of common stock under employee stock purchase plan	234,826	-	-	-	264	-	-	264
Issuance of common stock upon exercise of pre-funded warrants	76,170	-	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	11,706	-	-	11,706
Net loss	-	-	-	-	-	-	(129,766)	(129,766)
Unrealized loss on available-for-sale securities	-	-	-	-	-	(51)	-	(51)
Balances at December 31, 2025	52,625,035	$ 5	4,276,588	$ 1	$ 627,979	$ -	$ (504,862)	$ 123,123

The accompanying notes are an integral part of these consolidated financial statements

TScan Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (129,766)	$ (127,499)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,866	4,108
Accretion of marketable securities	(2,409)	(3,897)
Non-cash interest expense related to loan payable	462	773
Loss on extinguishment of debt	-	1,090
Stock-based compensation	11,706	9,549
Changes in current assets and liabilities:		
Prepaid expenses and other assets	(525)	(538)
Right-of-use assets and lease liabilities, net	2,909	1,881
Accounts payable	(3,011)	1,994
Accrued expense and other liabilities	(7,226)	4,532
Deferred revenue	(10,325)	(2,815)
Net cash used in operating activities	(135,319)	(110,822)
Cash flows from investing activities:		
Purchases of property and equipment	(4,407)	(3,825)
Purchases of marketable securities	(87,471)	(241,445)
Proceeds from maturities of marketable securities	201,250	192,657
Net cash provided by (used in) investing activities	109,372	(52,613)
Cash flows from financing activities:		
Repayment of loan payable, net	-	(17,144)
Proceeds from borrowings under loan agreement, net	-	32,457
Proceeds from issuance of common stock, net of offering costs	-	33,131
Proceeds from issuance of pre-funded warrants, net of offering costs	-	158,271
Issuance of common stock under employee stock purchase plan	264	333
Proceeds from exercise of stock options	-	1,717
Cash paid for debt issuance costs	(400)	-
Cash paid for financing costs	(200)	-
Net cash provided by (used in) financing activities	(336)	208,765
Net increase (decrease) in cash, cash equivalents and restricted cash	(26,283)	45,330
Cash, cash equivalents, and restricted cash - beginning of year	183,720	138,390
Cash, cash equivalents, and restricted cash - end of year	$ 157,437	$ 183,720
Summary of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents	152,406	178,689
Restricted cash	5,031	5,031
Total cash, cash equivalents, and restricted cash	$ 157,437	$ 183,720
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,307	$ 2,881
Supplemental disclosure of non-cash investing and financing activities:		
Debt issuance costs not yet paid	$ -	$ 400
Financing costs not yet paid	$ -	$ 200
Lease liability arising from obtaining right-of-use asset	$ -	$ 6,133
Purchase of property and equipment in accounts payable and accrued liabilities	$ 7	$ 84
Issuance of common stock upon note conversion	$ -	$ 14,750

The accompanying notes are an integral part of these consolidated financial statements

1. Nature of Business and Basis of Presentation

Nature of Business

TScan Therapeutics, Inc. (the Company) is a biotechnology company that was incorporated in Delaware on April 17, 2018, and has a principal place of business in Waltham, Massachusetts. The Company is a biopharmaceutical company focused on developing a pipeline of T cell receptor (TCR)-engineered T cell (TCR-T) therapies for the treatment of patients with cancer.

Risks, Uncertainties and Going Concern

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies, clinical studies and clinical trials, the need to obtain marketing approval for its product candidates and the ability to successfully market its therapies any products that receive approval, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to scale manufacturing to large scale production. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from therapy sales.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has primarily funded its operations with proceeds from sales of capital stock, including the IPO completed in July 2021, issuance of convertible debt in September 2022, issuance of term loan in December 2024 and with payments received under its license and collaboration agreements. Since its inception, the Company has incurred recurring losses, including net losses of $129.8 million and $127.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $504.9 million. The Company expects to continue to generate operating losses in the foreseeable future. The Company expects that its cash and cash equivalents as of December 31, 2025 will be sufficient to fund the Company's operations for at least the next twelve months from the date of the issuance of the financial statements.

The Company will need to obtain substantial additional funding through equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements in order to fund its research and development and ongoing operating expenses. The Company may not be able to obtain financing on acceptable terms, when needed or at all, and the Company may not be able to enter into collaborations, strategic alliances or licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. Any collaborations, strategic alliances or licensing arrangements may require the Company to relinquish rights to certain of its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. If the Company is unable to obtain funding, the Company could be forced to delay, limit, reduce or eliminate some or all of its research and development programs, pipeline expansion or future commercialization efforts or grant rights to develop and market product candidates, which could adversely affect its business prospects. Although management will continue to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations when needed or at all.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements reflect the operations of the Company and the Company's wholly owned subsidiary, TScan Securities Corporation. The accompanying consolidated financial statements have been prepared in conformity with US GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative US GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in accordance with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

Cash includes cash in readily available checking and money market accounts. Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. The cash equivalents consisted of money market funds and government securities.

Restricted Cash

In connection with the Company's facility lease agreements, the Company is required to provide letters of credit totaling of $5.0 million for the benefit of the landlords to serve as security deposits. As of December 31, 2025 and 2024, the cash securing the letter of credit was classified as restricted cash (non-current) on the consolidated balance sheets.

Marketable Securities

The Company classifies all of its marketable securities as available-for-sale based upon its intent with regard to such investments. Unrealized gains on available-for-sale debt securities are reported as a component of accumulated other comprehensive loss in stockholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest and other income, net. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities, are included in interest and investment income.

The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest and other income, net. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary.

Concentrations of Credit Risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash deposits on hand at any one financial institution often exceed federally insured limits. The Company places its cash in financial institutions that management believes to be of high credit quality. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated useful life
Laboratory equipment	3 - 5 years
Furniture and fixtures	3 - 5 years
Office and computer equipment	3 - 5 years
Software	3 - 5 years
Leasehold improvements	Shorter of the asset's estimated useful life or the remaining lease term

Major additions and betterments are capitalized; expenditures for repairs and maintenance, which do not improve or extend the life of the respective assets, are charged to operating expense as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property and equipment, are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be fully recoverable. Evaluation of the recoverability of the asset or asset group is based on an estimate of undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, an impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value. The Company did not record any impairment losses on long-lived assets during the periods presented.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under US GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the user of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- **Level 1**—Unadjusted quoted prices in active markets that are accessible to the reporting entity at the measurement date for identical assets and liabilities.
- **Level 2**—Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability. Level 2 inputs include the following:
  - quoted prices for similar assets and liabilities in active markets
  - quoted prices for identical or similar assets or liabilities in markets that are not active
  - observable inputs other than quoted prices that are used in the valuation of the asset or liabilities (e.g., interest rate and yield curve quotes at commonly quoted intervals)
  - inputs that are derived principally from or corroborated by observable market data by correlation or other means
- **Level 3**—Unobservable inputs for the assets or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

Leases

The Company records leases under ASU No. 2016-02 *Leases* (Topic 842) whereby the Company determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, the Company has elected to not recognize a right-of-use asset or lease liability. The Company's operating leases are recognized on the consolidated balance sheets as other noncurrent assets, other current liabilities, and other noncurrent liabilities. The Company does not have any finance leases.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the rate implicit on the Company's leases are not readily determinable, the Company uses an estimate of its incremental borrowing rate for secured borrowings with terms similar to the lease term based on the information available at the lease commencement date in determining the present value of lease payments. Operating lease right-of-use assets also include the effect of any lease payments made, including lease payments made in advance of lease commencement and excludes lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs that are paid in advance of performance (if any) are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Accrued Research and Manufacturing Contract Costs

The Company has entered into various research and development and manufacturing contracts. These agreements are generally cancelable, and related payments are recorded as the corresponding expenses are incurred. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the research studies or clinical trials and manufacturing activities, 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 from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs 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.

Revenue Recognition

The Company accounts for revenue under ASU No. 2014-19, *Revenue from Contracts with Customers* (ASC 606). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, certain collaboration arrangements and financial instruments. ASC 606 provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the performance obligations are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration that it is entitled to in exchange for the goods or services the Company transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct combined performance obligation is identified.

The Company then allocates the transaction price (that is, the amount of consideration the Company expects to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied. The allocation is based upon standalone selling price. The standalone selling price is the price at which an entity would sell a promised good or service separately to a customer. Because the Company have not sold the same goods or services in our contracts separately to any customers on a standalone basis, the Company estimated the standalone selling price of each performance obligation by taking into consideration internal estimates of research and development personnel needed to perform the research and development services, estimates of expected cash outflows to third parties for services and supplies and typical gross profit margins.

The Company enters into collaboration and licensing arrangements that are within the scope of ASC 606, under which the Company may exclusively license to third parties' rights to develop, manufacture and commercialize its product candidates as well as options to acquire additional rights. The terms of these arrangements typically include payment to the Company of one or more of the following: nonrefundable, upfront license fees; development, regulatory and sales milestone payments; and royalties on net sales of licensed products.

Revenue is typically recognized using a cost-to-cost input model as the measure of progress. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete the Company's performance obligations under an arrangement. The Company evaluates the measure of progress each

reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Amounts received prior to revenue recognition are recorded as deferred revenue in the balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as the current portion of deferred revenue in the balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion in the balance sheets.

Customer Options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. To date, none of our arrangements have included any material rights. The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The observable price of a good or service sold separately provides the best evidence of standalone selling price. However, when standalone selling prices are not readily available, the Company is required to estimate the standalone selling price of each performance obligation. Key assumptions to determine the standalone selling price. Amounts allocated to a material right are not recognized as revenue until the option is exercised or terminates.

Milestone Payments

For each arrangement that includes milestone payments upon the achievement of performance-based milestones, such as development and regulatory milestones, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal of revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. Upfront and ongoing development milestones per the Company's collaboration and license agreement are not subject to refund if the development activities are not successful. The Company reevaluates the probability of achievement of such milestones and any related constraint at each reporting period, and any adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. To date, the Company has not recognized any milestone revenues.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license to the Company's intellectual property is deemed to be the predominant item to which the royalties relate as it is the primary driver of value, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception. To date, the Company has not recognized any royalty revenue resulting from the Company's collaboration and licensing agreements.

Income Taxes

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax asset to an amount, which, more likely than not, will be realized.

The Company recognizes the tax benefit from any uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement. Interest and penalties associated with uncertain tax positions are recorded as a component of income tax expense. As of December 31, 2025 and 2024, the Company has not identified any uncertain tax positions for which reserves would be required.

Segment Information

Operating segments are defined as components of an entity for which discrete information is available for evaluation by the chief operating decision maker, who is the CEO, in deciding how to allocate resources and in assessing performance. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. All of the Company's assets are held in the U.S.

Stock-Based Compensation

The Company accounts for stock option awards at fair value, which is measured using the Black-Scholes option-pricing model. The measurement date is generally the date of grant.

The Company recognizes stock-based compensation expense over the requisite service period, which is generally the vesting period of the respective award. For awards that include performance-based vesting conditions, stock-based compensation expense is recognized using the accelerated attribution method when the performance condition is deemed to be probable. The Company accounts for forfeitures as they occur. The Company determines the fair value of restricted stock awards in reference to the fair value of its common stock less any applicable purchase price

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only element of other comprehensive income was unrealized gains on marketable securities.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average common shares outstanding during the period.

Diluted net loss per share is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net income (loss) per share calculation, convertible debt and stock options are considered to be common stock equivalents. All common stock equivalents have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This ASU updates income tax disclosure requirements primarily by requiring specific categories and greater disaggregation within the rate reconciliation and disaggregation of income taxes paid by jurisdiction. This ASU is effective for annual periods beginning after December 15, 2024, and is applicable to the Company's fiscal year beginning January 1, 2025, with early application permitted. The Company adopted this standard for the fiscal year ended December 31, 2025. The adoption of ASU 2023-09 did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Effective

In November 2024, the FASB issued Accounting Standards Update (ASU) 2024-04, Debt-Debt with Conversions and Other Options. ASU 2024-04 is intended to clarify requirements for determining whether certain settlements of convertible debt instruments, including convertible debt instruments with cash conversion features or convertible debt instruments that are not currently convertible, should be accounted for as an induced conversion. This ASU is effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the potential impact of this guidance on its disclosures.

In November 2024, the FASB issued Accounting Standards Update (ASU) 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures. ASU 2024-03 is intended to improve disclosures about a public business entity's expense and provide more detailed information to investors about the types of expenses in commonly presented expense captions. The amendments in this ASU are 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 potential impact of this guidance on its disclosures.

3. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2025	2024
Laboratory equipment	$ 21,550	$ 19,371
Leasehold improvements	5,391	3,258
Furniture and fixtures	1,721	1,721
Office and computer equipment	1,496	1,496
Construction-in-progress	118	100
Property and equipment	30,276	25,946
Less: accumulated depreciation and amortization	(21,570)	(18,704)
Property and equipment, net	$ 8,706	$ 7,242

Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was $2.9 million and $4.1 million, respectively.

4. Fair Value Measurements

The following tables set forth by level, within the fair value hierarchy, the assets carried at fair value (in thousands):

	Fair value measurements at December 31, 2025 using:			
	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total
Assets				
Cash equivalents – money market funds	$ 146,196	$ -	$ -	$ 146,196
Cash equivalents – government securities	1,987	-	-	1,987
Total financial assets	$ 148,183	$ -	$ -	$ 148,183

	Fair value measurements at December 31, 2024 using:			
	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Total
Assets				
Cash equivalents – money market funds	$ 169,744	$ -	$ -	$ 169,744
Marketable securities – government securities	111,421	-	-	111,421
Total financial assets	$ 281,165	$ -	$ -	$ 281,165

Money market funds and government securities are valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no transfers among Level 1, Level 2, or Level 3 categories in the periods presented.

Assets and Liabilities Not Carried at Fair Value

The carrying value of accounts payable and accrued expenses that are reported on the consolidated balance sheets approximate fair value due to the short-term nature of these liabilities. Based on the borrowing rates currently available to the Company for bank loans with similar maturities, the fair value of long-term debt is approximately equal to its carrying amount as of December 31, 2025 and 2024.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued employee compensation and benefits	$ 4,145	$ 6,845
Accrued research and development	2,458	6,735
Accrued consulting and professional services	568	1,473
Accrued legal services and license fee	301	281
Other	196	76
Total accrued expenses and other current liabilities	$ 7,668	$ 15,410

6. Stockholders' Equity

ATM Program

On May 16, 2023, the Company entered into a sales agreement (the Sales Agreement) with Wedbush Securities, Inc. (Wedbush), as sales agent, pursuant to which the Company could offer, issue and sell up to an aggregate amount of $75.0 million of shares of the Company's voting common stock, par value $0.0001 per share (Voting Common Stock), from time to time in "at-the-market" (ATM) offerings during the term of the Sales Agreement under a registration statement on Form S-3 (File No. 333-268260) filed with the SEC, which was declared effective on May 16, 2023. No Voting Common Stock has been sold under this Sales Agreement to date.

Equity Offerings

On June 1, 2023, the Company completed an underwritten public offering resulting in the issuance and sale of (a) 23,287,134 shares of Voting Common Stock, at a price of $2.00 per share, and (b) pre-funded warrants (Pre-Funded Warrants) to purchase up to 47,010,526 shares of the Voting Common Stock, with a purchase price of $1.9999 per warrant and an exercise price of $0.0001 per warrant. The Company received aggregate net proceeds of $134.7 million after deducting underwriting discounts, commissions and other offering expenses, with $42.4 million allocated to the Voting Common Stock and $92.3 million allocated to Pre-Funded Warrants.

On April 24, 2024, the Company completed an underwritten public offering resulting in the issuance and sale of (a) 4,958,068 shares of Voting Common Stock, including the partial exercise of the underwriters' option to purchase 2,485,487 additional shares of Voting Common Stock, at the closing market price on April 16, 2024, of $7.13 per share, and (b) Pre-Funded Warrants to purchase up to 18,577,419 shares of the Voting Common Stock, with a purchase price of $7.1299 per warrant and an exercise price of $0.0001 per warrant. The Company received aggregate net proceeds of approximately $161.4 million after deducting underwriting discounts, commissions and other offering expenses, with $33.1 million allocated to the Voting Common Stock and $128.3 million allocated to Pre-Funded Warrants.

On December 27, 2024, the Company completed a registered direct offering with an existing investor for the issuance of Pre-Funded Warrants to purchase up to 7,500,000 shares of the Company's Voting Common Stock, with an exercise price of $0.0001 per warrant. The Pre-Funded Warrants were issued at a purchase price of $4.00 per warrant, resulting in gross proceeds of approximately $30.0 million, before deducting offering expenses of $0.2 million.

The Pre-Funded Warrants are immediately exercisable subject to certain ownership limitations, have an exercise price of $0.0001 per share, may be exercised at any time and do not expire. The Pre-Funded Warrants were determined to be equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the Pre-Funded Warrants do not provide any guarantee of value or return. As such, proceeds received from the issuance of the Pre-Funded Warrants were recorded as a component of stockholders' equity within additional paid-in capital. During the year ended December 31, 2025, the Company issued an aggregate of 76,170 shares of its common stock pursuant to the cashless exercise of 76,178 Pre-Funded Warrants at a weighted average exercise price of $0.0001 per share. The Company did not issue any common stock pursuant to the exercise of Pre-Funded Warrants during the year ended December 31, 2024.

Common Stock Reserved for Future Issuance

The Company has reserved the following shares of common stock for future issuance:

	December 31,	
	2025	2024
Stock options outstanding	16,004,393	12,467,782
Pre-Funded Warrants outstanding	73,011,767	73,087,945
Shares available for future grant under 2021 Plan	7,432,023	5,781,492
Shares available for future issuance under 2021 ESPP	1,316,566	985,486
Total shares of common stock reserved	97,764,749	92,322,705

7. Stock-Based Compensation

2021 Equity Incentive Plan

The 2021 Equity Incentive Plan (the 2021 Plan) was approved by the Company's Board on April 22, 2021 and became effective immediately, although no awards were permitted to be granted under the 2021 Plan until July 15, 2021. The 2021 Plan replaced the 2018 Plan, however, awards outstanding under the 2018 Plan continue to be governed by their existing terms. In addition, shares of common stock subject to awards granted under the 2018 Plan that cease to be subject to such awards by forfeiture or otherwise after the termination of the 2018 Plan will be available for issuance under the 2021 Plan.

There were 3,278,048 shares of common stock initially reserved for issuance under the 2021 Plan and as of December 31, 2025, there were 7,432,023 shares of common stock available for issuance. The number of shares reserved for issuance under the 2021 Plan will be increased automatically on the first business day of each fiscal year, commencing in 2022 and ending in 2031. The aggregate number of common shares that may be issued under the 2021 Plan shall automatically increase by a number equal to the least of (a) 4% of the number of the total outstanding common shares on the last day of the preceding fiscal year, or (b) a number of shares common stock determined by the Company's Board.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") was approved by the Company's Board on April 22, 2021 and became effective immediately, although no awards were permitted to be granted under the 2021 Plan until July 15, 2021. A total of 254,390 shares of common stock were initially reserved for issuance under the 2021 ESPP. As of December 31, 2025 and 2024, there were 463,359 and 228,533 shares issued under the 2021 ESPP, respectively. As of December 31, 2025, there were 1,316,566 shares of common stock available for issuance under the 2021 ESPP. The number of shares reserved for issuance will automatically be increased on the first business day of each fiscal year, commencing on January 1, 2022 and ending on January 1, 2041. The aggregate number of shares of common stock that may be issued under the 2021 ESPP shall automatically increase by a number equal to the least of (i) one percent (1%) of the total number of shares of common stock actually issued and outstanding on the last day of the preceding fiscal year, or (ii) a number of shares of common stock determined by the Company's Board.

Stock Compensation

Stock-based compensation expense related to stock options and the stock purchase plan for the years ended December 31, 2025 and 2024 was classified in the consolidated statement of operations as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 5,964	$ 4,846
General and administrative	5,742	4,703
Total stock-based compensation expense	$ 11,706	$ 9,549

Stock Options

The Company typically grants stock options at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant, based upon the quoted price of the Company's common stock.

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company lacks sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected

term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. 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 and does not expect to pay any cash dividends in the foreseeable future.

The weighted-average for each of the assumptions the Company used to determine the grant-date fair value of options granted were as follows:

	Year Ended December 31,	
	2025	2024
Risk free interest rate	4.36%	4.03%
Expected term (in years)	6.20	6.19
Expected dividend yield	0%	0%
Expected volatility of underlying common stock	96%	89%

The following table summarizes the stock option activity:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Intrinsic Value (in thousands)
Outstanding January 1, 2025	12,467,782	$ 4.22	8.29	$ 3,912
Granted	6,247,600	2.73		
Exercised	—	—		
Canceled	(2,710,989)	3.62		
Outstanding December 31, 2025	16,004,393	$ 3.74	7.28	$ —
Options vested or expected to vest as of December 31, 2025	16,004,393	$ 3.74	7.28	$ —
Stock options exercisable as of December 31, 2025	7,472,443	$ 4.34	5.88	$ —

Other information related to the option activity for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Weighted-average fair value of options granted	$ 2.19	$ 4.90
Intrinsic value of options exercised (in thousands)	-	1,954

As of December 31, 2025, the unrecognized compensation cost related to outstanding options was $18.8 million, which is expected to be recognized over a weighted-average period of 2.37 years.

8. Income Taxes

During the years ended December 31, 2025 and 2024, the Company did not record an income tax provision due to the losses incurred and a full valuation allowance provided on the net deferred tax assets.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," effective for annual periods beginning after December 15, 2024. ASU 2023-09 requires companies to present a detailed reconciliation of the statutory and effective income tax rates, including specified categories such as state and local taxes, foreign taxes, tax credits, and changes in valuation allowances, to provide greater transparency into the factors affecting the effective tax rate. The standard also mandates disclosure of income taxes paid, disaggregated by federal, state, and foreign jurisdictions, enabling users to better understand the company's cash tax payments across different tax authorities. Furthermore, companies must describe significant tax positions and valuation allowances, including the nature and amounts of such positions, and the judgments or assumptions underlying their recognition or measurement. ASU 2023-09 permits companies to apply these enhanced disclosure requirements either retrospectively to all periods presented or prospectively to periods beginning after the adoption date; the Company has elected to adopt the standard prospectively. The adoption of ASU 2023-09 had no impact to the Company's consolidated balance sheets, consolidated statements of comprehensive (loss) income, or consolidated statements of cash flows, as ASU 2023-09 affects disclosures only.

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted, providing taxpayers the option to fully deduct or continue capitalizing and amortizing domestic R&D expenditures under new Code Section 174A, effective for tax years beginning after December 31, 2024. The OBBBA also provides certain eligible taxpayers with the option to accelerate and deduct the remaining unamortized domestic R&D costs incurred during taxable years ending after December 31, 2021 and before January 1, 2025. The Company intends to continue amortizing domestic R&D costs incurred during taxable years ending after December 31, 2021 and

before January 1, 2025. As of December 31, 2025, $129.3 million remains unamortized related to domestic R&D costs. Final elections will be made with the 2025 tax return filing.

A reconciliation of the federal statutory income tax rate to the effective rate for the year ended December 31, 2024 is as follows:

	Year Ended December 31, 2024
Taxes at U.S. statutory rate	21.0 %
Changes from statutory rate:	
State taxes, net of federal benefit	7.5 %
Tax credits	5.0 %
Share-based compensation	(0.9)%
Change in valuation allowance	(30.9)%
Other	(1.7)%
Effective income tax rate	0.0%

A reconciliation of the federal statutory income tax rate to the effective rate for the year ended December 31, 2025 is as follows (in thousands, except percentages):

	Year Ended December 31, 2025	
U.S. Federal Statutory Income Tax (Benefit) at 21%	$ (27,225)	21.0 %
Domestic Federal		
Tax Credits		
R&D Credit	(3,904)	3.0 %
Non Taxable or Non Deductible		
Excess Officer Compensation	1,022	(0.8)%
Stock Compensation	954	(0.7)%
Other	19	(0.0)%
Change in valuation allowance	29,134	(22.5)%
Total	-	0.0%

Deferred tax assets and liabilities reflect the net tax effects of net operating loss carryovers and temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 48,477	$ 31,332
Tax credits	32,102	25,427
Deferred revenue	716	3,536
Depreciation and amortization	897	1,216
Amortization	386	432
Stock-based compensation	2,319	1,681
Leasehold liability	16,830	17,842
Capitalized R&D costs	62,129	48,315
Other	13,177	9,391
Total deferred tax assets	177,033	139,172
Deferred tax liabilities:		
Right of use Asset	(15,775)	(17,582)
Valuation allowance	(161,258)	(121,590)
Net deferred tax assets and liabilities	$ -	$ -

In determining the need for a valuation allowance, the Company has given consideration to its cumulative book income and loss positions. The Company has assessed the available means of recovering deferred tax assets, including the ability to carryback net operating losses, the existence of reversing taxable temporary differences, the availability of tax planning strategies and forecasted future taxable income. As of December 31, 2025, the Company maintains a full valuation allowance against its net deferred tax assets. The valuation allowance increased by $39.7 million and $39.3 million during the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, the Company had U.S. federal net operating loss carryforwards of approximately $174.7 million. The U.S. federal net operating losses have an indefinite life carryforward. As of December 31, 2025, the Company had Massachusetts net operating loss carryforwards of approximately $186.6 million that expire at various dates through 2045. As of December 31, 2025, the Company had U.S. R&D federal credit carryforwards of approximately $21.8 million that expire at various dates through 2045. As of December 31, 2025, the Company had U.S. state R&D tax credit carryforwards of approximately $13.0 million that expire at various dates through 2040.

Under Sections 382 and 383 of the U.S. Internal Revenue Code, if a corporation undergoes an ownership change, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change attributes, such as net operating losses and research tax credits, to offset its post-change income and taxes may be limited. In general, an ownership change generally occurs if there is a cumulative change in ownership by 5% stockholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under U.S. state tax laws. The Company has experienced an ownership change in the past and may experience ownership changes in the future as a result of future transactions in its share capital, some of which may be outside the control of the Company. As a result, if the Company earns net taxable income, its ability to use its pre-change net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes is subject to significant limitations.

The Company accounted for uncertain tax positions using a more likely than not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates uncertain tax positions on an annual basis and adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. For the years ended December 31, 2025 and 2024, there were no accrued interest or penalties in the consolidated statements of operations.

The Company is subject to taxation for federal and Massachusetts purposes. As of December 31, 2025, the Company is subject to examination by these taxing authorities for all years since inception in 2018.

9. Collaboration and License Agreements

Amgen

On May 8, 2023, the Company entered into a Collaboration Agreement with Amgen Inc. (the Amgen Agreement) to identify antigens recognized by T cells in patients with Crohn’s disease in accordance with a research plan. Under the terms of the Amgen Agreement, Amgen will retain all global development and commercialization rights. The proceeds from the Amgen Agreements included an upfront payment of $30.0 million, which was collected in July 2023. In addition, the Company is eligible to earn success-based milestone payments of over $500 million, based upon the achievement of certain clinical development and commercial milestones, as well as tiered single-digit royalty payments on net sales of products developed from the collaboration, subject to reductions set forth in the Amgen Agreement.

The Company concluded that Amgen meets the definition of a customer, as the Company is delivering research and development activities and a license of intellectual property. The Company identified performance obligations for research and development activities, the license, data reporting and participation in joint steering and research committees, which were determined to be a single combined performance obligation due to the services and licenses being highly interrelated.

For a certain time period during the term of the Amgen Agreement, Amgen has an option to add targets to the collaboration for payments specified in the agreement. Pursuant to the Amgen Agreement, the option for Amgen to select additional targets and to license, develop, and commercialize targets is not a performance obligation at the outset as these are customer options that do not represent material rights.

The Company looked to the promises in the arrangement to determine the method of recognition that best depicted the transfer of the services and the satisfaction of the combined performance obligations. The Company concluded that the performance of the

research services over the expected research term was the predominant promise within the performance obligation. The Company will recognize the revenue associated with the performance obligation using an input method. The method of measuring progress towards delivery of the services incorporates actual internal and external costs incurred, relative to total internal and external costs expected to be incurred to satisfy the performance obligation. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment. As costs are incurred, the Company will recognized revenue over time. At this time, it is estimated that the research term will be approximately 3 years.

The Company determined the $30.0 million upfront payment to be the entirety of the consideration to be included in the transaction price. The option to add additional targets was not included in the transaction price as this option was assessed to be improbable at this time. The potential milestone and royalty payments that the Company is eligible to receive were also excluded from the transaction price, as all milestone and royalty amounts were fully constrained based on the assessed probability of achievement. The Company will continue to assess the probability of the option to add additional targets and the probability of milestone achievement throughout the research term and will adjust the consideration in the contract accordingly.

For the years ended December 31, 2025 and 2024, the Company recognized $10.3 million and $2.8 million, respectively, of revenue associated with the Amgen Agreement. As of December 31, 2025, the Company recorded $2.6 million of deferred revenue which is classified as short-term.

10. Commitments and Contingencies

Leases

The Company leases two facilities at 880 Winter Street and 830 Winter Street in Waltham, Massachusetts. Each lease has specified terms and includes renewal options. Given uncertainty as to the Company's intentions with respect to these leases, the renewal options were not deemed reasonably certain.

On October 28, 2024, the Company entered into a second lease amendment expanding the rentable space of 830 Winter Street. The amendment provides for an additional 25,628 square feet of space with a commencement date of December 1, 2024 and an expiration date of October 31, 2029 with one option to renew for a five-year period. This amendment resulted in an increase in the lease liability of $6.1 million.

Summary of lease cost

The following table summarizes the presentation in the Company's consolidated balance sheets of its operating leases (in thousands):

	As of December 31,	
	2025	2024
Assets:		
Operating lease assets	$ 57,743	$ 64,357
Liabilities:		
Operating lease liabilities, current	7,167	4,570
Operating lease liabilities, net of current portion	54,437	60,739
Total operating lease liabilities	$ 61,604	$ 65,309

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations (in thousands):

	Years Ended December 31,	
	2025	2024
Operating lease costs	$ 12,997	$ 11,564
Variable lease costs	5,643	3,408
Total lease costs	$ 18,640	$ 14,972

During the years ended December 31, 2025 and 2024, the Company made cash payments for operating leases of $10.1 million and $9.8 million, respectively.

As of December 31, 2025, future payments of operating lease liabilities are as follows (in thousands):

	As of December 31, 2025
2026	$ 12,958
2027	13,329
2028	13,712
2029	13,354
2030 and thereafter	30,640
Total future payments of operating lease liabilities	83,993
Less: imputed interest	(22,389)
Present value of operating lease liabilities	$ 61,604

As of December 31, 2025, the weighted average remaining lease term was 6.3 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 9.9%. As of December 31, 2024, the weighted average remaining lease term was 7.3 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 10.0%.

Brigham and Women's License Agreement

The Company obtained the worldwide exclusive license to its foundational technology from The Brigham and Women's Hospital, Inc. (or BWH). The license, as amended, grants worldwide exclusive use to the patent underlying the TargetScan technology in exchange for fees including development milestones and various royalties on product sales should they occur in the future.

Royalty Agreement

In June 2018, the Company amended and restated an existing royalty agreement with one of its founders. Under the amended and restated royalty agreement, the Company agreed to pay the founder an aggregate royalty of 1% of net sales of any product sold by the Company or by any of its direct or indirect licensees for use in the treatment of any disease or disorder covered by a pending patent application or issued patent held or controlled by the Company as of the last date that the founder was providing services to the Company as a director or consultant under a written agreement in perpetuity. Royalties are payable with respect to each applicable product for a defined period of time set forth in the royalty agreement. The founder assigned his rights and obligations under the royalty agreement to one of his affiliated entities in January 2021.

11. Loan and Security Agreements

K2 HealthVentures LLC

On September 9, 2022 (the Closing Date), the Company entered into a Loan and Security Agreement (the Loan Agreement) with K2 HealthVentures LLC (K2HV), pursuant to which convertible term loans in an aggregate principal amount of up to $60.0 million is available to the Company in three tranches, subject to certain terms and conditions. The Company drew the first tranche of $30.0 million from K2HV on the Closing Date. The Company had the option to draw the second tranche of $10.0 million upon the achievement of certain financial and clinical milestones and an uncommitted third tranche of $20.0 million could be funded by joint agreement of the Company and K2HV. On the Closing Date, the Company paid a facility fee of $0.4 million to K2HV and is subject to an additional 1% of the principal amount of any amount drawn on third tranche.

The term loan was expected to mature on September 1, 2026 (the Maturity Date), and was subject to interest only payments for 24 months, which could be extended to 36 months upon achievement of certain financial and clinical milestones, following which the term loans would amortize in equal monthly installments until maturity. The Company had the ability to repay the loan at any time either in cash or in shares, subject to applicable premiums as specified in the Loan Agreement. The term loans accrued interest at a per annum rate equal to the greater of (i) 8.75% and (ii) the sum of (A) the prime rate (as last quoted in The Wall Street Journal) and (B) 4.75%, subject to a cap of 9.90%.

On September 26, 2024, K2HV confirmed to the Company that the amortization commencement date would be October 1, 2025, thereby extending the interest-only period under the Loan Agreement for 12 months. This extension met the definition of an accounting debt modification in accordance with ASC 470-50 and was accounted for prospectively as a yield adjustment, with no resulting gain or loss recognized.

The lenders could elect at any time following the closing prior to the payment in full of the term loans to convert any portion of the principal amount of the term loans then outstanding into shares of the Company's common stock. The first tranche of the loan was convertible at the option of K2HV at a conversion price of $4.785 per share and future tranches could be convertible as specified in the agreement, provided that, such price shall be subject to the applicable conversion price floor and other adjustments in accordance with the Loan Agreement. The embedded conversion option met the derivative accounting scope exception since the embedded conversion option was indexed to the Company's own common stock and qualifies for classification within stockholders' equity.

The Company had the option to prepay all, but not less than all, of the outstanding principal balance of the term loans under the Loan Agreement subject to a prepayment fee ranging from 4% to 1% depending upon when the prepayment occurs. The Company was obligated to pay a final fee equal to 6.00% of the aggregate amount of the term loans funded (the Exit Fee), to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. If, upon equity conversion, K2HV received gross proceeds in an amount equal to at least 1.5 multiplied by the principal amount converted from the sale or other disposition of such Conversion Shares (as defined in the Loan Agreement), then as to such principal amount, the Exit Fee would be reduced to zero.

On November 20, 2024, K2HV elected to convert $15.0 million of the outstanding principal balance into 3,134,796 shares of the Company's voting common stock at a price of $4.785, in accordance with the agreement.

On December 20, 2024 the Company repaid the remaining obligation of the debt agreement, which included $15.0 million in remaining principal, a $1.8 million Exit Fee, and a $0.3 million prepayment fee. The Company recognized a loss from extinguishment of $1.1 million.

The Company recorded $3.6 million in interest expense for the year ended December 31, 2024. The effective interest rate on the Loan Agreement, including the amortization of the debt discount and issuance costs, and accretion of the Exit Fee, was 12.61% upon extinguishment.

Silicon Valley Bank

On December 20, 2024 (the effective date), the Company entered into a Loan and Security Agreement (SVB Loan Agreement) with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (SVB). Under the SVB Loan Agreement, SVB will extend up to $52.5 million in a term loan facility, consisting of a first tranche of $32.5 million fully funded on the Effective Date and a second tranche of $20.0 million to be available to the Company at the Lender's sole discretion on or prior to June 30, 2026.

The term loans will mature on September 1, 2029, and will be subject to monthly interest only payments until September 30, 2027, provided the Company achieves certain financial and clinical milestones, following which the term loans will amortize in equal monthly installments until maturity. If the Company does not achieve such financial and clinical milestones by June 30, 2026, the maturity date will be September 1, 2028, and the interest only period will end on September 30, 2026, following which the term loans will amortize in equal monthly installments until maturity.

The term loans will accrue interest at a per annum rate equal to the greater of (i) 7.00% and (ii) the prime rate (as last quoted in The Wall Street Journal), minus 0.75%; provided that such interest rate shall not exceed 9.75% per annum. The Company will be liable for a final payment that is due on the earliest to occur of (a) the maturity date, (b) the repayment of the term loans in full, and (c) the date upon which the term loans are accelerated by the Lender, in an amount equal to the aggregate original principal amount of the term loans extended by the Lender to the Company, multiplied by 5.0% (Exit Fee). In addition, the Company will be liable for a prepayment fee equal to (x) 3.0% of the principal amount of term loans prepaid during the first year of the term, (y) 2.0% of the principal amount of term loans prepaid during the second year of the term, and (z) 1.0% of the principal amount of term loans prepaid thereafter. The term loans will automatically accelerate upon the occurrence of a bankruptcy or insolvency event involving the Company or its subsidiaries.

The SVB Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict the Company's and its subsidiaries' ability to, among other things, dispose of assets, make changes to its business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, grant liens on its assets, pay dividends or other distributions, repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain thresholds and exceptions. The SVB Loan Agreement does not require the Company to comply with a financial maintenance covenant. As collateral for its obligations under the SVB Loan Agreement, the Company granted the Lender a first-priority security interest on substantially all of the Company's assets (other than intellectual property), subject to certain exceptions. The Company's obligations under the SVB Loan Agreement will be guaranteed by each of the Company's future direct or indirect subsidiaries, subject to certain exceptions.

The Company recorded $2.8 million and $0.1 million in interest expense for the years ended December 31, 2025 and 2024, respectively. The effective interest rate on the SVB Loan Agreement, including the amortization of the debt discount and issuance costs, and accretion of the Exit Fee, was 8.46% at December 31, 2025.

Future principal payments as of December 31, 2025 are as follows (in thousands):

2027	$	4,063
2028		16,250
2029		12,187
Total principal payments		32,500
Plus: Final payment fee		1,625
Less: unamortized debt discount and final fee		(1,591)
Total debt	$	32,534

12. Retirement Plan

The Company initiated a defined contribution plan under Section 401(k) of the IRC (the Plan) covering all qualified employees effective January 1, 2019. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company made contributions to the Plan of $1.3 million and $1.0 million for the years ended December 31, 2025 and 2024, respectively.

13. Restructuring

On November 3, 2025, following the Company's alignment with the U.S. Food and Drug Administration (FDA) on the registrational path forward for the TSC-101 program, the Company made the strategic decision to prioritize clinical development of its heme program and pause further enrollment in its solid tumor Phase 1 trial, while focusing its preclinical efforts on in vivo engineering for solid tumors and target discovery in autoimmunity. Pursuant to this strategy, the Company also implemented a workforce reduction of approximately 30%, or 66 roles. As part of this strategic restructuring, the Company incurred expenses of approximately $2.0 million for severance-related benefits and other costs, of which $1.6 million is included in research and development expenses and $0.4 million is included in general and administrative expenses in the accompanying consolidated statements of operations.

Approximately $1.0 million of accrued severance-related benefits and other costs are included in accrued expenses on the consolidated balance sheet as of December 31, 2025. These payments are expected to be completed in the fourth quarter of 2026.

The following table summarizes the Company's liability recognized in connection with the restructuring (in thousands):

Balance as of January 1, 2025	$	-
Severance-related benefits and other costs		2,041
Cash payments		(1,026)
Balance as of December 31, 2025	$	1,015

14. Segment Reporting

Operating segments are defined as components of the entity for which separate financial information is made available and that is regularly evaluated by the chief operating decision maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company's CODM is its chief executive officer and the Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on the development of T cell receptor (TCR)-engineered T cell (TCR-T) therapies for the treatment of patients with cancer.

The CODM assesses the Company's performance by reviewing GAAP net loss and significant expenses by function along with the annual budget. The chief operating decision maker considers budget-to-actual variances on a quarterly basis when making decisions about the allocation of operating and capital resources.

The following table provides information about the Company's single operating segment which includes significant expenses by function along with significant non-cash expense items.

	Year Ended December 31,	
	2025	2024
Revenue:		
Collaboration and license revenue	$ 10,325	$ 2,816
Operating expenses:		
Research and development:		
Laboratory supplies, research materials and studies	35,157	31,468
Personnel expenses	33,904	31,742
Facility-related and other	20,068	16,669
Clinical studies	16,847	19,245
Stock-based compensation	5,964	4,846
Depreciation expense	2,210	3,380
General and administrative:		
Personnel expenses	11,415	10,900
Legal and professional fees	7,217	7,380
Facility-related and other	6,958	6,576
Stock-based compensation	5,742	4,703
Depreciation expense	656	728
Other (expense) income:		
Interest and other income, net	8,816	12,065
Interest expense	(2,769)	(3,653)
Loss on extinguishment of debt	-	(1,090)
Net Loss	$ (129,766)	$ (127,499)

15. Net Loss Per Share

Net Loss Per Share

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share data):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (129,766)	$ (127,499)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	129,777,415	111,990,417
Net loss per share, basic and diluted	$ (1.00)	$ (1.14)

The 73,011,767 shares of the Company's common stock issuable upon exercise of the Pre-Funded Warrants described in Note 6 are included as outstanding common stock in the calculation of basic and diluted net loss per share.

The Company has two classes of common stock, each with identical participation rights to earnings and liquidation preferences, and therefore the calculation of net loss per share as described above is identical to the calculation under the two-class method. The Company excluded the following potential common shares from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	December 31,	
	2025	2024
Options to purchase common stock	16,004,393	12,467,782
Potential shares issuable under the ESPP	167,703	138,133
Total	16,172,096	12,605,915

EXECUTIVE OFFICERS

Gavin MacBeath, Ph.D.
Chief Executive Officer

Jason A. Amello
Chief Financial Officer and Treasurer

Chrystal Louis, M.D., M.P.H.
Chief Medical Officer

Zoran Zdraveski, J.D., Ph.D.
Chief Legal and Strategy Officer and Secretary

BOARD OF DIRECTORS

Stephen Biggar, M.D., Ph.D.
Chair of the Board of Directors
Partner at Baker Bros. Advisors LP

Gavin MacBeath, Ph.D.
Chief Executive Officer

Katina Dorton, J.D., M.B.A.
Former Chief Financial Officer of Nodthera Inc.

Gabriela Gruia, M.D.
Founder of Gabriela Gruia Consulting, LLC

Barbara Klencke, M.D.
Chief Medical Officer of ALX Oncology Holdings Inc.

Garry Nicholson
Chair of the Board of Directors of Abdera Therapeutics Inc. and Day One Biopharmaceuticals, Inc.

R. Keith Woods
Chief Operating Officer of Scholar Rock Biotechnology Company

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