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 001-40908

MiNK Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-2142067**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
149 Fifth Avenue **Suite 500** **New York, NY**	**10010**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 212-994-8250

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	INKT	Nasdaq Capital Market

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 Section 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

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

As of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of Common Stock held by non-affiliates of the registrant was: $10.9 million.

The number of shares of Registrant's Common Stock outstanding as of March 27, 2026 was 4,965,858.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2026 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Report.

Auditor Firm Id: 185 Auditor Name: KPMG LLP Auditor Location: Boston, Massachusetts

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Note Regarding Forward Looking Statements

This Annual Report on Form 10-K and other written and oral statements we make from time to time contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. Forward-looking statements include all statements other than statements of historical fact contained in this Annual Report on Form 10-K, including without limitation statements regarding our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations, and intentions. Words such as “could,” “expect,” “anticipate,” “estimate,” “target,” “may,” “project,” “guidance,” “intend,” “plan,” “believe,” “will,” “potential,” “opportunity,” “future” and other words and terms of similar meaning and expression are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Although we believe we have been prudent in our plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved, and readers are cautioned not to place undue reliance on such statements, which speak only as of the date of this report. We undertake no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events or otherwise, except as required by law.

The risks identified in this Annual Report on Form 10-K, including, without limitation, the risks set forth in Part I-Item 1A. “Risk Factors,” could cause actual results to differ materially from forward-looking statements contained in this Annual Report on Form 10-K. We encourage you to read those descriptions carefully. Such statements should be evaluated in light of all the information contained in this document.

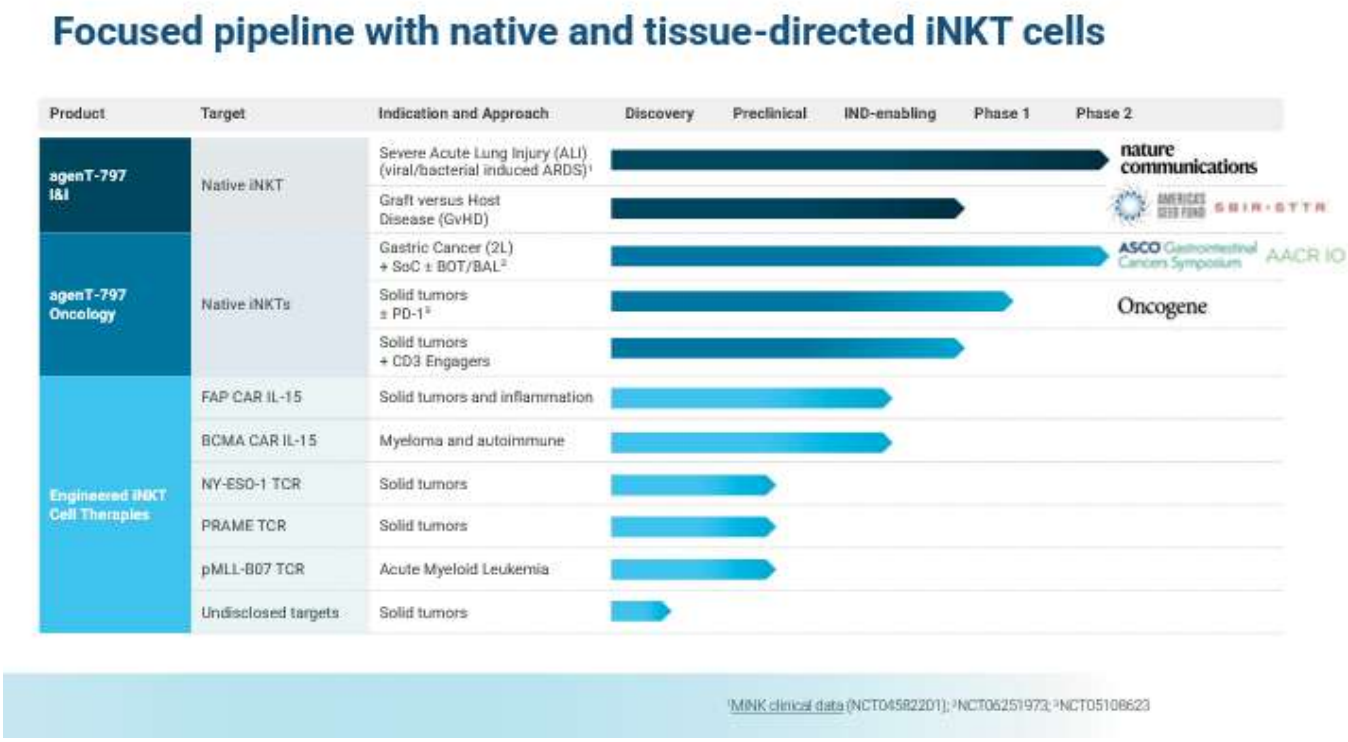
PART I

Item 1. Business.

MiNK Therapeutics, Inc. (“we,” “our,” or “MiNK”) is focused on developing innovative treatments for cancer and immune-mediated diseases using allogeneic, ex-vivo expanded invariant natural killer T ("iNKT") cells. Amid a broader industry renaissance in innate immunity—highlighted by surging investment and clinical activity in NK, γδ T, and iNKT-based therapies—iNKT cells represent a distinct T cell (“T”) population that uniquely bridges innate and adaptive immunity. They combine durable memory responses characteristic of adaptive T cells with rapid, MHC-independent rapid cytolytic capabilities of natural killer ("NK") cells. This dual functionality enables direct tumor killing via CD1d and stress ligands, potent orchestration of the tumor microenvironment through activation of dendritic cells and NK cells, elimination of immunosuppressive myeloid populations, and restoration of exhausted T-cell function—all while naturally suppressing graft-versus-host disease ("GvHD"). This unique combination positions iNKT cells as an optimal platform for allogeneic therapy, given their natural homing capabilities, tumor clearance potential, and efficacy against infected cells.

Our approach includes advancing both native and engineered iNKT cell therapies, leveraging a pipeline composed of wholly owned or exclusively licensed assets. Additionally, we have developed a proprietary personalized neoantigen library to facilitate personalized T Cell Receptor ("TCR") development. This library enables us to identify patient-specific tumor neoantigens, which we use to create highly tailored TCR-based therapies. By harnessing these personalized neoantigen libraries, we aim to enhance precision, efficacy, and overall therapeutic outcomes for patients with various cancers and immune-mediated diseases. Our goal is to discover, develop and commercialize novel allogeneic, off-the-shelf, iNKT cell therapies to treat cancer and other immune-mediated diseases with high unmet need. We are employing iNKT cells in their native form, through our lead program agenT-797, in diseases where iNKT cells have demonstrated activity and accelerated approval pathways exist. These indications include but are not limited critical pulmonary immune failure (including severe hypoxemic respiratory failure / pneumonia), GvHD, solid tumor cancers, and other severe immune-related diseases. Our discovery efforts are focused applying our proprietary technologies to build a broad pipeline of engineered iNKT cells, including CRs, CAR-iNKTs (such as MiNK-215 (FAP-CAR-iNKT) and MiNK-413 (BCMA-CAR-iNKT)), and INKT cell engager technology.

The following table summarizes our current product development pipeline:



Agenus Inc, therapeutic candidates botensilimab (BOT, Fc-enhanced anti-CTLA-4) and balstilimab (BAL, anti-PD-1).

Our most advanced product candidate, agenT-797, is an off-the-shelf, allogeneic, native iNKT cell therapy. Having treated nearly 100 patients with agenT-797 across oncology and critical pulmonary immune failure, we have generated mechanistic and clinical insights that support continued development of our iNKT platform beyond oncology into pulmonary diseases and auto-immune diseases, including in graft-versus-host disease prevention.

Under the leadership of Dr. Terese C. Hammond, our Head of Inflammatory and Pulmonary Diseases, we are advancing a differentiated franchise in critical pulmonary immune failure with agenT-797, our off-the-shelf, allogeneic iNKT cell therapy.

Building on the foundational Phase 1/2 data published in Nature Communications in February 2024 — which demonstrated >70% 30-day survival (80% in the veno-venous extracorporeal membrane oxygenation (“VV-ECMO”) subgroup) in mechanically ventilated patients with severe viral ARDS versus ~10% in contemporaneous controls — we are now advancing agenT-797 in a randomized Phase 2 adaptive, placebo-controlled trial in patients with severe pneumonia and moderate-to-severe hypoxemic acute respiratory failure ("AHRF"). Our published results highlighted rapid inflammation resolution, rescue of exhausted T cells, and reduced secondary infections, supporting the broad therapeutic potential of iNKT cells in life-threatening respiratory conditions, including interstitial lung disease ("ILD").

In cancer, our Phase 1 clinical trial enrolled 34 patients evaluating agenT-797 in refractory solid tumor cancers, as a monotherapy and in combination with anti-PD-1 checkpoint inhibitors, pembrolizumab and nivolumab. Updated data presented at SITC 2025 demonstrated durable clinical activity, including complete remissions and long-term survivors (>2–3+ years) in heavily pretreated, checkpoint-refractory cancers such as metastatic testicular cancer, gastric cancer, thymoma, cholangiocarcinoma, renal cell carcinoma, and adenoid cystic carcinoma, with median overall survival of approximately 23 months in combination with anti-PD-1. These data showed that agenT-797, both as monotherapy and in combination with anti-PD-1 agents, produced meaningful disease control in the majority of heavily pretreated patients, including reductions in target and non-target lesions and prolonged disease stabilization. A detailed case report describing a durable confirmed partial response (42% tumor reduction with progression-free survival exceeding nine months) in a patient with chemotherapy- and PD-1-refractory gastric cancer following a single infusion of agenT-797 was published in Oncogene in January 2024 (Hadfield et al., 2024). Subsequently, a separate case report published in Oncogene in 2025 described a complete clinical, radiologic, and biochemical remission in a patient with heavily pretreated metastatic testicular (germ cell) cancer following a single infusion of agenT-797 in combination with anti-PD-1 therapy; the patient remains without evidence of

disease more than two years post-treatment (Garmezy et al., 2025). AgenT-797 also exhibited long-term persistence in peripheral blood (detected up to 6 months post-infusion), independent of HLA matching and without the need for lymphodepletion.

Building on these encouraging results, a Phase 2 investigator-sponsored trial led by Dr. Yelena Janjigian at Memorial Sloan Kettering Cancer Center was initiated, with the first patient dosed in February 2024. This study is evaluating the safety and efficacy of agenT-797 in combination with Agenus Inc.'s ("Agenus") botensilimab (an Fc-enhanced anti-CTLA-4 inhibitor) and balstilimab (anti-PD-1), together with ramucirumab and paclitaxel, in patients with previously treated, advanced esophageal, gastric, or gastro-esophageal junction ("GEJ") adenocarcinoma. Early translational data from the first patients in the ongoing Phase 2 combination study were presented at the inaugural AACR Advances in Cancer Immunotherapy (AACR IO) meeting in 2025. These data demonstrated that addition of agenT-797 to botensilimab and balstilimab drove robust immune activation, including elevated interferon-gamma (IFN-γ) levels, rapid tumor infiltration, CD8+ T-cell activation, and immune reprogramming in patients with PD-1-refractory gastroesophageal cancers. Additional data are expected in early 2026.

In addition, we are advancing a pipeline of next-generation allogeneic, engineered iNKT programs. Our two most advanced preclinical engineered programs are (1) MiNK-413, an IL-15 armored CAR-iNKT program targeting B cell maturation antigen ("BCMA"), and (2) MiNK-215, an IL-15 armored tumor stromal targeting FAP-CAR-iNKT program. MiNK-413 has demonstrated tumor clearance and improved persistence in preclinical models, as well as manufacturing and logistical improvements over current BCMA cell therapies. MiNK-215 reported therapeutic activity in non-small cell lung cancer models, which resulted in substantial tumor elimination and improved survival compared to T cells alone. MiNK has presented data that showcased MiNK-215's activity in preclinical colorectal cancer models. In human organoid models of CRC with liver metastases, MiNK-215 potently enhanced tumor killing by T cells and was associated with depletion of immune suppressive FAP-expressing stellate cells and increased CD8+ T cell infiltration. Investigational new drug application ("IND") enabling studies for MiNK-215 are underway.

With our vertically integrated manufacturing capabilities and experienced team, we are accelerating the development of accessible, off-the-shelf iNKT-based therapies with transformative potential across oncology, critical pulmonary immune failure, and GvHD.

Our Strategy

Our goal is to discover, develop and commercialize novel allogeneic, off-the-shelf, iNKT cell therapies to treat cancer and other immune-mediated diseases with high unmet needs. We believe that allogeneic iNKT cells exhibit highly adaptable properties for broad therapeutic development, and we plan to achieve our goal by executing a strategy with the following key elements:

- **Expand into immune-mediated and inflammatory diseases:** Leverage clinical and translational insights from our Acute Respiratory Distress Syndrome ("ARDS") program to advance agenT-797 in severe pulmonary conditions, including acute respiratory failure, and in immune-mediated diseases such as GvHD.
- **Advance agenT-797 across oncology indications:** Progress agenT-797, our native allogeneic iNKT cell therapy, in solid tumors as both a monotherapy and in combination with checkpoint inhibitors and other immunotherapies.
- **Build a pipeline of engineered iNKT cell therapies:** Apply our proprietary technologies to develop next-generation engineered iNKT candidates, including MiNK-215 (FAP CAR-iNKT), with IND-enabling activities ongoing, and additional programs targeting both oncology and fibrosis.
- **Scale manufacturing and operational capabilities:** Continue to enhance our proprietary, closed-system manufacturing processes to improve scalability, reduce cost of goods, and increase flexibility and speed of production.
- Build on strategic collaborations to enhance platform value and expand our technological capabilities, pipeline breadth, or clinical impact. These include:
    - Leverage a collaboration with C-Further to support an optimal TCR-PRAME candidate for pediatric patients with cancer.
    - Advance research collaboration with Autonomous Therapeutics(October 2024) to evaluate encrypted RNA™ technologies in combination with MiNK-215 and agenT-797 in metastatic solid tumor models;
    - A collaboration with Immunoscape (December 2023) to discover and develop TCR-based therapies across multiple immune cell modalities; and
    - Our Intellectual Property Assignment and License Agreement with Agenus(September 2021), providing access to a portfolio of immuno-oncology assets and adjuvants to support combination strategies.

Our Approach to Cell Therapy – iNKT Cells

While engineered CAR-T cell therapies have demonstrated clinical benefit in certain hematologic malignancies, their broader application has been limited by manufacturing complexity, toxicity, and logistical constraints. Our approach focuses on iNKT cells, a distinct immune cell population that combines features of innate and adaptive immunity.

NKT cells express an invariant TCR that recognizes glycolipid antigens presented by the monomorphic CD1d molecule, enabling HLA-independent targeting. This biology supports both direct cytotoxic activity and coordinated activation of the immune system.

Based on preclinical and clinical observations, iNKT cells have demonstrated the ability to traffic to sites of disease, activate antigen-presenting cells, reduce immunosuppressive myeloid populations, enhance T-cell function, and recruit additional immune effector cells. iNKT cells have also been associated with suppression of alloreactive T cell responses, supporting their potential use in GvHD.Our iNKT cells use an invariant TCR α-chain to recognize glycolipid antigens presented by the monomorphic CD1d molecule, supporting direct tumor killing and broad immune activation within the tumor microenvironment ("TME"). Clinically, higher iNKT cell presence correlates with improved cancer prognosis and reduced GvHD risk post-transplantation.

Key Design Features of iNKT Cells

- Bridging innate and adaptive immunity: iNKT cells integrate rapid effector responses with antigen-specific recognition, enabling both direct cytotoxicity and immune orchestration.
- Activity in solid tumors and inflamed tissues: iNKT cells can localize to tissues and recognize CD1d-expressing cells, supporting modulation of the tumor microenvironment and inflammatory responses.
- Suitability for allogeneic use: CD1d-restricted recognition reduces dependence on HLA matching and has been associated with lower risk of GvHD.
- Favorable tolerability results: Early clinical experience suggests iNKT cells may be administered without lymphodepletion and with manageable adverse events.
- Scalable manufacturing: Our manufacturing processes enable expansion of iNKT cells from healthy donors while maintaining functional characteristics.

Our iNKT Cell Platform

Our platform leverages the unique therapeutic features of native iNKT cells and advanced manufacturing and engineering capabilities, enabling us to produce highly pure, scalable, and off-the-shelf allogeneic therapies for global patient populations. We believe allogeneic iNKT cell therapies, derived from healthy donors, have the potential to rapidly treat patients upon diagnosis, enhance response rates and durability, broaden treatment indications, improve tolerability without the need for lymphodepletion, and achieve cost-effective scalability.

Key Platform Elements:

Novel Cell Type Bridging Innate and Adaptive Immunity: We utilize iNKT cells, uniquely positioned to bridge innate and adaptive immune responses, potentially offering powerful tumor-killing properties of NK cells combined with durable memory capabilities of T cells, along with the potential to reshape the tumor microenvironment.

Broad Therapeutic Applications: Our pipeline includes both native and engineered iNKT cell therapies targeting multiple indications across oncology and immune-mediated diseases.

Demonstrated Clinical Proof-of-Concept in Phase 1 and 2 clinical trials: Observed the potential safety, tolerability, and immune-modulatory effects of allogeneic iNKT cells in various cancer types and pulmonary diseases.

Advanced Proprietary Cell Engineering: Our proprietary cell engineering platforms include CARDIS, a hybrid phage and mammalian display technology enabling highly selective and functionally optimized CAR, TCR, and bispecific engager

discovery. This technology is designed to produce candidates with improved pharmaceutical quality, minimal off-target toxicity, and reduced immunogenic risk through fully human antibody fragments.

Scalable, Proprietary Manufacturing Process: Our closed-system current Good Manufacturing Practice ("cGMP") manufacturing process is designed to ensure minimized contamination risk and efficient production, enabling the generation of thousands of doses per healthy donor.

Strategic Access to Validated Immuno-Oncology Therapies: We maintain access to Agenus' validated pipeline of immuno-oncology antibodies and adjuvants, enhancing our ability for rapid clinical development and flexible commercial opportunities.

Our Product Candidate

agenT-797 – our lead allogeneic, native iNKT cell therapy and is being evaluated across multiple clinical indications

agenT-797, our allogeneic, native iNKT cell therapy, is our most advanced product candidate and is currently in Phase 2 clinical development across multiple different trials and indications, constituting a pipeline within a single product candidate. In oncology, we have shown that agenT-797 cells have the potential to reduce or eliminate hematologic and solid tumor cancers as a monotherapy and in combination with checkpoint modulating antibodies, as they (1) home to sites of disease via CD1d and NK related ligands; (2) attack suppressive myeloid cells in the TME to eliminate tumor escape mechanisms; (3) recruit and activate NK cells and T cells for enhanced tumor killing (a distinguishing feature not shared by other innate lymphocytes such as NK and gamma delta T cells); and (4) promote tumor killing without lymphodepletion. In phase 1 and 2 clinical trials, our data demonstrated that agenT-797 appeared to overcome resistance to immune checkpoint inhibitors, with durable disease stabilization and a confirmed response in chemotherapy and anti-PD-1 refractory gastric cancer. A Phase 2 investigator sponsored trial is underway, evaluating agenT-797 in second-line gastroesophageal cancers.

agenT-797 – Pulmonary and Inflammatory Diseases

We are advancing agenT-797 in severe pulmonary and inflammatory conditions, where there remains a high unmet medical need and limited effective therapies. Hypoxemic respiratory failure affects hundreds of thousands of patients annually in the United States and globally, with mortality rates ranging from approximately 30% to 50% in severe cases and higher in mechanically ventilated populations. Despite this burden, there are no approved cell therapies and limited disease-modifying treatments. Preclinical studies suggest that iNKT cells can promote viral clearance, enhance secondary antiviral immune responses, and modulate excessive inflammation, supporting their potential to reduce lung injury and improve outcomes in ARDS and related conditions.

We completed a Phase 1/2 clinical study evaluating agenT-797 in patients with ARDS secondary to infectious diseases, including COVID-19 and influenza. In a cohort of 21 mechanically ventilated patients, 30-day survival exceeded 70%, including approximately 80% among patients receiving VV-ECMO, compared to approximately 10% in contemporaneous in-hospital controls.

agenT-797 was generally well tolerated at doses up to 1×10^{9} cells, with no observed cytokine release syndrome or neurotoxicity. Treatment was associated with reductions in inflammatory markers and a lower incidence of secondary infections.

Based on these findings, we are advancing a randomized, adaptive Phase 2, placebo-controlled clinical trial in patients with severe pneumonia and moderate-to-severe AHRF. We believe these data support the potential application of agenT-797 across a broad range of acute and chronic pulmonary diseases, including ILD, representing a significant market opportunity across critical care and pulmonary medicine.

agenT-797 – GvHD

We are also advancing agenT-797 in hematopoietic stem cell transplantation ("HSCT"), GvHD remains a major clinical challenge. More than 50,000 HSCT procedures are performed annually worldwide, with GvHD occurring in approximately 50% of patients and representing a leading cause of morbidity and mortality. iNKT cells have been shown to modulate alloreactive immune responses and may support improved engraftment, reduction of GvHD, and enhanced immune reconstitution. We are developing agenT-797 for use in the peri-transplant setting with the goal of improving transplant outcomes and reducing complications associated with current conditioning regimens, particularly in older or higher-risk patients.

Enhance iNKT Activity and Expand Targeting through Engineering

We are advancing a pipeline of allogeneic, engineered iNKT cell product candidates that leverage our proprietary technologies to enhance iNKT activity and expand tumor targeting through CARs, TCRs and bispecific iNKT engagers. Our two most advanced engineered programs are (1) MiNK-413, a BCMA-CAR-iNKT, and (2) MiNK-215, a FAP-CAR-iNKT. These programs are both in preclinical development with IND-enabling studies underway for MiNK-215. In addition, we plan to utilize our bispecific iNKT engagers, TCRs and CAR technologies, as well as our access to a large portfolio of proprietary targets, to further expand our pipeline of novel allogeneic, engineered iNKT cell product candidates.

Our CARs are designed to work in conjunction with the invariant TCR and the array of innate receptors expressed natively by iNKT cells. They increase the range of tumor targets that can be addressed by iNKT cells and carry optimized intracellular domains that augment and expand native signaling. The resulting CAR-iNKT cells exhibit an augmented and finely integrated response to the tumor through a combination of CAR target recognition, TCR activation and innate receptor activation by CD1d or stress ligands in the TME.

In addition to genetically engineered CAR-expressing iNKT products, we are developing bispecific iNKT cell engagers. Our bispecific iNKT cell engagers are designed to expand tumor targeting in tumors that are difficult to treat due to immunologic or biologic factors, which may include low CD1d expression. Our engagers bind to the invariant TCR with one arm, and to tumor targets with the other arm. They extend the range of tumor targets that can be engaged by iNKT cells and are designed to work in conjunction with allogeneic iNKT cells, CAR-iNKT cells as well as endogenous iNKT cells.

Our Proprietary Manufacturing Process and Capabilities

Our experienced management team and fully operational cGMP manufacturing suite directly address the challenges often associated with capital intensive cell therapy companies. We believe this site pioneered the industrialization and international distribution of autologous cancer vaccines and later the customization of synthetic, off-the-shelf cancer vaccines, immune stimulating adjuvants and antibodies.

Our allogeneic iNKT manufacturing platform allows for cell manufacturing at step function improvement in scale cost, and availability. We currently conduct manufacturing for all native iNKT cells program in-house in Lexington, MA. Our automated, closed-system allogeneic cell product batch production is designed to provide rapid, scalable, production with rigorous quality control and consistent and reproducible product release with minimal risk of batch failure. This closed-system process potentially reduces hands-on time and optimizes personnel usage and facility qualification and validation processes. Our proprietary reagents and process are designed to generate a product that is over 99% pure iNKT cells that can be stably cryopreserved with full retention of functional properties. We believe this will enable us to further increase reproducibility, minimize run failures and greatly increase scalability.

Immuno-Oncology Combination Therapy Collaboration with Agenus

While we have retained the rights to develop our wholly owned or exclusively licensed pipeline independent of Agenus, we have entered into the Agenus License Agreement which provides us with access to immuno-oncology antibodies, adjuvants and other potential synergistic combinations. We intend to pursue the development of combination products between our allogeneic iNKT cell product candidates and products in Agenus' immuno-oncology portfolio.

iNKT cell therapy adds critical new immune system functionality to cancer patients whose immune system cannot effectively combat the tumor. Infused iNKT cells home to the tumor, where the iNKT cells attack the cancer cells and reshape the TME, attracting additional endogenous immune cells to the tumor, such as T cells and NK cells, and diminishing the suppressive effect of infiltrating myeloid cells. Due to their allogeneic nature, infused iNKT cells disappear over time, at which point the endogenous immune system must continue to provide effective immune surveillance to prevent relapse. While there is significant development opportunity for iNKT cells as a monotherapy, we have also demonstrated the benefits of these cells in combination with anti-PD-1 and/or enhanced anti-CTLA-4 antibodies in preclinical models. We believe current cancer therapy developments indicate that anti-PD-1 and anti-CTLA-4 immuno-oncology antibodies have the potential to become the standard of care for many tumor indications and will form the basis for most, if not all, future combination therapies in cancer. Access to Agenus' immuno-oncology products allows us to combine our iNKT cells with immuno-oncology antibodies, creating more flexibility in our clinical strategy, a better window for optimization dosing and timing, and more control over commercial pricing of the combinations.

As part of our collaboration with Agenus, we are evaluating agenT-797 in combination with Agenus' botensilimab and balstilimab with ramucirumab and paclitaxel for patients with previously treated, advanced esophageal, gastric, or GEJ adenocarcinoma through a Phase 2 investigator sponsored study. The study is led by Dr. Yelena Janjigian at Memorial Sloan Kettering Cancer Center.

Intellectual Property

We protect our intellectual property rights and proprietary technology with a combination of patent rights, trademark rights, proprietary procedures and contractual provisions. We seek to protect our intellectual property rights and proprietary technology in select key global markets. Further, in order to supplement our existing intellectual property protection and support commercialization of current and future product candidates, we continue to seek protection for our technological innovations and branding efforts by filing new patent and trademark applications when and where appropriate. As of December 31, 2025, we own four issued U.S. patents, five issued foreign patents and at least 30 pending patent applications in the U.S. and other major jurisdictions worldwide. One of the issued U.S. patents is directed to a process for the discovery of TCRs and the term of the patent is estimated to expire in 2041. The other three issued U.S. patents are intended to protect intellectual property relating to a TCR for cell therapy targeting NY-ESO-1 and a TCR for cell therapy targeting Phosphopeptides. The term of these three patents is estimated to expire in 2039. Patent term extensions, supplementary protection certificates, and regulatory exclusivity periods, including pediatric exclusivity periods might also be available.

Our process to manufacture iNKT cells at scale from healthy donor PBMCs, using cGMP-grade proprietary resources, including a humanized iNKT-TCR mAb to enable iNKT cell isolation and an α-GalCer lipid ligand to enable iNKT cell expansion, is proprietary technology.

Government Regulation

As a biopharmaceutical company, we are subject to extensive regulation. Our iNKT cell product candidates, if approved, will be regulated by the FDA and comparable regulatory authorities as biologics. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with cGMPs for biologics.

Human immunotherapy products are a new category of therapeutics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization.

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacturing, packaging, labeling, storage, record keeping, reimbursement, advertising, promotion, distribution, post-approval monitoring and reporting and import and export, pricing and reimbursement of pharmaceutical products, including biological products. In the United States, the FDA regulates biological products under the Public Health Service Act (the "PHSA"), the Federal Food, Drug and Cosmetic Act (the "FDCA") and implementing regulations. Failure to comply with the applicable regulatory requirements at any time during the product development process or post-approval may subject a product sponsor to delays in development or approval, as well as administrative and judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters and similar public notice of alleged non-compliance with laws, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions and compliance with applicable statutes and regulatory requirements, both pre- and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to drug and biological product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business. Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. We cannot predict whether legislative changes will be enacted or if regulatory authorities' guidance or interpretations will change.

U.S. Product Development Process

To obtain FDA approval of a product candidate, we must, among other things, submit clinical data providing substantial evidence of safety and efficacy of the product for its intended use, as well as detailed information on product composition, its manufacture and controls, and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

Our biological product candidates must be approved by the FDA through the BLA process before they may be legally marketed in the United States. The process required before a biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLPs"), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as Good Clinical Practices ("GCPs"), and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation and submission to the FDA of a BLA, for marketing approval that includes substantive evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- payment of user fees for FDA review of the BLA;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities where the drug or biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls used in product manufacture are adequate to preserve the drug or biological product's identity, strength, quality and purity and, if applicable, the FDA's current Good Tissue Practices ("GTPs"), for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA acceptance, review and approval, or licensure, of the BLA, which might include review by an advisory committee, a panel typically consisting of independent clinicians and other experts who provide recommendations as to whether the application should be approved and under what conditions.

Preclinical Studies and Investigational New Drug Applications

Before testing any drug or biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations as well as *in vitro* and animal studies to assess the potential safety and efficacy of the product candidate. After sufficient preclinical testing has been conducted, the conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit an IND to the FDA before clinical testing can begin in the United States. An IND must contain the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature, a proposed clinical protocol, an investigator's brochure, a sample informed consent form, and other materials. Some preclinical testing, such as toxicity studies, may continue even after the IND is submitted.

An IND is an exemption from the FDCA that allows an unapproved drug or biological product to be shipped in interstate commerce for use in an investigational clinical trial. The IND seeks FDA authorization to test the drug or biological product candidate in humans and automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trials can begin. Preclinical or nonclinical testing typically continues even after the IND is submitted.

FDA may, at any time during the initial 30-day IND review period or while clinical trials are ongoing under the IND, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would delay the initiation of a proposed clinical trial or cause suspension of an ongoing trial until all outstanding concerns have been adequately addressed, and the FDA has notified the company that investigations may proceed. Imposition of a clinical hold could cause significant delays or difficulties in completing planned clinical studies in a timely manner. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that require the suspension or termination of such trials.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products under an IND by the company or the treating physician

for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

There is no requirement for a manufacturer to provide expanded access to an investigational product. However, if a manufacturer decides to make its investigational product available for expanded access, FDA reviews requests for expanded access and determines if treatment may proceed. Expanded access may be appropriate when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with initiation, conduct or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

Under the FDCA, sponsors of one or more investigational products for the treatment of a serious disease(s) or condition(s) must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study, or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product or regenerative medicine advanced therapy.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides an additional mechanism for patients with a life-threatening condition who have exhausted approved treatments and are unable to participate in clinical trials to access certain investigational products that have completed a Phase 1 clinical trial, are the subject of an active IND, and are undergoing investigation for FDA approval. Unlike the expanded access framework described above, the Right to Try Pathway does not require FDA to review or approve requests for use of the investigational product. There is no obligation for a manufacturer to make its investigational products available to eligible patients under the Right to Try Act.

Human Clinical Trials

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain FDA regulatory requirements in order to use the trial as support for an IND or application for marketing approval in the United States. Specifically, the FDA requires that such trials be conducted in accordance with GCP requirements intended to ensure the protection of human subjects and the quality and integrity of the study data, including requirements for review and approval by an independent ethics committee and obtaining subjects' informed consent.

For clinical trials conducted in the United States, an IND is required, and each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. Clinical trials must also comply with extensive GCP rules and the requirements for obtaining subjects' informed consent. The FDA, IRB or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements, including GCP, or the subjects or patients are being exposed to an unacceptable health risk.

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 may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated checkpoints based on access to certain data from the study. Finally, research activities involving infectious agents, hazardous chemicals, recombinant DNA and genetically altered organisms and agents may be subject to review and approval of an Institutional Biosafety Committee (IBC), in accordance with National Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population, generally at geographically dispersed clinical trial sites. These clinical trials are intended to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk to benefit profile of the product and to provide an adequate basis for product labeling.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety or effectiveness after approval. Such post approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs or biologics approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board, an independent group of experts that evaluates study data for safety and makes recommendations concerning continuation, modification or termination of clinical trials, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Under the Pediatric Research Equity Act of 2003 (the "PREA"), a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must submit a pediatric study plan to FDA outlining the proposed pediatric study or studies they plan to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The FDA must then review the information submitted, consult with the sponsor and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after FDA's receipt of the study plan. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements, under specified circumstances. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website. Similar requirements for posting clinical trial information in clinical trial registries exist in the European Union and in other countries outside the United States.

Concurrently with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the physical characteristics of the drug or biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the premarketing application for filing and, even if filed, that any approval will be granted on a timely basis, if at all as the FDA has significant discretion to approve or reject BLAs and to require additional preclinical or clinical studies.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for approved prescription biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission has been accepted for filing, the FDA begins an in depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from filing in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review application. A major amendment to a BLA submitted at any time during the review cycle, including in response to a request from the FDA, may extend the goal date by three months. The FDA does not always meet its PDUFA goal dates for standard and priority applications. The FDA reviews the application to determine, among other things, whether the proposed product is safe, potent and/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.

During its review of a BLA, the FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions about a BLA.

Before approving a BLA, the FDA 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 adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents 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 ("HSCT/Ps"), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP 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 GTP regulations also require tissue establishments to register and list their HSCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND and GCP requirements. To assure cGMP, GTP and GCP

compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, recordkeeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. If the agency decides not to approve the BLA in its present form, the FDA will issue a Complete Response Letter, which generally outlines the specific deficiencies in the application identified by the FDA and may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Even with the submission of additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post approval studies, including Phase 4 clinical trials, to further assess the product's safety or efficacy after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including Risk Evaluation and Mitigation Strategy ("REMS"), to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("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 patent registries. The FDA may prevent or limit further marketing of a product based on the results of post market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Development and Review Programs

The FDA has several programs designed to expedite the development and approval of drugs and biological products intended to treat serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review designation, accelerated approval, and regenerative medicine advanced therapy ("RMAT") designation. These designations are not mutually exclusive, and a product candidate may qualify for one or more of these programs. While these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

First, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have more frequent interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious disease or condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Fourth, 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 to confirm efficacy using a clinically meaningful endpoint, thereby confirming efficacy observed pre-approval using a surrogate endpoint. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. If the FDA determines that the conditions of approval are not being met, the FDA can withdraw its accelerated approval.

Fifth, a product may receive RMAT designation, which provides for an expedited program for the advancement and approval of regenerative medicine therapies that are intended to treat, modify, reverse or cure a serious condition and where preliminary clinical evidence indicates the potential to address unmet medical needs for life-threatening diseases or conditions. Similar to Breakthrough Therapy designation, the RMAT designation allows companies developing regenerative medicine therapies to work earlier, more closely, and frequently with the FDA, and RMAT-designated products may be eligible for priority review and accelerated approval. Regenerative medicine therapies include 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 PHS Act and Title 21 of the Code of Federal Regulations Part 1271. The FDA confirmed that gene therapies, including genetically modified cells that lead to a sustained effect on cells or tissues, may meet the definition of a regenerative medicine therapy. For product candidates that have received a RMAT designation, 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. The timing of a sponsor's request for designation and FDA response are the same as for the Breakthrough Therapy designation program.

We cannot be sure that any of our product candidates will qualify for any of these expedited development, review and approval programs, or that, if a product candidate does qualify, that it will be approved, will be accepted as part of any such program or that the review time will be shorter than a standard review.

Post-Approval Requirements

Upon FDA approval of a BLA, the sponsor must comply with extensive post approval regulatory requirements applicable to drugs and biological products, including any additional post approval requirements that the FDA may impose as part of the approval process. These post-approval requirements include, among other things:

- record keeping requirements;
- reporting of certain adverse experiences with the product and production problems to the FDA;
- submission of updated safety and efficacy information to the FDA;
- drug sampling and distribution requirements;
- notifying FDA and gaining its approval of specified manufacturing and labeling changes; and
- compliance with requirements concerning advertising, promotional labeling, industry-sponsored scientific and educational activities and other promotional activities.

Additionally, the sponsor and its third-party manufacturers are subject to periodic unannounced regulatory inspections for compliance with ongoing regulatory requirements, including cGMP and pharmacovigilance regulations. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

The FDA strictly regulates the advertising and labeling of prescription drug products, including both prescription drugs and biological products. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. In addition, the sponsor of an approved drug in the United States may not promote that drug for unapproved, or off-label, uses, although a physician may prescribe a drug for an off-label use in accordance with the practice of medicine. If a company is found to have promoted off-label uses, it may become subject to administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against

companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

After approval, some types of changes to the approved product, such as adding new indications or dosing regimens, manufacturing changes, or additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

The FDA may withdraw product approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency or issues with manufacturing processes, may result in revisions to the approved labeling to add new safety information; imposition of post market studies or clinical trials to assess new safety signals; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product;
- fines, warning letters or holds on post approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure, or detention or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop drug and biological products intended for the treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain tax credits. In addition, if a drug candidate that has orphan drug designation subsequently receives the first FDA approval for that drug for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years following product approval unless the subsequent product candidate is demonstrated to be clinically superior. Absent a showing of clinical superiority, the FDA cannot approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug or biologic. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation. To qualify for orphan exclusivity, however, the drug must be clinically superior to the previously approved product that is the same drug for the same condition.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent regulatory exclusivity in the United States. Specifically, the Best Pharmaceuticals for Children Act provides for the attachment of an additional six months of exclusivity, which is added on to the term of any remaining regulatory exclusivity or patent periods at the time the pediatric exclusivity is granted. 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, even if the data do not show the product to be effective in the pediatric population studied.

Biosimilars and Exclusivity

The 2010 Patient Protection and Affordable Care Act (the "PPACA"), which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"). The BPCIA established a regulatory scheme

authorizing the FDA to approve biosimilars and interchangeable biosimilars. The FDA has approved over 20 biosimilar products for use in the United States to date. No interchangeable biosimilars, however, have been approved.

Under the BPCIA, a manufacturer may submit an application for licensure of a biological product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that 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.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. This 12-year exclusivity period is referred to as the reference product exclusivity period and bars approval of a biosimilar but notably does not prevent approval of a competing product pursuant to a full BLA (i.e., containing the sponsor's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of the product). The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent infringement, validity and enforceability prior to the approval of the biosimilar.

There have been ongoing federal legislative and administrative efforts as well as judicial challenges seeking to repeal, modify or invalidate some or all of the provisions of the PPACA. While none of those efforts have focused on changes to the provisions of the PPACA related to the biosimilar regulatory framework, if those efforts continue and if the PPACA is repealed, substantially modified or invalidated, it is unclear what, if any, impact such action would have on biosimilar regulation.

Patent Term Restoration and Extension

A patent claiming a new drug or biological product may be eligible for a limited patent term extension under the Hatch Waxman Act, which permits a patent restoration of up to five years for a single patent for an approved product as compensation for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically one half the time between the effective date a clinical investigation involving human beings is begun and the submission date of a marketing application less any dime during which the applicant failed to exercise due diligence, plus the time between the submission date of an application and the ultimate approval date less any dime during which the applicant failed to exercise due diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Competition

The biopharmaceutical industry is highly competitive. We face competition from established pharmaceutical and biotechnology companies, as well as emerging companies developing cell therapies, including autologous and allogeneic CAR-T, TCR-T, NK cell, γδ T cell, and iNKT cell therapies. Many competitors are advancing programs across solid tumors, hematologic malignancies, autoimmune diseases, and, in some cases, inflammatory and pulmonary conditions.

Key competitors developing autologous CAR-T and TCR-based therapies include large pharmaceutical and biotechnology companies such as Bristol-Myers Squibb (including former Celgene and Juno Therapeutics assets), Gilead Sciences, Johnson & Johnson, Novartis, AstraZeneca, and BioNTech.

Companies developing iNKT cell-based therapies are generally earlier-stage and include Arovella Therapeutics and Brightpath Biotherapeutics, among others. We are also aware of companies pursuing approaches to activate endogenous iNKT cells, including Gri Bio and Portage Biotech. These approaches differ from our ex vivo expanded, allogeneic iNKT cell platform.

Key competitors developing allogeneic or gene-edited T cell therapies include Allogene Therapeutics, Atara Biotherapeutics, Cellectis, CRISPR Therapeutics, Precision BioSciences, and others. Certain companies in this space have undergone consolidation, including Poseida Therapeutics, which has been acquired by Roche.

Key competitors in the NK cell therapy space include Fate Therapeutics, Nkarta, Artiva Biotherapeutics, Dragonfly Therapeutics, and programs within larger pharmaceutical companies such as Sanofi and Takeda Pharmaceutical Company.

Competitors in the γδ T cell therapy space include Adicet Bio, IN8bio, and TC BioPharm.

In addition, we are aware of companies pursuing other immunomodulatory or cell-based approaches, including stem cell-based therapies, for the treatment of acute respiratory distress syndrome (ARDS) and related pulmonary conditions.

We compete with these organizations for scientific and management talent, clinical trial sites, patient enrollment, and access to complementary technologies. Many of our current and potential competitors have significantly greater financial, technical, and human resources, as well as greater experience in research and development, manufacturing, clinical development, and commercialization. Early-stage companies may also become significant competitors, particularly through collaborations with larger pharmaceutical companies.

Our commercial opportunity may be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, more convenient, or less costly than our product candidates. In addition, competitors may obtain regulatory approval for their products more rapidly than we do, which could allow them to establish a market position before we are able to enter the market.

Human Capital Resources and Employees

As of February 28, 2026, we had 15 full-time employees, 33% of whom have Ph.D. degrees. Our ability to manage growth effectively will require us to continue to implement and improve our management systems, recruit and train new employees and select qualified independent contractors. Functions in legal, finance, information technology and human resources are provided by Agenus pursuant to a services agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. We provide compensation and benefit programs to attract and retain employees. In addition to salaries, these programs include potential annual discretionary bonuses, various stock awards under our equity incentive plans, a 401(k) Plan, healthcare and insurance benefits, flexible spending accounts, paid time off, family leave, and flexible work schedules, among others.

MiNK Website

Our Internet website address is www.minktherapeutics.com. The contents of the websites referred to above are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our audited financial statements and the related notes, as well as our other public filings with the SEC, before deciding to invest in our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects, as well as the price of our common stock, could be materially and adversely affected.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties. The following summarizes factors that could have a material adverse effect on the Company's business, reputation, results of operations, financial condition and stock price. The Company may not be able to accurately predict, control or mitigate these risks. Statements in this section are based on the Company's beliefs and opinions regarding matters that could materially adversely affect the Company in the future and are not representations as to whether such matters have or have not occurred previously. The risks and uncertainties described below are not exhaustive and should not be considered a complete statement of all potential risks or uncertainties that the Company faces or may face in the future.
The following is a summary of the principal risk factors described in this section:

Risks Related to Our Financial Position and Need for Additional Capital

- We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- If we fail to raise additional capital, we would be forced to delay, reduce, or eliminate certain projects.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies.
- Our short history as an independent company may make it difficult to evaluate the success of our business and to assess our future viability.
- Our future ability to utilize certain tax attributes may be limited.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements.

Risks Related to Discovery, Development and Commercialization of Our Allogeneic iNKT Cells and Other Product Candidates

- Our business is highly dependent on the success of our lead product candidate, agenT-797, and we may fail to develop agenT-797 successfully or be unable to obtain marketing approval for it.
- Allogeneic iNKT cells represent a novel approach to immunotherapy, which may result in significant challenges to the development, marketing approval, and commercialization of product candidates.
- Our business is highly dependent on our iNKT cell platform, and our product candidates will require significant additional testing before we can seek marketing approval.
- Serious adverse events, undesirable side effects or unexpected characteristics caused by our product candidates could delay or prevent marketing approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.
- The data produced in our clinical trials is at an early stage and future data may not show responses in patients treated or support continued development.
- Even if any product candidates we may develop receive marketing approval, they may fail to achieve commercial success.
- We face significant competition and there is a possibility that our competitors may achieve marketing approval before us or develop adoptive cell therapies that are safer or more advanced or effective than ours.
- Any product candidates we develop may be complex and difficult to manufacture.

Risks Related to Regulatory Review and Other Legal Compliance Matters

- If our clinical trials fail to demonstrate safety and efficacy, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of product candidates.
- We may experience delays or difficulties in the enrollment of patients in our clinical trials.
- The regulatory landscape that will govern any product candidates we may develop is uncertain and may change.
- Any failure to comply with laws and regulations could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.
- Healthcare and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize any product candidates.

- Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, or we may fail to satisfy certain arrangements with governmental authorities.
- Laws and regulations governing our international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us implement costly compliance programs.
- We are subject to stringent privacy and information security laws, regulations, policies and contractual obligations and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.
- Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes could hinder their ability to review and approve new products in a timely manner.

Risks Related to Our Relationship with Agenus

- We may experience difficulty in separating our resources from Agenus.
- Agenus owns a significant portion of our common stock and will be able to exert control over specific matters subject to stockholder approval.
- Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with Agenus.

Risks Related to Our Relationships with Third Parties

- We rely on third parties, which may not perform satisfactorily, including failing to meet deadlines for the completion of trials, research, or testing.
- Reliance on third parties increases the risk that we will not have sufficient quantities of materials, product candidates, or any medicines that we may develop and commercialize, or that it will not be available at an acceptable cost.
- If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

Risks Related to Our Intellectual Property

- We may be unable to obtain and maintain satisfactory patent and other intellectual property protection for any product candidates we develop and for our cell-based immunotherapies.
- Our rights to develop and commercialize our cell-based immunotherapies and product candidates are subject, in part, to the terms and conditions of assignments and licenses granted to us by others, including Agenus.
- We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world.
- We may not be successful in acquiring or in-licensing necessary rights to key technologies or any product candidates we may develop.
- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights.
- We may not obtain patent term extension ("PTE") and data exclusivity for any product candidates we may develop.
- We may be unable to protect the confidentiality of our proprietary knowledge.

Risks Related to Employee Matters, Managing Growth, Information Technology and Our Operations

- We may be unable to retain our key executives and to attract, retain and motivate qualified personnel.
- We may encounter difficulties in managing our growth, which could disrupt our operations.
- Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, and we and certain of our third-party providers may experience cyberattacks and other incidents.

Risks Related to Ownership of Our Common Stock

- A market for our common stock may not be sustained. We may be delisted from the Nasdaq Capital Market if we are unable to comply with Nasdaq Listing Rules.
- Provisions in our organizational documents and Delaware law may have anti-takeover effects.
- Our organizational documents designate courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
- Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could cause the market price of our common stock to decline.
- Unfavorable global economic conditions, including tariffs and trade policy changes, could adversely affect our business, financial condition or results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred operating losses associated with our research, clinical development and manufacturing efforts. We have devoted substantially all of our efforts and financial resources in building our iNKT cell platform, identifying our current product candidates, conducting preclinical development and initiating clinical trials of agenT-797. Our net loss was $12.5 million and $10.8 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $156.7 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue our clinical and preclinical development of product candidates;
- seek to develop our iNKT cell platform further and identify additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify and develop from our current research programs;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any biologics for which we may obtain marketing approval;
- hire additional research and development personnel;
- hire clinical and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development; and
- acquire or in-license product candidates, intellectual property and technologies.

Our lead product candidate, agenT-797, is in clinical development, and all of our other product candidates remain in preclinical development. We do not have any products approved for sale and have not generated any revenue from product supplies or royalties. Based on our current plans, we do not expect to generate product or royalty revenues unless and until we obtain marketing approval for a product candidate. We expect that it will be many years, if ever, before we have a product candidate that receives such approval. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a product candidate with significant market potential. This will require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. Even if one or more of the product candidates we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the United States Food and Drug Administration ("FDA") or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations and, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We will need additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.

We expect our expenses to increase in connection with the maturation of our programs and ongoing activities, particularly as we identify, continue the research and development of, initiate and continue clinical trials of, and seek marketing approval for, our product candidates, including agenT-797. In addition, if we obtain marketing approval for any product candidates we may develop, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a collaborator. Furthermore, we incur significant costs associated with operating as a standalone public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

Our primary source of funding prior to our initial public offering was through Agenus. As of December 31, 2025, our cash balance was $13.4 million. We expect that our cash as of December 31, 2025, plus anticipated additional funding, will be sufficient to satisfy our liquidity requirements for more than one year from when these financial statements were issued. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek funding sooner than planned.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements and any future collaboration agreements may also be terminated if we are unable to meet payment or other obligations under such agreements. We could be required to seek collaborators for product candidates we may develop at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, or relinquish or license on unfavorable terms our rights to product candidates we may develop in markets where we otherwise would seek to pursue development or commercialization ourselves. In addition, any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates we may develop.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and 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, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends and possibly other restrictions.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates we may develop, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our 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.

Our short operating history as an independent company may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We were formed in 2017 as a subsidiary of Agenus. Our operations to date have been limited to organizing and staffing our company, business planning, identifying potential product candidates and undertaking clinical trials and preclinical studies, and some of these activities have been performed by Agenus pursuant to services agreements between the parties. We have initiated clinical trials for agenT-797 and our other programs are still in the preclinical or research stage of development, where the risk of failure is high. We have not yet demonstrated an ability to successfully complete any large-scale, pivotal clinical trials, obtain marketing approvals; manufacture a commercial-scale product, or arrange for a third party to do so on our behalf; or conduct sales and marketing activities necessary for successful commercialization. It takes many years to develop a new product from the time it is discovered to when it is available for treating patients. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer independent operating history.

Our limited independent operating history, particularly in light of rapidly evolving cell therapies, may make it difficult to evaluate our technology and industry and predict our future performance, and to make any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as a new business, we may encounter other unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

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

We have incurred substantial net operating losses ("NOLs") during our history. U.S. federal and certain state NOLs generated in taxable years beginning after December 31, 2017 are not subject to expiration. Federal NOLs generally may not be carried back to prior taxable years except that, under the Coronavirus Aid, Relief, and Economic Securities Act, federal NOLs generated in 2018, 2019 and 2020 may be carried back to each of the five taxable years preceding the taxable year in which the loss arises. Additionally, for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in taxable years beginning after

December 31, 2017 is limited to 80% of our taxable income in such taxable year. NOLs generated in tax years beginning before January 1, 2018 may still be used to offset future taxable income without regard to the 80% limitation, although they have the potential to expire without being utilized if we do not achieve profitability in the future. In addition, in general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. For these reasons, we may not be able to use a material portion of our NOLs, even if we attain profitability.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements, and it is possible that such report on our financial statements may include such an explanation again in the future.

We believe we have sufficient capital, including the additional funding anticipated to be received subsequent to year end, to satisfy our liquidity requirements for more than one year from when the financial statements in this Annual Report on Form 10-K were issued. If we are unable to obtain sufficient funding to support our operations, we could be forced to delay, reduce or eliminate all of our research and development programs, or product portfolio expansion, our financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. In the future, reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

Risks Related to Discovery, Development and Commercialization of Our Allogeneic iNKT Cells

Our business is highly dependent on the success of our lead product candidate, agenT-797, which is our only product candidate in clinical development. We have a limited history of conducting clinical trials and may fail to develop agenT-797 successfully or be unable to obtain marketing approval for it.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our agenT-797 and our other product candidates. We cannot guarantee that agenT-797, will demonstrate the degree of safety, purity, potency, or efficacy required by the FDA or other regulatory authorities, or will be approved for commercialization on a timely basis or at all. Although certain of our employees and consultants have prior experience with clinical trials, marketing approvals and current Good Manufacturing Practice ("cGMP") compliance, we have not previously completed any pivotal clinical trials or submitted a Biologics License Application ("BLA") to the FDA, or similar marketing approval applications to comparable foreign authorities, for any product candidate, and we cannot be certain that agenT-797 or any other product candidate will be successful in clinical trials or receive marketing approval. The success of our product candidates will depend on several factors, including the following:

- successful initiation and completion of preclinical studies with favorable results, including toxicology and other studies designed to be compliant with good laboratory practice ("GLP"), requirements;
- allowance to proceed with clinical trials under Investigational New Drug applications ("INDs"), by the FDA, or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates;
- successful initiation, enrollment and completion of clinical studies in accordance with good clinical practice ("GCP"), requirements and other applicable rules and regulations;
- the frequency and severity of adverse events observed in clinical trials;
- maintaining and establishing relationships with contract research organizations ("CROs"), and clinical sites for the clinical development of our product candidates;
- demonstrating the safety purity, and potency, or efficacy of our product candidates to the satisfaction of the FDA and other applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including approvals of BLAs from the FDA, and maintaining any such approvals;

- making arrangements with third-party manufacturers for, or establishing, clinical or commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, either alone or in collaboration with others;
- obtaining, establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our product candidates following marketing approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell our product candidates, if approved; and
- acceptance of our product candidates, if approved, by patients, the medical community and third-party payors.

Furthermore, because agenT-797 is our most advanced product candidate and our only product candidate in clinical development , and because our other product candidates are based on similar technology, if our clinical trials of agenT-797 encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for agenT-797 and our other product candidates in our pipeline could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, marketing approval and commercialization of agenT-797 and our other product candidates, which may never occur. In the future, we may also become dependent on other product candidates that we may develop or acquire; however, given our stage of development, it may be several years, if at all, before we have demonstrated the safety, purity, and potency (or efficacy) of a candidate sufficient to warrant approval for commercialization. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Utilizing allogeneic iNKT cells represents a novel approach to immunotherapy, and we must overcome significant challenges to develop, commercialize and manufacture our product candidates.

We have concentrated our research and development efforts on utilizing allogeneic iNKT cells as a potential immunotherapy. To date, the FDA has approved only a few adoptive cell therapies for commercialization and no allogeneic iNKT cell therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our product candidates. Because our allogeneic iNKT cell platform product candidates are novel, and adoptive cell therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like our iNKT cell product candidates, including our lead product candidate, agenT-797. This novelty may heighten regulatory scrutiny of our therapies or lengthen the regulatory review process, including the time it takes for the FDA to review our INDs if and when submitted, increase our development costs and delay or prevent commercialization of our allogeneic iNKT cell platform products.

Additionally, advancing novel cell therapies involve significant challenges for us, including:

- educating medical personnel regarding the potential side-effect profile of our product candidates and, as the clinical program progresses, on observed side effects with the therapy;
- training a sufficient number of medical personnel on how to properly administer our product candidates;
- enrolling sufficient numbers of patients in clinical trials;
- developing a reliable, safe and effective means of genetically modifying certain of our cells;
- establishing a cost-effective and large-scale manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical trials and our projected commercial requirements;
- sourcing starting material suitable for clinical and commercial manufacturing; and
- establishing sales and marketing capabilities to successfully launch and commercialize our product candidates if and when we obtain any required marketing approvals, and risks associated with gaining market acceptance of a novel

therapy if we receive approval, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges in order for us to develop, commercialize and manufacture our product candidates utilizing allogeneic iNKT cells. Failure to do so could materially adversely affect our business, financial condition, results of operations and growth prospects.

Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies involving our product candidates are not necessarily predictive of our future results. Our product candidates may not show favorable results in preclinical studies or clinical trials or receive marketing approval on a timely basis, if at all.

Preclinical and clinical drug development 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 or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and the historical failure rate for product candidates in our industry is high.

The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted certain clinical studies evaluating agenT-797, we do not know whether our product candidates will perform similarly in future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for marketing approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining approval from the FDA or other regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety purity, potency (or efficacy) of the product candidate in humans. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitrodata to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards ("IRBs"), or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- our failure, or failure of our CMOs to produce adequate quantities of clinical trial materials in accordance with cGMP, regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.
In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of marketing approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

If any of the product candidates we may develop, or the delivery modes we rely on to administer them, cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent marketing approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates, whether used alone on in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or lead to the delay or denial of marketing approval by the FDA or

comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

To date, we have completed and published preliminary data from clinical trials for agenT-797. Moreover, there have been only a limited number of clinical trials involving the use of iNKT cells and none involving therapies similar to our therapies. It is impossible to predict when or if any product candidates we may develop will be deemed safe in humans. In the adoptive cell therapy field, there have been significant adverse events from allogeneic cell treatments in the past, including cytokine release syndrome, peripheral neuropathies and adverse events linked to lymphodepleting chemotherapy regimens used in the field prior to administration of cell therapy products. While in our trials to date, we have not observed neurotoxicity or cytokine release syndrome, there can be no assurance that our product candidates will not cause undesirable side effects in the future, which may include serious adverse effects that are related to our product candidates.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects. Many product candidates that initially showed promise in early stage testing for treating cancer or life-threatening diseases have later been found to cause side effects that prevented further clinical development of the product candidates.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. If such significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS"), to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. The FDA has required REMS programs for certain other cell therapies, including autologous CAR-T cell therapies, and we may be required to implement similar programs if any of our product candidates obtains marketing approval . Furthermore, if we or others later identify undesirable side effects caused by any product candidate that we develop, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label or limit the approved use of such product candidate;
- we may be required to create a medication guide outlining the risks of a product for patients;
- we may be required to conduct additional clinical trials;
- we may be required to change the way a product is administered;
- a product may become less competitive;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any product candidates we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we experience delays or difficulties in the enrollment of patients in our clinical trials for agenT-797 or any future trials, our receipt of necessary marketing approvals could be delayed or prevented.

We or our collaborators may not be able to continue our current and anticipated clinical trials for agenT-797 or initiate trials for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. In addition, if patients are unwilling to participate in our clinical trials because of negative publicity from adverse events related to the biotechnology, adoptive cell therapy, competitive clinical trials for similar patient populations, clinical trials in competing products or for other reasons, the timeline for recruiting patients, conducting studies and obtaining marketing approval of any product candidates we may develop may be delayed. Moreover, our competitors may have ongoing clinical trials for product candidates that are intended to address the same patients as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in our competitors' clinical trials.

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- size of the patient population and process for identifying patients;
- design of the trial protocol;
- availability and efficacy of approved medications for the disease under investigation;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- perceived risks and benefits of adoptive cell therapy as a therapeutic approach;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients, especially for those conditions which have small patient pools.

Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- different standard-of-care for patients with a particular disease;
- difficulty in locating qualified local consultants, physicians and partners; and
- potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments and of cell-based immunotherapies.

In addition, our clinical trials may also compete to recruit patients with other clinical trials for product candidates that are in a similar adoptive cell therapy area as our product candidates, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may 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.

Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may develop, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate

ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

Interim, "topline" and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may develop our product in combination with other therapies, which exposes us to additional risks

We intend to develop agenT-797 and our other product candidates for use in combination with one or more existing therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing, or supply issues could arise with these existing therapies. Developing combination therapies using approved therapeutics, as we plan to do for our product candidates, also exposes us to additional clinical risks, such as the requirement that we demonstrate the safety and efficacy of each active component of any combination regimen we may develop. If the FDA or similar foreign regulatory authorities revoke the approval of combination agents, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates for combination therapy regimens. Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, if approved, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations, and prospects.

We may conduct clinical trials for our product candidates outside of the U.S. and the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business

We may choose to conduct one or more of our clinical trials or a portion of our clinical trials for our product candidates outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the

application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Even if any product candidates we may develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

The commercial success of any of the product candidates we may develop will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages compared to alternative treatments;
- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our product candidates for sale at competitive prices, if approved;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA or other regulatory agencies;
- the willingness of the target patient population to try novel therapies and of physicians to prescribe these therapies;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support;
- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If any of the product candidates we develop are approved, but do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

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

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of the product candidates we may develop if and when they are approved.

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

Factors that may inhibit our efforts to commercialize the product candidates we may develop on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute the product candidates we may develop to segments of the patient population;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

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

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve marketing approval before us or develop adoptive cell therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new adoptive cell therapy products is highly competitive. We face competition from existing and future competitors with respect to each of our product candidates currently in development, and will face competition with respect to other product candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide, as well as academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There is no guarantee that our product candidates will be able to compete with potential future products being developed by our competitors including those described under “Item 1. Business – Competition.”

Some of our competitors have initiated clinical trials for GvHD, solid tumors and multiple myeloma, settings in which our iNKT cell therapy platform is currently being investigated. We are also aware of competitors pursuing cell therapy drug candidates, including but not limited to stem cell-based approaches, for the treatment of ARDS secondary to COVID-19. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for the product candidates we may develop. This may include other types of therapies, such as bispecific T cell engagers, oncolytic viruses and antibody drug conjugates.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and adoptive cell therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and

established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other marketing approval for their product candidates 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. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidates that we may develop and commercialize.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for or product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing and reimbursement for new therapies vary widely from country to country. Some countries require approval of the sale price of a therapy before the product 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 candidate in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues 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 we may develop, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government authorities or healthcare programs, private health plans and other organizations. Government authorities and third-party payors, such as private health plans, 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, third-party payors are challenging the prices charged for medical products and requiring that drug companies provide them with discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with its prescription or creating coverage uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any product that we may commercialize or, if reimbursement is available, that the level of reimbursement will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Further, the increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for recently approved products and, as a result, they may not cover or provide adequate payment. Even if we show improved efficacy or improved convenience of administration, third-party payors may deny or revoke the reimbursement status of our product candidates, if approved, or establish prices for our product candidates at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return. Further, as we continue to grow as an organization, previously-established prices may no longer be sufficient and could create additional pricing pressure for us.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement 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 any product candidate for which we obtain marketing approval to each payor separately, and coverage and adequate reimbursement may not be applied consistently or obtained in the first instance or that step edits or other conditions on reimbursement may be imposed.

Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or other regulatory authorities outside the United States. Coverage by one payor does not mean that other payors will also provide coverage. Moreover, eligibility for reimbursement does not imply that any product 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 products, 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 product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for product may be reduced by mandatory discounts or rebates required to be provided to government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Additionally, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. 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 any products we may develop, and our overall financial condition.

If we are required by the FDA to obtain clearance or approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA clearance or approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such test, which would be subject to premarket review requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

Further, in November 2025, the FDA announced its intention to o reclassify certain types of companion diagnostic tests, specifically oncology nucleic acid-based tests used in conjunction with gene-specific therapies, from Class III to Class II. If such reclassification occurs, any companion diagnostics that are the subject of the down-classification may no longer require premarket approval, but rather may be marketed pursuant to the generally less burdensome 510(k) clearance process. However, there is no assurance that any companion diagnostic required for our pharmaceutical development programs will benefit from the reclassification, or that the reclassification, even if it does occur, will result in a shorter timeline to development or marketing of the companion diagnostic If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains marketing approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain marketing approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We face an inherent risk of product liability exposure related to the testing in clinical trials of any product candidates we may develop and will face an even greater risk if we commercially sell any product candidates that we may develop. If we cannot successfully

defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any product candidates that we may develop, if approved.

Although Agenus maintains product liability insurance coverage for us, it may not be adequate to cover all liabilities that we may incur. In the future, we may need to procure our own insurance coverage. Additionally, we anticipate that we will need to increase our insurance coverage when we begin additional clinical trials and if we successfully commercialize any product. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Adoptive cell therapy treatments are novel, and any product candidates we develop may be complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates we may develop or otherwise harm our business.

Any product candidates we may develop will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as the product candidates we intend to develop generally cannot be fully characterized. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our potential IND submissions. Furthermore, as product candidates progress through clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, stability, purity, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives and/or may lead to delays and additional costs. Additionally, any changes we may make to our product candidates may cause such candidates to perform differently than in prior clinical trials, or could negatively affect our ability to utilize or interpret our existing data. Such changes could delay initiation or completion of clinical trials, lead to negative trial results, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay potential marketing approval and jeopardize our ability to commercialize our product candidates or generate revenue.

If we successfully develop product candidates, we may nevertheless encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we not distribute a lot until the 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. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

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

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or

restriction on the use of biologically derived substances in the manufacture of any product candidates we may develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in third-party manufacturing process or facilities also could restrict our ability to ensure sufficient clinical material for any clinical trials we may be conducting or are planning to conduct and meet market demand for any product candidates we develop and commercialize.

Additionally, we may be unable to find sufficient healthy donors for isolation of the iNKT cells that form the basis of our products to meet clinical or market demands, or we may be unable to timely access our donor pool due to events outside of our control.

Risks Related to Regulatory Review and Other Legal Compliance Matters

The marketing approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. In the U.S., we are not permitted to market our product candidates in the U.S. until we receive approval of a BLA from the FDA. The process of obtaining such marketing approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, marketing approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses, and in the case of biological products in the U.S., that such product candidates are safe, pure and potent for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety purity, potency, or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain marketing approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of a BLA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable marketing approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Because adoptive cell therapy is novel and the regulatory landscape that will govern any product candidates we may develop is uncertain and may change, we cannot predict the time and cost of obtaining marketing approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel cell-based immunotherapies we develop are not entirely clear and may change. Within the broader adoptive cell therapy field, we are aware of a limited number of adoptive cell therapies and products that have received marketing authorization from the FDA. Even with respect to more established products that fit into the categories of adoptive cell therapy, the regulatory landscape is still developing. Regulatory requirements governing adoptive cell therapy products have changed frequently and will likely continue to change in the future.

Adverse developments in post-marketing experience or in clinical trials conducted by others of adoptive cell therapy may cause the FDA and other regulatory bodies to revise the requirements for development or approval of any product candidates we may develop or limit the use of products utilizing adoptive cell therapy, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The marketing approval process for novel product candidates such as the product candidates we may develop can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing adoptive cell therapy in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we may develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

To market and sell any product candidates we may develop in the European Union, the United Kingdom, and other foreign jurisdictions, we or our third-party collaborators must obtain separate marketing approvals (a single one for the European Union) and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product candidate be approved for reimbursement before the product candidate can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any jurisdiction, which would materially impair our ability to generate revenue.

Even if we receive marketing approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

For any approvals that we may receive for 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 ongoing compliance with cGMPs and GCPs for any clinical trials we may conduct. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by

the FDA and other regulatory authorities for compliance with cGMPs and other applicable regulations and standards. In addition, any marketing approvals we may receive will require the submission of periodic reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product. Such approvals may also contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted, or suspension or revocation of approvals;
- product seizures or detentions, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, the FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any marketing approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies caused by, funding shortages, staffing limitations, or policy changes could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and

other agencies may also slow the time necessary for new drugs or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, which have led to substantial personnel changes, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or similar factors hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our relationships with healthcare providers, third-party payors and patients as well as our activities generally will be subject to a broad range of healthcare laws and regulations and any failure to comply with such laws and regulations could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products, if approved. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the Health Insurance Portability and Accountability Act (HIPAA), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information on certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by physicians and their immediate family members;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and

foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved. Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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 prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Current and future healthcare reform and other legislation or regulation may increase the difficulty and cost for us and any collaborators to commercialize any product candidates we may develop and affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post-approval activities with respect to any product candidate for which we obtain marketing approval, and may affect our ability, or the ability of any future collaborators, to profitably sell our products for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States and elsewhere, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative and regulatory initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any future collaborators, may receive for any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business, results of operations and financial condition.

The Affordable Care Act (ACA) was signed into law in 2010. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affects the U.S. pharmaceutical industry. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale, are

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;
- a Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, including prescription drug spending.

Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges and may be subject to additional challenges in the future. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States. There have been several Congressional inquiries, as well as legislative and regulatory initiatives and executive orders designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

The Inflation Reduction Act (IRA) was enacted in 2022. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which became effective in 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for any product candidate for which we obtain marketing approval. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

Moreover, the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure, drug price increase reporting, and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for any product candidate for which we obtain marketing approval or the frequency with which any product candidate for which we obtain marketing approval is prescribed or used.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage and payment criteria and in additional downward pressure on the price that we receive for any approved drug. 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 drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of any product candidate for which we obtain marketing approval to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates which we may develop, and even if we do, that exclusivity may not prevent the FDA from approving other competing products.

Regulatory authorities in some jurisdictions, including the U.S., may designate biologics or drugs designed to address relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States, where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the U.S., orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances..

We may seek Orphan Drug Designations for agenT-797 or for our other product candidates. There can be no assurances that we will be able to obtain such designations. Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active ingredients may be approved for the same uses or indications. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same use or indication within the same rare disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care with respect to the exclusivity-protected use or indication, or if the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity to meet the needs relating to the relevant indication or use. Orphan drug designation neither shortens the development or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for

any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of specific marketplace and regulatory factors.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, or we may fail to satisfy certain arrangements with governmental authorities.

We are exposed to the risk of fraud or other misconduct by our employees, consultants, commercial partners and our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

If we or any contract manufacturers and suppliers we engage 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 and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance through Agenus 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Laws and regulations governing any of our international operations or those we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act (the "FCPA"), prohibits any U.S. individual or business from paying, offering, 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 United States to comply with certain accounting provisions requiring the company 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. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The Securities and Exchange Commission (the "SEC") is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States and the European Union. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. For example, HIPAA and its implementing regulations establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. We have also assumed contractual obligations related to protecting the privacy and security of personal information. While we have determined that we are neither a "covered entity" nor a "business associate" directly subject to HIPAA, many of the U.S. health care providers, including U.S. clinical trial sites, with which we interact

are subject to HIPAA, and we have assumed contractual obligations related to protecting the privacy of personal information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts and we could face civil and criminal penalties.

The Federal Trade Commission ("FTC") and state regulators enforce a variety of data privacy issues, such as promises made in privacy policies or failures to appropriately protect information about individuals, as unfair or deceptive acts or practices in or affecting commerce in violation of the Federal Trade Commission Act or similar state laws. In recent years, certain states have adopted or modified data privacy and security laws and regulations that may apply to our business. For example, the California Consumer Privacy Act ("CCPA") requires businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which creates a patchwork of overlapping but different state laws. Certain states have also enacted new laws regulating specific types of personal information, such as health data, some of which impose onerous notice and consent obligations, prohibit certain personal information processing, and/or provide for a private right of action. As a result, our processing of health data in such states may subject us to additional compliance obligations and expose us to increased risk of liability. Moreover, the FTC and state attorneys general have focused particular attention on the processing of health data in recent years, which elevates the risk of our processing of such data even in states that have not enacted specific laws.

In addition, we may be subject to privacy and security laws in the various additional jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. For example, the processing of personal data in the European Economic Area (the "EEA"), is subject to the General Data Protection Regulation (the "GDPR"), which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, responding to data subjects who exercise their rights and reporting certain data breaches to regulators and affected individuals. The GDPR also requires us to enter certain contractual arrangements with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the European Commission to lack an adequate level of data protection, such as the United States. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20.0 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. Additionally, following Brexit, we must comply with the GDPR and the United Kingdom GDPR, each regime having the ability to fine up to the greater of €20.0 million or 4% of global turnover for violations. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems. Our efforts to comply may also be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the European Union and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages by data subjects, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Risks Related to Our Relationship with Agenus

We may experience difficulty in separating our resources from Agenus.

On August 2, 2022, Agenus and MiNK entered into the Amended and Restated Services Agreement effective April 1, 2022 (the "Services Agreement"). Pursuant to the terms of the Services Agreement, Agenus provides MiNK with certain general and administrative support, including, without limitation, financial, facilities management, human resources and information technology administrative support (the "Agenus Services"), and MiNK and Agenus provide each other with certain research and development services (the "R&D Services") and other support services, including legal and regulatory support (the "Shared Services"). MiNK pays 10% of Agenus' costs related to the Agenus Services, and the costs of R&D Services are based upon pass-through costs related to such services plus an allocation of the costs of the employees performing the services. No payment is due from either party for the Shared Services, provided that the services provided by each party are proportional in scope and volume.

The Services Agreement also covers MiNK's use of Agenus' business offices and laboratory space and equipment, provided we pay Agenus a proportionate amount for the use of such facilities and equipment. We currently utilize business offices, laboratory space and equipment in Agenus' Lexington, Massachusetts facility and office space in Agenus' New York City office.

Because our operations have not been fully separated from Agenus, we may have difficulty doing so in the future. We may need to acquire resources in addition to, and eventually in lieu of, those provided by Agenus to us, and may also face difficulty in separating our resources from Agenus' resources and integrating newly acquired resources into our business. At present, we have prioritized separating our research and development functions from Agenus while continuing to rely on Agenus to provide human resources, finance, information technology, legal and other general and administrative functions. We plan to internalize such functions in the future as our business evolves. We continue to rely on, and plan to continue relying on, access to Agenus' facilities for our research and development and the eventual manufacturing of our product candidates, which, among other things, presents challenges in maintaining the confidentiality of our intellectual property and proprietary information due the proximity of our employees in their workspace to Agenus' employees and third party providers.

In addition, Agenus may prioritize its own needs ahead of the services Agenus has agreed to provide us or could terminate the Services Agreement. Agenus employees who conduct services for us may prioritize Agenus' interests over our interests, Agenus employees we rely upon to provide certain services may leave Agenus or Agenus ceases to provide services that are critical to our business. Our business, financial condition and results of operations could be harmed if we have difficulty operating as a standalone company, fail to acquire resources that prove to be important to our operations or incur unexpected costs in separating our resources from Agenus' resources or integrating newly acquired resources.

If Agenus or MiNK terminates the Services Agreement, we will need to replicate or replace certain functions, systems and infrastructure to which we will no longer have the same access after our initial public offering. We may also need to make investments or hire additional employees to operate without the same access to Agenus's existing operational and administrative infrastructure. These initiatives may be costly to implement. Due to the scope and complexity of the underlying projects relative to these efforts, the amount of total costs could be materially higher than our estimate, and the timing of the incurrence of these costs is subject to change.

We may not be able to replace these services or enter into appropriate third-party agreements on terms and conditions, including cost, comparable to those that we will receive from Agenus under the Services Agreement. Additionally, after the Services Agreement terminates, we may be unable to sustain the services at the same levels or obtain the same benefits as when we were receiving such services and benefits from Agenus. When we begin to operate these functions separately, if we do not have our own adequate systems and business functions in place, or are unable to obtain them from other providers, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline. In addition, we have historically received informal support from Agenus, which may not be addressed in the Services Agreement and may diminish or be eliminated at any time.

Agenus owns a significant amount of our common stock and will be able to exert control over specific matters subject to stockholder approval.

Agenus beneficially owns approximately 46% of our outstanding common stock. Therefore, Agenus has the ability to substantially influence us through this ownership position. Agenus' interests may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of us or our other stockholders. So long as Agenus continues to own a significant amount of our equity, it will continue to be able to strongly influence or effectively control our decisions. Agenus could remain our significant stockholder for an extended period of time or indefinitely. Agenus may be able to influence the outcome of our corporate actions so long as it owns a significant portion of our common stock.

Agenus may sell or distribute a portion of the shares of our common stock it currently holds to its stockholders, which could impact our share price or volatility.

Agenus owns a significant equity interest in our company. This means that Agenus could choose to sell some or all of its shares of our common stock. If Agenus sells a substantial number of our common stock in the public market, the sales could adversely impact the market price of our common stock. See "—***Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could cause the market price of our common stock to decline.***"

If Agenus sells its significant equity interest in our company in a privately negotiated transaction, we may become subject to influence of a presently unknown third party. Such third party may have conflicts of interest with those of other stockholders. In addition, if Agenus sells a significant interest in our company to a third party, such a sale could negatively impact or accelerate any future indebtedness we may incur, and negatively impact any other commercial agreements and relationships, all of which may adversely affect our ability to run our business as described herein and may have a material adverse effect on our operating results and financial condition. Furthermore, Agenus may elect to distribute to its stockholders a portion of the shares of our common stock that it holds. Such Agenus stockholders may then sell the shares of our common stock into the public market, which may adversely impact our stock price or volatility.

Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with Agenus.

Garo H. Armen, Ph.D. (Chairman of the Board), Jennifer S. Buell, Ph.D. (President, Chief Executive Officer and Director), Brian Corvese (Director) and Ulf Wiinberg (Director) are all current or former officers and/or directors of Agenus. These individuals own Agenus equity and Agenus equity awards. Their relationship with Agenus and the ownership of any Agenus equity or equity awards creates, or may create the appearance of, conflicts of interest when we ask these individuals to make decisions that could have different implications for Agenus than the decisions have for us. In addition, our certificate of incorporation provides for the allocation of certain corporate opportunities between us and Agenus. Under these provisions, neither Agenus or its other affiliates, nor any of their officers, directors, agents or stockholders, will have any obligation to present to us certain corporate opportunities. For example, a director of our company who also serves as a director, officer or employee of Agenus or any of its other affiliates may present to Agenus certain acquisitions, in-licenses, potential development programs or other opportunities that may be complementary to our business and, as a result, such opportunities may not be available to us. To the extent attractive corporate opportunities are allocated to Agenus or its other affiliates instead of to us, we may not be able to benefit from these opportunities. Additionally, conflicts of interest and certain other disputes may arise between us and Agenus, and we may not be able to resolve favorably such disputes with respect to our past and ongoing relationships.

Risks Related to Our Relationships with Third Parties

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We depend upon independent investigators, such as medical institutions, universities, CROs, clinical data management organizations and clinical investigators to conduct our ongoing clinical trials for agenT-797 and expect to rely on third parties for future clinical trials for all of our product candidates. We also currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time under certain criteria. If we need to enter into alternative arrangements, it may delay our product development activities.

Although we designed clinical trials for agenT-797, and will design any future clinical trials for our product candidates, independent investigators, and third parties may also conduct our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities.

In particular, we and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, for our product candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP, GCP or other requirements, the 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, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other activities that could harm our competitive position. In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any BLA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of GMP lentiviral vectors for our early phase programs. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any product candidates that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

Although we maintain in-house manufacturing capabilities for our product candidates, we rely, and expect to continue to rely, on third parties for the manufacture of certain elements for our product candidates and related raw materials. The facilities used by our third-party manufacturers must be approved for the manufacture of our product candidates by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit a BLA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain approval for the use of their manufacturing facilities in connection with our product candidates.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or commercialize our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of our product candidates in a timely manner;
- delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of materials; and
- in the event of approval to market and commercialize any product candidate, an inability to meet commercial demands.

In addition, we do not have any long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture materials according to our specifications;
- failure to manufacture materials on schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement, which would have a material adverse impact on our financial position.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are

conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these collaborations with us. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for the product candidates we may develop.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely marketing approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we 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. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

We may also be restricted under future collaboration agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to develop product candidates or bring them to market and generate product revenue.

Risks Related to Our Intellectual Property

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

Our commercial success will depend in large part on our ability to obtain and maintain patent, trademark, trade secret and other intellectual property protection of our cell-based immunotherapies, product candidates and other therapies, methods used to manufacture them and methods of treatment, as well as successfully defending our patent and other intellectual property rights against third-party challenges. It is difficult and costly to protect our cell-based immunotherapies and product candidates, and we may not be able to ensure their protection. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing the product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We seek to protect our proprietary position by in-licensing intellectual property relating to our platform technology and filing patent applications in the United States and abroad related to our cell-based immunotherapies and product candidates that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our cell-based immunotherapies and product candidates we may develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours and our ability to commercialize any product candidates we may develop may be adversely affected.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all desired markets or in a particular market. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside 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 jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be deemed patentable over the prior art. Furthermore, publications of discoveries in the scientific literature lag behind the discoveries per se and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all before the grant of patent rights. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, whether patent rights will be granted and the scope, validity, enforceability and commercial value of our patent rights are highly uncertain, and we may become involved in complex and costly litigation. Our pending and future patent applications intended to protect our cell-based immunotherapies and product candidates we may develop may not be granted, and if granted may not effectively prevent others from commercializing competitive technologies and products.

No consistent policy regarding patentability in the field of cell-based immunotherapies has emerged in the United States. Patentability in this field outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our licensed patent rights. With respect to our in-licensed intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will be deemed valid and enforceable and provide sufficient protection from competitors.

Moreover, the scope of claims being pursued in a patent application can be significantly reduced before a patent is issued, and the scope of claims can be reinterpreted after issuance. Even if patent applications we in-license or own currently or in the future were to issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our future in-licensed patents and patent applications may in the future be co-owned by our licensors with third parties. If we are unable to obtain an exclusive license to the rights of such third-party co-owners in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our rights to develop and commercialize our cell-based immunotherapies and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, including Agenus.

We depend on intellectual property licensed from third parties, and our licensors may not act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We have in-licensed and are dependent on certain rights and proprietary technology from third parties that are important or necessary to the development of some of our cell-based immunotherapies and product candidates. If we fail to comply with our obligations under any license, the licensor may have the right to terminate the license, in which event we would not be able to develop or market our cell-based immunotherapies or any other therapies or product candidates covered by the licensed intellectual property.

Our in-licenses may not provide 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 cell-based immunotherapies and product candidates in the future. Some licenses granted to us may be expressly subject to certain preexisting rights held by the licensor or certain third parties. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in certain territories or fields. If we determine that rights to such excluded fields are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the chance to access technology that is important to our business.

We will not have complete control in the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications intended to protect the technology that we license from third parties in the future. It is possible that our licensors' enforcement of patents against infringers or defense of such patents against challenges to validity or enforceability may be less vigorous than if we had conducted the proceedings ourselves. We cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced or defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend such patents, or if they lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of the product candidates we may develop that rely in any way on such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using, selling and importing competing products.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties and may not be the sole and exclusive owners of the intellectual property we have in-licensed. If other third parties have ownership rights to our in-licensed patents, the license granted to us in jurisdictions where the consent of a co-owner is necessary to grant such a license may not be valid and such co-owners may be able to license such patents to our competitors, and our competitors could market competing products and technology. If one or more of such joint owners breaches any pertinent inter-institutional or operating agreements, our rights to in-licensed patents and patent applications may be adversely affected. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In the event any of our third-party licensors takes the position that, in spite of our efforts, we have materially breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable license agreement or, in some cases, one or more license(s) under the applicable license agreement and such termination would result in our no longer having the ability to develop and commercialize product candidates and technology covered by that license agreement or license. In the event of such termination of a third-party in-license, or if the underlying patents under a third-party in-license fail to provide the intended exclusivity, competitors would have the freedom to seek marketing approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our patent, patent applications and any future patents may not provide sufficient protection of our cell-based immunotherapies, our product candidates and our future product candidates or result in any competitive advantage.

Agenus has assigned to us a U.S. patent and a U.S. patent application directed to T cell receptor discovery technologies, as well as a number of U.S. and foreign patent applications directed to T cell receptors. Agenus has also assigned to us know-how that supports our cell-based immunotherapies and uses with respect to treatment of particular diseases and conditions and that may provide us with the opportunity to obtain additional patent protection. U.S. provisional patent applications do not themselves mature into granted patent rights, but a non-provisional U.S. and other applications that can result in granted patent rights may claim the benefit of a provisional application if filed within 12 months of the filing date of the provisional application. In any particular case, the failure to file a non-provisional patent application claiming the benefit of the provisional application within the 12-month period could cause us

to lose the ability to obtain patent protection for the inventions disclosed in the provisional application. We cannot be certain that any patent applications that we file will issue as patents, and if they do, that such patents will protect our cell-based immunotherapies or our product candidates, or that such patents will not be challenged, narrowed, circumvented, invalidated or held unenforceable. Any failure to obtain or maintain patent protection with respect to our cell-based immunotherapies and product candidates could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Claims to therapeutic methods in a patent do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of such claims. Moreover, even if competitors or other third parties do not actively promote their product to treat the indications recited in such patent claims, health care providers may recommend that patients use the competitor products off-label, or patients may do so themselves.

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 in the future may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or other countries. For example, during the pendency of any of our patent applications, we may be subject to a third party pre-issuance submission of prior art to the United States Patent and Trademark Office (the "USPTO"), or we may become involved in interference or derivation proceedings, or various pre-grant third-party challenges in foreign jurisdictions. Even if patents are issued, third parties may challenge the inventorship, validity, enforceability or scope thereof, including through opposition, revocation, reexamination, post-grant review and *inter partes* review proceedings, and litigation. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and product candidates. Furthermore, even if they are unchallenged, our current and future patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we own with respect to our cell-based immunotherapies and 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 development, testing and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced.

Given that patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we or our licensors were in the past or will be in the future the first to file any patent application related to our cell-based immunotherapies or product candidates. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued. As a result, there may be prior art of which we or our licensors are not aware that may affect the validity or enforceability of a patent claim, and we or our licensors may be subject to priority disputes. For our in-licensed patent portfolios, we will rely on our licensors to determine inventorship, and to obtain and file inventor assignments of any given priority application before the filing of a subsequent PCT or other application claiming the benefit of the priority application. The failure to do so in a timely fashion may give rise to a challenge as to entitlement of priority for such subsequent applications in jurisdictions outside the United States.

We may be required to disclaim part or all of the term of certain patents or patent applications. 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 or our future licensors are aware, but which we or our future licensors do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our current or future patents would be declared by a court, patent office or other governmental authority 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 our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities being found to infringe such claims. It is possible that our competitors may have filed, and may in the future file, patent applications with claims covering our products or technology similar to ours. Those patent applications may have priority over our in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. The possibility also exists that others will develop on an independent basis products that have the same effect as our product candidates and that do not infringe our patent or other intellectual property rights, or will design around the claims of our patent applications or our in-licensed patents or patent applications that cover our product candidates.

Likewise, our patent applications directed to our proprietary cell-based immunotherapies and our product candidates, if issued, would result in patents expected to expire from 2038 through 2042, without taking into account any possible patent term adjustments or extensions. Our potential future patents may expire before, or soon after, our first product candidate achieves marketing approval in the United States or foreign jurisdictions. Additionally, no assurance can be given that the USPTO or relevant foreign patent offices will grant any of the pending patent applications we own currently or in the future. Upon the expiration any patents, we would lose the right to exclude others from practicing the respective claimed inventions. The expiration of these patents could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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 rights, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products by third parties in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our patents and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Moreover, the initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to enforce or defend our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We depend on intellectual property licensed from third parties and may in the future need to obtain additional licenses from third parties to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations and prospects significantly. We cannot provide any assurances that there are no third-party patents that might be enforced against our current therapies, including our cell-based immunotherapies, manufacturing methods, product candidates, or future methods or products, resulting in either an injunction prohibiting our manufacture or future sales, or an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the

intended exclusivity, competitors or other third parties would have the freedom to seek marketing approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of or cell-based immunotherapies or product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights to third parties under our collaborative development relationships;
- our diligence obligations under the license agreement 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 and know-how 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.

In addition, the agreement under which we currently license intellectual property or technology from Agenus is complex, and certain provisions in such agreement 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 broaden what we believe to be the scope of Agenus' rights to our intellectual property and technology, or increase what we believe to be our financial or other obligations under the agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize our cell-based immunotherapies or other product candidates or we could lose other significant rights, any of which could have a material adverse effect on our business, financial conditions, results of operations and prospects. It is also possible that a third party could be granted limited licenses to some of the same technology, in certain circumstances.

We may not be successful in acquiring or in-licensing necessary rights to key technologies or any product candidates we may develop.

The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

Furthermore, there has been extensive patenting activity in the field of cell-based immunotherapies, and pharmaceutical companies, biotechnology companies and academic institutions are competing with us or are expected to compete with us in the field of cell-based immunotherapies and are filing patent applications potentially relevant to our business, and there may be certain third-party patent applications that, if issued, may allow the third party to limit our activities. To market our product candidates, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license the rights to any compositions, methods of use, processes or other technology from third parties that we identify as necessary for product candidates we may develop and cell-based immunotherapies. We may also require licenses from third parties for certain other cell-based immunotherapies including certain delivery methods that we are evaluating for use with product candidates we may develop. Some institutions may receive funding that obligates the institution to require certain terms from collaborators or that creates rights in the funding body, such as a government, that cannot be waived. The obligations and rights may limit the scope or exclusivity of a potential patent right arising from the collaboration. For example, if a patent right is created as part of a collaboration with an entity funded by the United States government, the government may have rights under the Bayh-Dole Act, including "march-in" rights to allow use of the patent right by the government or third parties.

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. Even if we hold such an option, we may be unable to negotiate a license from the institution 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.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our existing collaboration arrangements and any that we may enter into in the future may not be successful and we may not realize the benefits of such relationships, which could adversely affect our ability to develop and commercialize our product candidates.

Our current collaborations and any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- current or future collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- current or future collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test 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;
- disputes may arise between us and a current or future collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- current or future collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- a current or future collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our current or future collaborators that would prevent us from collaborating with others;
- current or future collaborators 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 or business risk;
- current or future collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products or products;
- current or future 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 develop or commercialize such intellectual property; and a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety, efficacy (or purity and potency) or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. As a result, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property, our product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, any potential future collaborations may limit our control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license, or strategic transaction, we will achieve an economic benefit that justifies such transaction, and such transaction may not yield additional development product candidates for our pipeline.

Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of any such product candidate is questioned, or the sales of an approved product candidate, are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and, if approved, commercialization of our product candidates, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and, if approved, commercialization of such product candidates, and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The intellectual property landscape around cell-based immunotherapies is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

The field of cell-based immunotherapies is still in its infancy. Due to the intense research and development being conducted in this field by several companies, including us and our competitors, the intellectual property landscape is evolving and in flux, and it may remain uncertain for the coming years. There may be significant intellectual property-related litigation and proceedings relating to our in-licensed, and other third-party, intellectual property and proprietary rights in the future, or any such intellectual property we may own in the future. Our commercial success depends upon our ability and the ability of our collaborators and licensors to develop, manufacture, market and sell any product candidates that we may develop and to use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our cell-based immunotherapies and any product candidates we may develop, including interference proceedings, post-grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office ("EPO"). Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and such third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of the merits thereof.

As the biotechnology and pharmaceutical industries expand and more patents are issued, this increases the risk that our cell-based immunotherapies and 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 which of various types of therapies, products or their methods of use or manufacture. We are aware of certain third-party patent applications that, if issued, may be construed to cover our cell-based immunotherapies and product candidates. There may also be third-party patents of which we are currently unaware with claims to technologies, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon those patents.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates.

A large number of patents and patent applications exist in our field. Third parties may allege that they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement lawsuits against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

Our ability to commercialize any product candidates we may develop in the United States and abroad may be adversely affected if we cannot obtain a license on commercially reasonable terms to relevant third-party patents that cover our cell-based immunotherapies and product candidates. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a

presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing any product candidates we may develop and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our cell-based immunotherapies or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Defense of third-party claims of infringement, misappropriation or other violation of intellectual property rights involves substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Some 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, financial condition, results of operations and prospects. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our present or future patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful and could result in a finding that such patents are unenforceable or invalid.

Competitors may infringe our present or future patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our present or future patents or the patents of our licensing partners also are, and may in the future become, involved in inventorship, priority, validity or enforceability disputes. Countering or defending against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our present patent, or potential future owned patents, do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our present, or potential future, owned or in-licensed patents at risk of being invalidated or interpreted narrowly.

In patent litigation in the United States, defendant 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. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent 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 future licensors, 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 the patent protection on our therapies and/or product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We are currently challenging, and in the future may choose to challenge, third party patents in patent opposition proceedings in the EPO or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates, cell-based immunotherapies or other proprietary therapies.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. Furthermore, because of the substantial

amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have acquired patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications must be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our present, or potential future, owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees. The USPTO and foreign patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during and after the patent application process. We are also 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 be cured in some instances by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in a partial or complete loss of patent rights in the relevant jurisdiction. Were a non-compliance event to occur, our competitors might be able to enter the market with similar or identical products or therapies, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, public health pandemics, geopolitical instability, natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our or our licensors' or collaborators' abilities to obtain or maintain patent protection for our programs and technology. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our cell-based immunotherapies and product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents. For example, under the Leahy-Smith America Invents Act (the "America Invents Act"), the United States changed from a "first to invent" to a "first-inventor-to-file" patent system. Under a "first-inventor-to-file" system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on an invention regardless of whether another inventor made the invention earlier. For example, under the first-inventor-to-file system, if we and a third party independently make the same invention, and the third party files a patent application in the USPTO before we do, the third party could be awarded the patent and we could be denied the patent even if we were the first to make the invention. U.S. patent law requires us to be cognizant going forward of the time from invention to the filing of a patent application seeking to protect the invention. Since patent applications in the United States and most other countries are confidential for at least a period of time after filing and in some cases until issuance, we cannot be certain that we or our licensors were the first to file any patent application related to our therapies or product candidates or the first to invent any of the inventions claimed in our or our licensor's patents or patent applications. The America Invents Act also included a number of other significant changes to U.S. patent law, including provisions affecting the way patent applications are prosecuted, allowing third party submission of prior art and establishing post-grant review, inter partes review and derivation proceedings. The full effects of these

changes are still unclear because the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act, and many of the substantive changes to patent law, including the "first-inventor-to-file" provisions which became effective in March 2013, continue to be interpreted by the courts. In addition, the courts have yet to address many of these provisions, and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. There also remains many subsisting issued patents and some pending patent applications in the U.S. that were filed prior to its enactment and are therefore subject to the pre-America Invents Act U.S. patent laws and that may have relevance to our freedom-to-operate or ability to obtain patent issuances. Generally, the America Invents Act and its implementation has and could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

In addition, recent U.S. Supreme Court rulings 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 validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change further in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how recent and future decisions or actions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws or practice of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan. The term of a patent in any particular jurisdiction depends on the law governing patent term in the jurisdiction. In most countries, including the United States, the basic term of a utility patent expires 20 years from the earliest effective non-provisional filing date, if all necessary maintenance fees are paid on time. The nature and duration of protection afforded by a patent varies from country to country and depends upon many factors, including the type of patent, the scope of its claims, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Some countries, including the United States, provide for patent term adjustment ("PTA"), which increases the term of a patent beyond its basic term to compensate for certain delays in prosecution of the underlying patent application. PTE may also be available when a patent claims certain kinds of inventions requiring regulatory approval in order to market, including certain pharmaceutical-related inventions, and can also increase the term of a patent beyond its basic term. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our present, or potential future, owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain PTE and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited PTE under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments provide for a PTE term of up to five years as compensation for patent term that could not be enjoyed during the FDA regulatory review process. PTE cannot extend the remaining term of a patent such that the patent would expire beyond 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug or a method for using it may be extended. Even if we were to seek PTE, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy 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 PTE at all or the term of any such obtained extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

In addition to seeking patents for our technology and product candidates, we also rely on know-how, as well as confidentiality agreements, non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties to execute confidentiality agreements upon the commencement of employment, consulting or other relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed by 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 certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that 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 the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our proprietary technology and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of these parties may breach the agreements and disclose our proprietary information and we may not be able to obtain adequate remedies for such breaches.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, know-how can be difficult to protect. These measures may not provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our proprietary knowledge and providing it to a competitor, and any recourse we might have for this type of misconduct may not result in an adequate remedy. In addition, our proprietary technology and processes may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Also, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. We may then have to pursue litigation to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately conduct this type of litigation or proceedings. For example, some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

If our trademarks and trade names 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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- any product candidates we may develop will eventually become commercially available in generic or biosimilar product forms;
- others may be able to make adoptive cell therapy products that are similar to any product candidates we may develop or utilize similar cell-based immunotherapies but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by issued patents or pending patent applications that we license or own, currently or in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our license partners or current or future collaborators, may fail to meet our obligations to the U.S. government regarding any patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending or potential future owned or licensed patent applications or those that we may own in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patent, or parts of our patent;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later be issued with claims covering our product candidates or therapies similar to ours;
- it is possible that our current and future patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid, unenforceable or narrowed in scope, including as a result of legal challenges by our competitors;
- the claims of our patent or patent applications, if and when issued, may not cover our product candidates;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of license partners or current or future collaborators to the same extent as the laws of the United States;
- the inventors of our current and future patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or uncooperative as to the patents or patent applications on which they are named as inventors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the patents of others may harm our business; or
- we may choose not to file a patent application in order to maintain certain subject matter as trade secrets or know-how, and a third party may subsequently develop and file a patent application disclosing the same subject matter.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Employee Matters, Managing Growth, Information Technology and Our Operations

We currently have a limited number of employees, and our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our management and scientific teams, as well as our majority stockholder. Such principal members are employed "at will," meaning we or they may terminate the employment at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, including our scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

We expect to expand our development, regulatory and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

In connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage the future development and expansion of our company.

Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business (collectively, "IT Systems"). We own and manage some of these IT Systems but also rely on third parties for a range of IT Systems and related products and services, including but not limited to cloud computing services. We and certain of our third-party providers collect, maintain and process data about customers, employees, business partners and others, including information about individuals, as well as proprietary information belonging to our business such as trade secrets (collectively, "Confidential Information").

We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our IT Systems and Confidential Information, including from diverse threat actors, such as state-sponsored organizations, opportunistic hackers and hacktivists, as well as through diverse attack vectors, such as social engineering/phishing, malware (including ransomware), malfeasance by insiders, human or technological error, and as a result of malicious code embedded in open-source software, or misconfigurations, bugs or other vulnerabilities in commercial software that is integrated into our (or our suppliers' or service providers') IT Systems, products or services. Successful cyberattacks that disrupt or result in unauthorized access to third party IT Systems can materially impact our operations and financial results. Remote and hybrid working arrangements at our company (and at many third-party providers) also increase cybersecurity risks due to the challenges associated with managing remote computing assets and security vulnerabilities that are present in many non-corporate and home networks. Additionally, any integration of artificial intelligence in our or any service providers' operations, products or services is expected to pose new or unknown cybersecurity risks and challenges.

Cyberattacks are expected to accelerate on a global basis in frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools—including artificial intelligence—that circumvent security controls, evade detection and remove forensic evidence. As a result, we may be unable to detect, investigate, remediate or recover from future attacks or incidents, or to avoid a material adverse impact to our IT Systems, Confidential Information or business. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our IT Systems and Confidential Information. Furthermore, given the nature of complex systems, software and services like ours, and the scanning tools that we deploy across our networks and products, we regularly identify and track security vulnerabilities. We are unable to comprehensively apply patches or confirm that measures are in place to mitigate all such vulnerabilities, or that patches will be applied before vulnerabilities are exploited by a threat actor. If attackers are able to exploit critical vulnerabilities before patches are installed or mitigating measures are implemented, significant compromises could impact our and our customers' IT Systems and/or Confidential Information.

While to date no cybersecurity incidents have had a material impact on our operations or financial results, we cannot guarantee that material incidents will not occur in the future. Any adverse impact to the availability, integrity or confidentiality of our IT Systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

Risks Related to Ownership of Our Common Stock

We do not know whether a market for our common stock will be sustained or what the market price of our common stock will be, we may be delisted from the Nasdaq Capital Market if we are unable to comply with Nasdaq Listing Rules, and, as a result, it may be difficult for you to sell your shares of our common stock.

If a market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

If we are unable to raise the value of our common stock, our securities may be delisted. For example, we were notified by the Nasdaq Stock Market Listing Qualifications Department on February 23, 2024 that we had failed to comply with the minimum value of listed securities requirement for the Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(b)(2) for the previous 30 consecutive trading days. Nasdaq Listing Rule 5550(b)(2) requires a listed company maintain a minimum value of listed securities ("MVLS") of $35.0 million.

On February 26, 2024, we received a notification from the Nasdaq Stock Market Listing Qualifications Department letting us know that our common stock failed to comply with the $1 minimum bid price required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) for the previous 30 consecutive trading days.

On January 28, 2025 we executed a 1:10 reverse stock split and in February 2025 we received letters from Nasdaq notifying the Company it had regained compliance with Nasdaq Listing Rules 5550(b)(2) and 5550(a)(2) and that it complies with the requirements for continued listing.

On May 13, 2025, we received a letter from the Listing Qualifications Department notifying us that for the previous 30 consecutive trading days the Company's MVLS was less than $35.0 million, as required by Nasdaq Listing Rule 5550(b)(2).

On July 28, 2025, the Company was notified by the Nasdaq Listing Qualifications Department staff that the Company's MVLS met or exceeded $35.0 million for at least ten consecutive business days. Accordingly, the Company regained compliance with the MVLS rule and this matter is now closed.

If, in the future, our common stock fails to meet the bid price requirement and we have effected a reverse stock split within the prior one-year period, we will not be eligible for any compliance period to address the bid price deficiency and would be issued a delisting determination rather than be granted a compliance period. Under these circumstances, we could appeal the delisting determination to a Nasdaq hearing panel, during which time any suspension or delisting action will ordinarily be stayed. If we were eligible for a compliance period, there can also be no assurance that we would regain compliance with the bid price requirement during the 180-day compliance period, secure a second 180-day period to regain compliance, maintain compliance with the other Nasdaq listing requirements, or be successful in appealing any delisting determination.

There can be no assurance as to whether the Company will remain compliant with the Nasdaq Listing Rules. A delisting of our common stock from Nasdaq could have significant adverse impacts on our business, financial condition, results of operations and cash flows by, among other things, reducing the liquidity, public float and market price of our common stock, reducing the number of investors, including institutional investors, willing to hold or acquire our common stock, which could negatively impact our ability to raise equity, decreasing the amount of news and analyst coverage relating to us, limiting our ability to issue additional securities, obtain additional financing or pursue strategic restructuring, refinancing or other transactions; and impacting our reputation and, as a consequence, our ability to attract new business.

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

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our common stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause our common stock price to decline.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could cause the market price of our common stock to decline.

Sales of a substantial number of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. This could also impair our ability to raise additional capital through the sale of our equity securities. In addition, the stock market in general has experienced, and will continue to experience from time to time, extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors have adversely impacted, and may continue to impact, the market price of our common stock, regardless of our operating performance. From time to time we have raised financing through the sale of our equity securities. If we sell, or the market perceives we intend to sell, substantial amounts of our common stock under our Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for each Annual Report on Form 10-K we file with the SEC. This assessment includes disclosure of any material weaknesses identified by our management in internal control over financial reporting. In the future, when we are no longer an emerging growth company, our independent registered public accounting firm will also be required to attest to the effectiveness of our internal control over financial reporting in each Annual Report on Form 10-K to be filed with the SEC pursuant to Section 404(b) of the Sarbanes-Oxley Act. We are also required to disclose material changes made in our internal control over financial reporting on a quarterly basis. Failure to comply with the Sarbanes-Oxley Act could potentially subject us to sanctions or investigations by the SEC, the stock exchange on which our securities are listed or other regulatory authorities, which would require additional financial and management resources. Compliance with Section 404 requires that we incur substantial costs and expend significant management efforts.

We can give no assurance that material weaknesses will not be identified in the future. We continue to implement measures designed to improve our internal controls over financial reporting. A material weakness in our internal control over financial reporting could result in an increased probability of fraud, litigation from our stockholders, reduction in our ability to obtain financing, and require additional expenditures to remediate. Our failure to implement and maintain effective internal control over financial reporting could

result in errors in our financial statements that could result in loss of investor confidence in the accuracy and completeness of our financial reports and a decline in our share price, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years following the fiscal year-end of the anniversary of our IPO. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404(b), 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, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We are also a "smaller reporting company," as defined in the Exchange Act. 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(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we 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 common stock price may be more volatile.

Provisions in our amended and restated certificate of incorporation, our amended and restated by-laws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, amended and restated by-laws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and by-laws, which became effective upon the closing of our initial public offering, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of our board of directors or our Chief Executive Officer;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may, unless and until filled by our stockholders, be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- do not permit any stockholder to cumulate votes at any election of directors;
- expressly authorized our board of directors to make, alter, amend or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation and amended and restated by-laws designate the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state or federal courts within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated by-laws, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated by-laws or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine. Under our amended and restated certificate of incorporation, this exclusive forum provision will not apply to claims that are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction and explicitly not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act of 1933, as amended (the "Securities Act"), the Exchange Act of 1934, as amended (the "Exchange Act"), or the rules and regulations thereunder. Furthermore, our certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated by-laws described above. These choice 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, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation or amended and restated by-laws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

The market price of our common stock may be volatile, which could result in substantial losses for investors.

Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies or clinical trials for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials or marketing approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- developments or changing views regarding the use of allogeneic cell therapies;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreement;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Although we have director and officer liability insurance, the coverage provided by our policy may be insufficient if we are the target of securities litigation.

Securities litigation could result in substantial costs and divert management's attention and resources from our business.

We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we do and will in the future incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our efforts to comply with the requirements of being, a public company, and our management and other personnel will continue to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a standalone public company may make it more difficult and more expensive for us to retain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We continue to evaluate these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and

governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business and other factors beyond our control, such as general conditions in the global economy and in the global financial markets, a weakened demand for any of our current or future product candidates, the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the ACA may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience difficulties in any eventual commercialization of our product candidates and our business, financial condition, results of operations and cash flows could be adversely affected.

Furthermore, the global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, rising inflation and interest rates, and uncertainty about economic stability. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, cost increases due to high and persistent inflation and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current global economic climate and global financial market conditions could adversely impact our business.

In addition, political tensions as a result of trade policies, such as the recent tariff changes implemented by the U.S., 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 changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. These tariffs may increase the cost of such products and negatively impact our results of operations.

Moreover, persistent economic downturns may require us to undertake optimization and cost saving initiatives, including streamlining our organization and adjusting the size and structure of our workforce. Any reduction in force may yield unintended consequences and costs, such as attrition beyond the intended reduction in force, the distraction of employees and reduced employee morale, which could, in turn, adversely impact productivity, including through a loss of continuity, loss of accumulated knowledge or inefficiency during transitional periods. Any of these impacts could also adversely affect our reputation as an employer, make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the restructuring.

Scrutiny on environmental, social, and governance ("ESG") initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There is scrutiny from investors, patients, environmental activists, the media and governmental and nongovernmental organizations, and other stakeholders on a variety of environmental, social, and governance and other sustainability matters, such as climate change and human capital. We may experience pressure to make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. Moreover, stakeholders have varying perspectives on environmental, social, and other sustainability matters, and both advocates and opponents of such matters are increasingly resulting to an array of activism forms; any failure to successfully navigate these expectations may result in adverse impacts. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. Such requirements and other expectations are not uniform, and in some instances policymakers have taken countervailing efforts to constrain companies' consideration of ESG matters, which can increase the complexity and cost of compliance. If we fail to comply with new laws, regulations or reporting requirements, or new interpretations of existing standards, our reputation and business could be adversely impacted. Additionally, many of our business partners and suppliers may be subject to similar reporting and stakeholder expectations, which may augment or create additional risks, including risks that may not be known to us.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We design and assess our program based on the Information Systems Audit and Control Association's Control Objectives for Information Technologies framework and National Institute of Standards and Technology cybersecurity framework, as well as threat trends identified by multiple external and internal cybersecurity intelligence reports.

We contract with external firms to assess our cybersecurity controls. We have processes in place to identify and evaluate risks associated with third party vendors and suppliers. In addition, we have systems in place to maintain business continuity and disaster recovery. Some or all of this work is done through our services agreement with Agenus.

To date, we have not experienced any material cybersecurity incidents.

We describe whether and how risks from cybersecurity threats are reasonably likely to affect our business, results of operations and financial condition, under the heading "Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business" included as part of our Item 1A. Risk Factors of this Annual Report on Form 10-K, which is incorporated by reference into this Item 1C.

Cybersecurity Governance

Our Audit Committee of the Board of Directors has oversight responsibility for risks and incidents related to cybersecurity threats. As part of our services agreement with Agenus, Agenus' Chief Information Officer provides the Audit Committee and the Board of Directors periodic reports on our cybersecurity risks and any material cybersecurity incidents.

Our team of cybersecurity professionals is led by Agenus' Chief Information Officer, who has over 20 years of experience in cybersecurity in regulated industries. Our cybersecurity team monitors the prevention and detection of cybersecurity events and is responsible for incident response and remediation.

Item 2. Properties.

We currently utilize a combined 3,500 square feet of Agenus' facilities in Lexington, MA and New York, NY. The space supports our research, clinical, manufacturing and administrative functions. There is current capacity to expand our operations within existing Agenus facilities.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Regardless of the outcome, litigation can have a material adverse effect on us because of defense and settlement costs, diversion of management resources 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 is currently listed on the Nasdaq Capital Market under the symbol "INKT."

Holders

As of February 28, 2026, there were approximately 376 holders of record of our common stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes included elsewhere in this Form 10-K. This discussion contains forward-looking statements based upon current plans, expectations and beliefs involving risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and in other parts of this Form 10-K.

Overview

MiNK Therapeutics, Inc. ("we," "us," "our," or "Company") is focused on developing innovative treatments for cancer and immune-mediated diseases using allogeneic, ex-vivo expanded invariant natural killer T ("iNKT") cells. Amid a broader industry renaissance in innate immunity—highlighted by surging investment and clinical activity in NK, γδ T, and iNKT-based therapies—iNKT cells represent a distinct T cell ("T") population that uniquely bridges innate and adaptive immunity. They combine durable memory responses characteristic of adaptive T cells with rapid, MHC-independent rapid cytolytic capabilities of natural killer ("NK") cells. This dual functionality enables direct tumor killing via CD1d and stress ligands, potent orchestration of the tumor microenvironment through activation of dendritic cells and NK cells, elimination of immunosuppressive myeloid populations, and restoration of exhausted T-cell function—all while naturally suppressing graft-versus-host disease ("GvHD"). This unique combination positions iNKT cells as an optimal platform for allogeneic therapy, given their natural homing capabilities, tumor clearance potential, and efficacy against infected cells.

Our approach includes advancing both native and engineered iNKT cell therapies, leveraging a pipeline composed of wholly owned or exclusively licensed assets. Additionally, we have developed a proprietary personalized neoantigen library to facilitate personalized T Cell Receptor ("TCR") development. This library enables us to identify patient-specific tumor neoantigens, which we use to create highly tailored TCR-based therapies. By harnessing these personalized neoantigen libraries, we aim to enhance precision, efficacy, and overall therapeutic outcomes for patients with various cancers and immune-mediated diseases. Our goal is to discover, develop and commercialize novel allogeneic, off-the-shelf, iNKT cell therapies to treat cancer and other immune-mediated diseases with high unmet need. We are employing iNKT cells in their native form, through our lead program agenT-797, in diseases where iNKT cells have demonstrated activity and accelerated approval pathways exist. These indications include but are not limited critical pulmonary immune failure (including severe hypoxemic respiratory failure / pneumonia), GvHD, solid tumor cancers, and other severe immune-related diseases. Our discovery efforts are focused on applying our proprietary technologies to build a broad pipeline of engineered iNKT cells, including CRs, CAR-iNKTs (such as MiNK-215 (FAP-CAR-iNKT) and MiNK-413 (BCMA-CAR-iNKT), and INKT cell engager technology.

Our business activities include product research and development, manufacturing, regulatory and clinical development, corporate finance, and support of our collaborations. To be successful, our product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. We are a party to an Amended and Restated Intercompany Services Agreement (the "New Intercompany Agreement") and an Intellectual Property Assignment and License Agreement with Agenus Inc. ("Agenus"). Under the New Intercompany Agreement, Agenus provides us with certain general and administrative support, including, without limitation, financial, facilities management, human resources and information technology administrative support, and we and Agenus provide each other with certain research and development services and other support services, including legal and regulatory support. We are also entitled to use Agenus' business offices and laboratory space and equipment in exchange for us contributing a proportionate payment for the use of such facilities and equipment, and we will be covered by certain Agenus insurance policies, subject to certain conditions, including us paying the cost of such coverage. Under the Intellectual Property Assignment and License Agreement, Agenus exclusively assigned patent rights and know-how related to our technology to us. We also have a field-limited exclusive license under certain Agenus patents and know-how; and we retain the rights to expand a proprietary pipeline of products and technologies.

Our most advanced product candidate, agenT-797, is an off-the-shelf, allogeneic, native iNKT cell therapy. Having treated nearly 100 patients with agenT-797 across oncology and critical pulmonary immune failure, we have generated mechanistic and clinical insights that support continued development of our iNKT platform beyond into pulmonary diseases and auto-immune diseases, including in graft-versus-host disease prevention.

Under the leadership of Dr. Terese C. Hammond, our Head of Inflammatory and Pulmonary Diseases, we are advancing a differentiated franchise in critical pulmonary immune failure with agenT-797, our off-the-shelf, allogeneic iNKT cell therapy.

Building on the foundational Phase 1/2 data published in Nature Communications in February 2024 — which demonstrated >70% 30-day survival (80% in the veno-venous extracorporeal membrane oxygenation ("VV-ECMO") subgroup) in mechanically ventilated patients with severe viral ARDS versus ~10% in contemporaneous controls — we are now advancing agenT-797 in a randomized Phase 2 adaptive, placebo-controlled trial in patients with severe pneumonia and moderate-to-severe hypoxemic acute respiratory failure ("AHRF"). Our published results highlighted rapid inflammation resolution, rescue of exhausted T cells, and reduced

secondary infections, supporting the broad therapeutic potential of iNKT cells in life-threatening respiratory conditions, including interstitial lung disease ("ILD").

In cancer, our Phase 1 clinical trial enrolled 34 patients evaluating agenT-797 in refractory solid tumor cancers, as a monotherapy and in combination with anti-PD-1 checkpoint inhibitors, pembrolizumab and nivolumab. Updated data presented at SITC 2025 demonstrated durable clinical activity, including complete remissions and long-term survivors (>2–3+ years) in heavily pretreated, checkpoint-refractory cancers such as metastatic testicular cancer, gastric cancer, thymoma, cholangiocarcinoma, renal cell carcinoma, and adenoid cystic carcinoma, with median overall survival of approximately 23 months in combination with anti-PD-1. These data showed that agenT-797, both as monotherapy and in combination with anti-PD-1 agents, produced meaningful disease control in the majority of heavily pretreated patients, including reductions in target and non-target lesions and prolonged disease stabilization. A detailed case report describing a durable confirmed partial response (42% tumor reduction with progression-free survival exceeding nine months) in a patient with chemotherapy- and PD-1-refractory gastric cancer following a single infusion of agenT-797 was published in Oncogene in January 2024 (Hadfield et al., 2024). Subsequently, a separate case report published in Oncogene in 2025 described a complete clinical, radiologic, and biochemical remission in a patient with heavily pretreated metastatic testicular (germ cell) cancer following a single infusion of agenT-797 in combination with anti-PD-1 therapy; the patient remains without evidence of disease more than two years post-treatment (Garmezy et al., 2025). AgenT-797 also exhibited long-term persistence in peripheral blood (detected up to 6 months post-infusion), independent of HLA matching and without the need for lymphodepletion.

Building on these encouraging results, a Phase 2 investigator-sponsored trial led by Dr. Yelena Janjigian at Memorial Sloan Kettering Cancer Center was initiated (NCT06251973), with the first patient dosed in February 2024. This study is evaluating the safety and efficacy of agenT-797 in combination with Agenus' botensilimab (an Fc-enhanced anti-CTLA-4 inhibitor) and balstilimab (anti-PD-1), together with ramucirumab and paclitaxel, in patients with previously treated, advanced esophageal, gastric, or gastro-esophageal junction ("GEJ") adenocarcinoma. Early translational data from the first patients in the ongoing Phase 2 combination study were presented at the inaugural AACR Advances in Cancer Immunotherapy (AACR IO) meeting in 2025. These data demonstrated that addition of agenT-797 to botensilimab and balstilimab drove robust immune activation, including elevated interferon-gamma (IFN-γ) levels, rapid tumor infiltration, CD8+ T-cell activation, and immune reprogramming in patients with PD-1-refractory gastroesophageal cancers. Additional data are expected in early 2026.

In addition, we are advancing a pipeline of next-generation allogeneic, engineered iNKT programs. Our two most advanced preclinical engineered programs are (1) MiNK-413, an IL-15 armored CAR-iNKT program targeting B cell maturation antigen ("BCMA"), and (2) MiNK-215, an IL-15 armored tumor stromal targeting FAP-CAR-iNKT program. MiNK-413 has demonstrated tumor clearance and improved persistence in preclinical models, as well as manufacturing and logistical improvements over current BCMA cell therapies. MiNK-215 reported therapeutic activity in non-small cell lung cancer models, which resulted in substantial tumor elimination and improved survival compared to T cells alone. MiNK has presented data that showcased MiNK-215's activity in preclinical colorectal cancer models. In human organoid models of CRC with liver metastases, MiNK-215 potently enhanced tumor killing by T cells and was associated with depletion of immune suppressive FAP-expressing stellate cells and increased CD8+ T cell infiltration. Investigational new drug application ("IND") enabling studies for MiNK-215 are underway.

With our vertically integrated manufacturing capabilities and experienced team, we are accelerating the development of accessible, off-the-shelf iNKT-based therapies with transformative potential across oncology, critical pulmonary immune failure, and GvHD.

Our research and development expenses for the years ended December 31, 2025 and 2024 were $5.8 million and $6.3 million, respectively. We have incurred losses since our inception. As of December 31, 2025, we had an accumulated deficit of $156.7 million.

Historical Results of Operations

For the Year Ended December 31, 2025 Compared to the Year Ended December 31, 2024

Research and development ("R&D") expense

R&D expense includes the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, manufacturing costs, costs of expert consultants, and administrative costs. R&D expense decreased 9% to $5.8 million for the year ended December 31, 2025 from $6.3 million for the year ended December 31, 2024. This decrease was primarily due to decreased costs associated with both the timing of our clinical trials and pre-clinical activities as well as decreased personnel costs, primarily due to decreased headcount.

General and administrative ("G&A") expense

G&A expense consists primarily of personnel costs, facility expenses, and professional fees. G&A expense increased 56% to $6.7 million for the year ended December 31, 2025 from $4.3 million for the year ended December 31, 2024. This increase was primarily

due to an increase in professional fees and the incremental share-based compensation expense resulting from the option award modification approved by shareholders in June 2025.

Other income (expense), net

Other expense increased to approximately $32,400 for the year ended December 31, 2025 from income of approximately $331,000 for the year ended December 31, 2024, primarily due to foreign currency exchange losses partially offset by the recognition of a refundable R&D tax credit in the UK in the year ended December 31, 2025 compared to the $185,000 gain recognized on the deconsolidation of a foreign subsidiary and the recognition of a refundable R&D tax credit in the UK in the year ended December 31, 2024.

Interest income, net

Interest income increased $7,700 for the year ended December 31, 2025, from income of $173,000 for the year ended December 31, 2024 to income of $180,000 for the year ended December 31, 2025, primarily due to increased interest earned on our money market funds partially offset by interest expense accrued under the related party note we issued to Agenus, under the Convertible Promissory Note Purchase Agreement (the "Note").

Research and Development Programs

R&D program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions.

	For the years ended December 31,	
	2025	2024
Payroll and personnel costs	$ 3,389,016	$ 4,634,647
Professional fees	53,416	1,353,448
Forgiveness of liability	—	(1,788,204)
Allocated services	560,486	517,861
Materials and other	1,754,569	1,618,323
Total	$ 5,757,487	$ 6,336,075

Our product candidates are in various stages of development and significant additional expenditures will be required if we start new clinical trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations and/or bring our product candidates to market. The total cost of any particular clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, number of patients and trial sponsorship. The process of obtaining and maintaining regulatory approvals for new products is lengthy, expensive and uncertain. Because of the current stage of our product candidates, among other factors, we are unable to reliably estimate the cost of completing our research and development programs or the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements, and, therefore, when, if ever, material cash inflows are likely to commence.

Liquidity and Capital Resources

We have incurred annual operating losses since inception, and we had an accumulated deficit of $156.7 million as of December 31, 2025. We expect to incur losses over the next several years as we continue development of our technologies and product candidates, manage our regulatory processes, initiate and continue clinical trials, and prepare for potential commercialization of products.

On July 15, 2025, we entered into a Sales Agreement with B. Riley Securities, Inc., as sales agent (the "Sales Agent") to sell shares of our common stock, from time to time through the Sales Agent, at a maximum aggregate offering price of $50.0 million. The issuances and sales under the Sales Agreement are pursuant to our registration statement on Form S-3 (File No. 333-268143) (the "2022 Registration Statement") filed with the Securities and Exchange Commission on November 3, 2022, the base prospectus included in the 2022 Registration Statement, dated November 8, 2022, and a prospectus supplement, dated July 15, 2025. On November 7, 2025, we filed a registration statement on Form S-3 (File No. 333-291388) (the "2025 Registration Statement") with the Securities and Exchange Commission to replace the 2022 Registration Statement when the 2025 Registration Statement is declared effective. We sold approximately 584,000 and 193,000 shares of our common stock pursuant to the Sales Agreement during the year ended December 31, 2025 and the period of January 1, 2026 through March 27, 2026, respectively, and received aggregate net proceeds totaling $17.5 million. As of March 27, 2026, approximately $32.0 million remained available under the Sales Agreement.

We had a Note outstanding as of December 31, 2025 of $5.0 million in principal plus accrued and unpaid interest of approximately $179,000. In January 2026, in accordance with the terms of the Note, we repaid the Note in full.

In May 2024, we entered into a stock purchase agreement with an investor, pursuant to which we issued and sold an aggregate of 464,000 shares of common stock, at a purchase price of $12.50 per share, for an aggregate purchase price of approximately $5.8 million.

Our cash and cash equivalents balance as of December 31, 2025 was $13.4 million. We believe that our cash and cash equivalents balance, plus anticipated funding, will be sufficient to satisfy our liquidity requirements for more than one year from when these financial statements were issued. Because the completion of anticipated funding is not entirely within our control, we are required to disclose that substantial doubt exists about our ability to continue as a going concern for a period of one year after the date of filing of this Annual Report on Form 10-K. The financial statements have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Management continually monitors the Company's liquidity position and adjusts spending as needed in order to preserve liquidity. To support our liquidity requirements we will require additional funding. Potential sources of additional funding include: (1) seeking strategic partnerships and collaborations, as well as out-licensing opportunities, for our portfolio programs and product candidates, (2) exploring avenues for securing non-dilutive financing, such as grants, collaborations, and providing fee-based services to strengthen our balance sheet, and (3) potential of equity or debt financing options.

Net cash used in operating activities for the years ended December 31, 2025 and 2024 was $5.9 million and $9.6 million, respectively. Our future ability to generate cash from operations will depend on achieving regulatory approval and market acceptance of our product candidates, and our ability to enter into collaborations. Please see the “Note Regarding Forward-Looking Statements” of this Annual Report on Form 10-K and the risks highlighted under Part I-Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

The SEC defines “critical accounting policies” as those that require the application of management’s most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base those estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

Our significant accounting policies are described in Note 2 of the notes to our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K. In many cases, the accounting treatment of a particular transaction is dictated by U.S. GAAP, with no need for our judgment in its application. There are also areas in which our judgment in selecting an available alternative would not produce a materially different result.

Recent Accounting Pronouncements

Refer to Note 2 to our consolidated financial statements included within Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

JOBS Act

We qualify as an “emerging growth company” as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by

non-affiliates or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected 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. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

MiNK Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of MiNK Therapeutics, Inc.and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2025, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated 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 years in the two-year period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

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

Boston, Massachusetts

March 31, 2026

MiNK THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET

	December 31, 2025	December 31, 2024
ASSETS		
Cash and cash equivalents	$ 13,360,340	$ 4,577,040
Prepaid expenses	276,431	246,600
Other current assets	211,202	164,244
Total current assets	13,847,973	4,987,884
Equipment, net of accumulated depreciation of $612,245 and $524,639 at December 31, 2025 and December 31, 2024, respectively	390,869	732,929
Total assets	$ 14,238,842	$ 5,720,813
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable	3,425,314	2,728,212
Accrued liabilities	1,579,147	1,873,561
Related party note	5,179,444	—
Other current liabilities	2,847,543	2,357,903
Total current liabilities	13,031,448	6,959,676
Related party note	—	4,924,612
Due to related parties	15,435,053	13,422,407
Commitments and contingencies		
Stockholders' deficit		
Common stock, par value $0.00001 per share; 150,000,000 shares authorized; 4,706,246 and 3,963,045 shares issued at December 31, 2025 and December 31, 2024, respectively	48	40
Additional paid-in capital	143,167,204	125,227,389
Accumulated other comprehensive loss	(718,916)	(631,576)
Accumulated deficit	(156,675,995)	(144,181,735)
Total stockholders' deficit	(14,227,659)	(19,585,882)
Total liabilities and stockholders' deficit	$ 14,238,842	$ 5,720,813

See accompanying notes to consolidated financial statements.

MiNK THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 5,757,487	$ 6,336,075
General and administrative	6,729,817	4,314,164
Change in fair value of related party note	154,832	638,046
Operating loss	(12,642,136)	(11,288,285)
Other income (expense), net:		
Interest income, net	180,246	172,568
Other income (expense), net	(32,370)	330,915
Net loss	(12,494,260)	(10,784,802)
Per common share data:		
Basic and diluted net loss per common share	$ (2.93)	$ (2.86)
Weighted average number of common shares outstanding	4,270,470	3,773,326
Other comprehensive loss		
Foreign currency translation loss	(87,340)	(200,629)
Comprehensive loss	$ (12,581,600)	$ (10,985,431)

See accompanying notes to consolidated financial statements.

MiNK THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid-In Capital	Treasury Stock		Other Comprehensive Loss	Accumulated Deficit	Total
	Number of shares	Par Value		Number of shares	Amount			
Balance at December 31, 2023	3,459,910	$ 35	$115,772,396	—	$ —	$ (430,947)	$(133,396,933)	$(18,055,449)
Net Loss	—	—	—	—	—	—	(10,784,802)	(10,784,802)
Other comprehensive loss	—	—	—	—	—	(200,629)	—	(200,629)
Sale of shares in private placement	464,000	5	5,799,995	—	—	—	—	5,800,000
Vesting of nonvested shares	30,173	—	0	—	—	—	—	0
Exercise of stock options and employee share purchases	8,962	—	19,986	—	—	—	—	19,986
Issuance of related party note	—	—	792,878	—	—	—	—	792,878
Grant and recognition of stock options	—	—	2,735,305	—	—	—	—	2,735,305
Recognition of parent stock options	—	—	106,829	—	—	—	—	106,829
Balance at December 31, 2024	3,963,045	$ 40	$125,227,389	—	$ —	$ (631,576)	$(144,181,735)	$(19,585,882)
Net Loss	—	—	—	—	—	—	(12,494,260)	(12,494,260)
Other comprehensive loss	—	—	—	—	—	(87,340)	—	(87,340)
Grant and recognition of stock options	—	—	2,638,036	—	—	—	—	2,638,036
Shares sold at the market	583,458	6	14,454,935	—	—	—	—	14,454,941
Issuance of shares for services	2,500	—	22,000	—	—	—	—	22,000
Share retirement	(45)	—	—	—	—	—	—	—
Exercise of stock options and employee share purchases	97,094	2	440,308	—	—	—	—	440,310
Vesting of nonvested shares	36,068	—	—	—	—	—	—	—
Issuance of shares for certain employee bonuses	35,412	—	543,928	(11,286)	(173,353)	—	—	370,575
Retirement of shares withheld from share-based bonuses	(11,286)	—	(173,353)	11,286	173,353	—	—	—
Recognition of parent stock options	—	—	13,961	—	—	—	—	13,961
Balance at December 31, 2025	4,706,246	$ 48	$143,167,204	—	$ —	$ (718,916)	$(156,675,995)	$(14,227,659)

See accompanying notes to consolidated financial statements.

MiNK THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CASH FLOWS

	For the Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (12,494,260)	$ (10,784,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	181,745	215,437
Share-based compensation	2,673,997	1,810,226
Loss on disposal of assets	169,800	—
Gain on deconsolidation	—	(185,351)
Gain on forgiveness of liability	—	(1,788,204)
Change in fair value of related party note	154,832	638,046
Interest accrued on related party note	100,000	79,444
Changes in operating assets and liabilities:		
Prepaid expenses	(29,788)	(194,173)
Accounts payable	689,710	(1,182,414)
Accrued liabilities and other current liabilities	720,196	(393,771)
Other operating assets and liabilities	1,908,600	2,230,086
Net cash used in operating activities	(5,925,168)	(9,555,476)
Cash flows from financing activities:		
Net proceeds from sale of equity	14,454,941	—
Proceeds from issuance of related party note	—	5,000,000
Proceeds from sale of shares in private placement	—	5,800,000
Payment for shares to satisfy tax withholdings	(173,353)	—
Proceeds from employee stock purchases and option exercises	440,309	19,986
Net cash provided by financing activities	14,721,897	10,819,986
Effect of exchange rate changes on cash	(13,429)	(54,699)
Net increase in cash and cash equivalents	8,783,300	1,209,811
Cash and cash equivalents, beginning of period	4,577,040	3,367,229
Cash and cash equivalents, end of period	$ 13,360,340	$ 4,577,040
Supplemental cash flow information:		
Cash paid for interest	$ 9,516	$ 13,135
Supplemental disclosures - non-cash activities:		
Issuance of common stock, $0.00001 par value, for payment of employee bonuses	$ 370,575	$ —
Issuance of stock options for payment of certain employee bonuses	—	1,031,908
Insurance financing agreement	257,164	172,000
Issuance of related party note (Note 10)	—	792,878

See accompanying notes to consolidated financial statements.

(1) Description of Business

MiNK Therapeutics, Inc. ("MiNK" or the "Company") is a clinical-stage biopharmaceutical company pioneering the discovery, development and manufacturing of allogeneic, off-the-shelf, invariant natural killer T ("iNKT") cell therapies to treat cancer and other immune-mediated diseases. iNKT cells are a distinct T cell population that combine durable memory responses with the rapid cytolytic features of natural killer cells. iNKT cells offer distinct therapeutic advantages as a platform for allogeneic therapy in that the cells naturally home to tissues, aid clearance of tumors and infected cells, and suppress graft-versus-host-disease. MiNK's proprietary platform is designed to facilitate scalable and reproducible manufacturing for off-the-shelf delivery. As such, the Company believes that its approach represents a highly versatile application for therapeutic development in cancer and immune diseases. MiNK is leveraging its platform and manufacturing capabilities to develop a wholly owned or exclusively licensed pipeline of both native and engineered iNKT cell.

Since its inception in 2017, MiNK has incurred losses and expects to continue incurring operating losses and negative cash flows in the future until it is able to generate sales and profits. As of December 31, 2025, MiNK had an accumulated deficit of $156.7 million and cash and cash equivalents of $13.4 million. MiNK believes that its cash and cash equivalents balance, plus additional anticipated funding, will be sufficient to satisfy its liquidity requirements for more than one year from when these financial statements were issued. Because the completion of anticipated funding is not entirely within the Company's control, the Company is required to disclose that substantial doubt exists about its ability to continue as a going concern for a period of one year after the date of filing of this Annual Report on Form 10-K. The financial statements have been prepared on a basis that assumes MiNK will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Management continually monitors MiNK's liquidity position and adjusts spending as needed in order to preserve liquidity. To support its liquidity requirements the Company will require additional funding. Potential sources of additional funding for the Company include: (1) seeking strategic partnerships and collaborations, as well as out-licensing opportunities, for the Company's portfolio programs and product candidates, (2) exploring avenues for securing non-dilutive financing, such as grants, collaborations, and providing fee-based services to strengthen the Company's balance sheet, and (3) potential of equity or debt financing options.

MiNK's product candidates are in various stages of development and additional expenditures will be required if the Company starts new trials, encounters delays in its programs, applies for regulatory approvals, continues development of its technologies, expands its operations, and/or brings its product candidates to market. The eventual total cost of each clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, and number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because all of the Company's programs are at an early stage of clinical development, the Company is unable to reliably estimate the cost of completing its research and development programs or the timing for bringing such programs to various markets or substantial partnering or out-licensing arrangements, and, therefore, when, if ever, material cash inflows are likely to commence.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") and include the accounts of MiNK and its subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation.

In the year ended December 31, 2024, the Company deconsolidated a foreign subsidiary and recognized a gain of approximately $185,000, included in "Other income, net" on its consolidated statements of operations and comprehensive loss.

On January 17, 2025, MiNK executed a reverse stock split of its issued and outstanding common stock, par value $0.00001, at a ratio of 1-for-10 with a record date of January 28, 2025 (the "Reverse Stock Split"). All common share, per share and related information included in the accompanying financial statements and footnote disclosures have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split. See Note 7 for further details.

(b) Segment Information

MiNK is managed and operated as one business segment. The Company does not operate separate lines of business with respect to any of its product candidates or geographic locations. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and does not have separately reportable segments as defined by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 280, *Segment Reporting*.

(c) Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases those estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

(d) Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities at acquisition of three months or less to be cash equivalents. Cash equivalents consist primarily of money market funds.

(e) Equipment

Equipment is carried at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, typically 4-10 years. Additions are capitalized, while repairs and maintenance are charged to expense as incurred. Depreciation expense was $182,000 and $215,000, for the years ended December 31, 2025 and 2024, respectively.

(f) Fair Value Measurements

Certain assets and liabilities are carried at fair value under 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 use 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—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash and cash equivalents are carried at fair value (a Level 1 measurement), determined according to the fair value hierarchy described above. The carrying values of the Company's, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

(g) Fair Value Option

Under the Fair Value Option subsection of Accounting Standards Codification Subtopic 825-10, Financial Instruments – Overall, the Company has the irrevocable option to report most financial assets and liabilities at fair value on an instrument-by-instrument basis with changes in fair value reported in earnings. The Company has elected to report the related party note it issued to Agenus Inc. ("Agenus") on February 12, 2024, under the Convertible Promissory Note Purchase Agreement (the "Purchase Agreement" or "Note") at fair value. The fair value of the Note is determined on a scenario based present value methodology. The outstanding principal amount of the Note was $5.0 million at December 31, 2025.

(h) Foreign Currency Transactions

Gains and losses from the Company's foreign currency-based accounts and transactions, such as those resulting from the remeasurement and settlement of receivables and payables denominated in foreign currencies, are included in the consolidated statements of operations within other income (expense). The Company recorded de minimis foreign currency losses for the years ended December 31, 2025 and 2024.

(i) Research and Development

Research and development expenses include the costs associated with the Company's internal research and development activities, including salaries and benefits, share-based compensation, occupancy costs, clinical manufacturing costs, related administrative costs and research and development conducted for the Company by outside advisors. Research and development expenses also include the cost of clinical trial materials shipped to the Company's research partners. Research and development costs are expensed as incurred.

(j) Share-Based Compensation

MiNK accounts for share-based compensation in accordance with the provisions of ASC 718, *Compensation—Stock Compensation*. Share-based compensation expense is recognized based on the estimated grant date fair value. Compensation cost is recognized on a straight-line basis over the requisite service period of the award. Forfeitures are recognized as they occur. See Note 8 for further discussion on share-based compensation.

(k) Income Taxes

Income taxes are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and net operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which such items are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the consolidated statement of operations in the period that includes the enactment date. Deferred tax assets are recognized when they are more likely than not expected to be realized.

(l) Net Loss Per Share

Basic income or loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted income per common share is calculated by dividing net income attributable to common stockholders by the weighted average number of common shares outstanding plus the dilutive effect of outstanding instruments such as stock options. Because the Company reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of December 31, 2025 and 2024, as they would be anti-dilutive:

	2025	2024
Stock options	876,533	895,002
Nonvested shares	77,866	80,646

(m) Recent Accounting Pronouncements

Recently Issued, Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 requires incremental annual disclosures around income tax rate reconciliations, income taxes paid and other related disclosures. As the Company is an Emerging growth company ("EGC"), ASU 2023-09 is effective for fiscal years beginning after December 15, 2025. Early adoption is permitted for any annual periods for which financial statements have not been issued or made available for issuance. The Company is currently evaluating the impact that ASU 2023-09 will have on the notes to its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (DISE). This new guidance requires all public entities to incorporate disclosures about specific types of expenses included in the expense captions presented on

the face of the income statement as well as disclosures about selling expenses. Public entities must adopt ASU 2024-03 prospectively for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption and retrospective application are permitted. The Company is currently evaluating the impact that ASU 2024-03 will have on its consolidated financial statements.

No other new accounting pronouncement issued or effective during the year ended December 31, 2025 had or is expected to have a material impact on the Company's consolidated financial statements or disclosures.

(3) Cash and Cash Equivalents

Cash equivalents consisted of the following as of as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025		December 31, 2024	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Institutional money market funds	$ 12,804	$ 12,804	$ 4,212	$ 4,212

(4) Equipment

Equipment, net, consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Equipment	$ 1,003	$ 1,258
Less accumulated depreciation	(612)	(525)
Equipment, net	$ 391	$ 733

(5) Income Taxes

The Company is subject to taxation in the United States and in various state, local and foreign jurisdictions. The Company remains subject to examination by U.S. Federal, state, local and foreign tax authorities for tax years 2021 through 2024. With few exceptions, the Company is no longer subject to U.S. Federal state, and foreign examinations by tax authorities for the tax year 2021. However, net operating losses from and after the tax year 2017 would be subject to examination if and when used in a future tax return to offset taxable income. The Company's policy is to recognize income tax related penalties and interest, if any, in its provision for income taxes and, to the extent applicable, in the corresponding income tax assets and liabilities, including any amounts for uncertain tax positions.

As of December 31, 2025, the Company had available net operating loss carryforwards of $71.0 million for Federal and state income tax purposes, which are available to offset future Federal and state taxable income, if any. $70.8 million of these Federal net operating loss carryforwards do not expire, while the remaining net operating loss carryforwards expire in 2037. The Company's ability to use these net operating losses is limited by change of control provisions under Internal Revenue Code ("IRC") Section 382 and may expire unused. The Company also has foreign net operating loss carryforwards, which do not expire, available to offset future foreign taxable income of $19.1 million generated in the United Kingdom. The potential impacts of these provisions are among the items considered and reflected in the Company's assessment of its valuation allowance requirements.

Beginning January 1, 2022, the Tax Cuts and Jobs Act (the "Tax Act") eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to Internal Revenue Code ("IRC") Section 174. Under the Tax Act the capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses. On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA contains, among other provisions, changes to the U.S. corporate income tax system, including allowing immediate expensing of U.S. qualifying research and development expenses and allowing taxpayers an election to accelerate the deduction for previously capitalized U.S. research and development costs. The favorable U.S. research and development expenditure provisions increase the net operating loss generated in 2025 but do not have a material impact on the Company's deferred tax expense as a result of the valuation allowance maintained against the Company's net deferred tax assets. The Company is electing to continue amortization of the domestic capitalized research and development expenses in 2025. The Company has considered the impact of these provisions, which results in capitalized research expense deferred tax assets of approximately $5.3 and $7.0 million as of December 31, 2025 and 2024 respectively.

The tax effect of temporary differences and net operating loss carryforwards that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2025 and 2024 are presented below (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
U.S. Federal and state net operating loss carryforwards	$ 19,363	$ 15,819
Foreign net operating loss carryforwards	4,778	7,310
Research and development tax credits	362	341
Share-based compensation	479	346
Capitalized research expenses	5,277	6,967
Other	1,482	180
Total deferred tax assets	31,741	30,963
Less: valuation allowance	(31,741)	(30,963)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating loss and tax credit carryforwards can be utilized or the temporary differences become deductible. The Company considers projected future taxable income and tax planning strategies in making this assessment. To fully realize the deferred tax asset, the Company will need to generate future taxable income sufficient to utilize net operating losses prior to their expiration. Based upon the Company's history of not generating taxable income, the Company believes that it is more likely than not that deferred tax assets will not be realized through future earnings. Accordingly, a valuation allowance has been established for the full value of the deferred tax assets. The valuation allowance on the deferred tax assets increased by $0.8 million and $1.3 million during the years ended December 31, 2025 and 2024, respectively.

Income tax expense was nil for the years ended December 31, 2025 and December 31, 2024. Income taxes recorded differed from the amounts computed by applying the U.S. Federal income tax rate of 21% to loss before income taxes as a result of the following (in thousands):

	December 31,	
	2025	2024
Computed "expected" Federal tax benefit	$ (2,624)	$ (2,265)
(Increase) reduction in income taxes benefit resulting from:		
Change in valuation allowance	476	1,436
Foreign income inclusion	16	295
State and local income benefit, net of Federal income tax benefit	(942)	(434)
Expiration of tax attributes	2,687	—
Permanent differences	737	1,004
Other, net	(350)	(36)
Income tax benefit	$ —	$ —

(6) Accrued Liabilities

Accrued liabilities consist of the following as of December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Payroll	$ 1,000	$ 718
Professional fees	501	374
Research services	78	191
Contract manufacturing costs	—	591
Total	$ 1,579	$ 1,874

(7) Equity

The Company's authorized capital stock consists of 155,000,000 shares, all with a par value of $0.00001 per share, of which:

- 150,000,000 shares are designated as common stock; and
- 5,000,000 shares are designated as preferred stock.

Stock Purchase Agreement

In May 2024, the Company entered into a Stock Purchase Agreement with an investor (the "Purchaser"), pursuant to which the Company issued and sold an aggregate of 464,000 shares of common stock, at a purchase price of $12.50 per share, a 25% premium to the 30-day volume-weighted average stock price, or an aggregate purchase price of approximately $5.8 million. The Purchaser agreed not sell of any of the common stock prior to November 9, 2024 and to vote all of the shares of common stock that it then owns in accordance with the recommendation of the Company's board of directors on all matters presented to the Company's stockholders through May 14, 2025.

Reverse Stock Split

On January 17, 2025, the Company's stockholders approved a proposal to amend its Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to effect the Reverse Stock Split at a ratio of 1-for-10. On January 17, 2025, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to its Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the Reverse Stock Split. Pursuant to the Certificate of Amendment, the Reverse Stock Split became effective at 12:01 a.m., Eastern Time, on January 28, 2025. As of the opening of trading on January 28, 2025, MiNK's common stock began trading on a post-split basis under CUSIP number 603693 201.

All common share, per share and related information included in the accompanying financial statements and footnote disclosures have been adjusted retroactively, where applicable, to reflect the Reverse Stock Split.

Nasdaq Compliance

On May 13, 2025, MiNK received a letter (the "MVLS Notice") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") notifying it that for the previous 30 consecutive trading days the Company's Minimum Value of Listed Securities ("MVLS") was less than $35.0 million, as required by Nasdaq Listing Rule 5550(b)(2) (the "MVLS Rule"). Nasdaq provided the Company with 180 calendar days, or until November 10, 2025, to regain compliance. To regain compliance, the Company's MVLS had to have met or exceeded $35.0 million for a minimum of ten consecutive trading days.

On July 28, 2025, the Company was notified by the Nasdaq Listing Qualifications Department staff that the Company's MVLS met or exceeded $35.0 million for at least ten consecutive business days. Accordingly, the Company regained compliance with the MVLS Rule and this matter is now closed.

At the Market Sales Agreement

On July 15, 2025, the Company entered into an At Market Issuance Sales Agreement (the "Sales Agreement") with B. Riley Securities, Inc., as sales agent (the "Sales Agent") to sell shares of the Company's common stock, from time to time through the Sales Agent, at a maximum aggregate offering price of $50.0 million. The issuances and sales under the Sales Agreement were pursuant to the Company's registration statement on Form S-3 (File No. 333-268143) (the "2022 Registration Statement") filed with the Securities and Exchange Commission on November 3, 2022, the base prospectus included in the 2022 Registration Statement, dated November 8, 2022, and a prospectus supplement, dated July 15, 2025. On November 7, 2025, the Company filed a registration statement on Form S-3 (File No. 333-291388) (the "2025 Registration Statement") with the Securities and Exchange Commission to replace the 2022 Registration Statement.

The Company sold approximately 584,000 shares of its common stock pursuant to the Sales Agreement during the year ended December 31, 2025, and received aggregate net proceeds totaling $14.5 million.

Controlled Company Status

As a result of the shares issued and sold under the Sales Agreement in July 2025, the Company's largest stockholder, Agenus, which previously owned more than 50% of the voting power of the Company's common stock, owned less than 50% of the voting power of the Company's common stock as of July 2025. As a result, the Company no longer qualifies as a "Controlled Company" as defined in Nasdaq Rule 5615(a)(7).

(8) Share-based Compensation Plans

The Company's 2018 Equity Incentive Plan (the "2018 Plan") provided for the grant of incentive stock options intended to qualify under Section 422 of the IRC, nonstatutory stock options, restricted stock, unrestricted stock and other equity-based awards, such as

stock appreciation rights, and stock units including restricted stock units for up to approximately 1.4 million shares of the Company's common stock (subject to adjustment in the event of stock splits and other similar events). As of December 31, 2025, no shares remain available for issuance under the 2018 Plan.

In connection with the Company's initial public offering ("IPO"), MiNK's board of directors adopted the MiNK Therapeutics, Inc. 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Code, nonstatutory stock options, restricted stock, unrestricted stock and other equity-based awards, for an initial share pool of approximately 0.6 million shares of the Company's common stock (subject to adjustment in the event of stock splits and other similar events). The initial share pool automatically increases on January 1st of each year from 2022 to 2031 by the lesser of (i) four percent of the number of shares of the Company's common stock outstanding as of the close of business on the immediately preceding December 31st and (ii) the number of shares determined by the Company's board of directors on or prior to such date for such year. The 2021 Plan share pool increased by approximately 159,000 and 140,000 shares in January 2025 and 2024, respectively. As of December 31, 2025, there were approximately 1.2 million shares reserved for issuance under the 2021 Plan.

In connection with the Company's IPO, MiNK's board of directors adopted the MiNK Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides eligible employees the opportunity to acquire the Company's common stock in a program designed to comply with Section 423 of the Code. There are approximately 175,000 shares reserved for issuance under the ESPP, plus an automatic annual increase on January 1st of each year from 2022 to 2031 equal to the lesser of (i) one percent of the number of shares of the Company's common stock outstanding as of the close of business on the immediately preceding December 31st and (ii) the number of shares determined by the Company's board of directors on or prior to such date for such year, up to a maximum of approximately 0.4 million shares in the aggregate.

On June 18, 2025, at the Company's annual meeting of stockholders, the Company's stockholders approved a one-time exchange of options to purchase shares of the Company's common stock issued under the 2021 Plan and the 2018 Plan that were held by the Company's executive officers, other employees, consultants, and non-employee directors, for new options to purchase shares of the Company's common stock (the "Option Exchange"). Pursuant to the Option Exchange, eligible options were cancelled in exchange for an equal number of new options to purchase shares of common stock with an exercise price equal to the fair market value of the Company's common stock at the time of the Option Exchange and a term of the option that extends ten years from the date of grant. An eligible stock option generally included any outstanding stock option that had an exercise price equal to or greater than $8.50 per share and greater than the closing price of the Company's common stock on the date of the Option Exchange, that vested based on continued service with the Company or based on the achievement of performance milestones and that was granted under the Equity Plans. The Option Exchange resulted in the re-pricing of 647,915 options to an exercise price of $7.43. The vesting conditions of the modified options remained the same and the modified awards have a 10-year term. Total expected incremental share-based compensation expense resulting from the modification was approximately $0.6 million, of which $0.4 million related to vested awards and was recognized immediately with $0.2 million being recognized over the remaining vesting period.

The Company primarily uses the Black-Scholes option pricing model to value options granted to employees and non-employees, as well as options granted to members of the Company's Board of Directors. All stock option grants have 10-year terms, service conditions, and generally vest ratably over a 3 or 4-year period.

The fair value of each option granted during the period was estimated on the date of grant using the following weighted average assumptions:

	2025	2024
Expected volatility	107%	93%
Expected term in years	7	6
Risk-free interest rate	3.9%	4.3%
Dividend yield	0%	0%

The expected term of stock options granted is based on historical data and other factors and represents the period of time that stock options are expected to be outstanding prior to exercise. The risk-free interest rate is based on U.S. Treasury strips with maturities that match the expected term on the date of grant.

A summary of option activity for 2025 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2024	895,002	$ 17.70		
Granted	121,653	11.73		
Exercised	(96,885)	4.53		
Forfeited	(23,858)	13.37		
Expired	(19,380)	13.46		
Outstanding at December 31, 2025	876,533	$ 6.68	8.48	$ 3,998,143
Vested or expected to vest at December 31, 2025	876,533	$ 6.68	8.48	$ 3,998,143
Exercisable at December 31, 2025	666,835	$ 5.62	8.13	$ 3,690,877

The weighted average grant-date fair values of options granted during the years ended December 31, 2025 and 2024, was $10.04 and $6.86, respectively. During both 2025 and 2024, all options were granted with exercise prices equal to the market value of the underlying shares of common stock on the grant date except certain awards dated January 16, 2024. In January 2024, the Company's Board of Directors approved certain awards. However, the awards were not communicated to employees until May 2024. Accordingly, these awards have a grant date of May 2024, with an exercise price as of the date the Board of Directors approved the awards in January 2024.

The aggregate intrinsic value in the table above represents the difference between the Company's closing stock price on the last trading day of fiscal 2025 and the exercise price, multiplied by the number of in-the-money options that would have been received by the option holders had all option holders exercised their options on December 31, 2025 (the intrinsic value is considered to be zero if the exercise price is greater than the closing stock price). This amount changes based on the fair market value of the Company's stock. The total intrinsic value of options exercised during the year ended December 31, 2025, determined on the dates of exercise, was approximately $797,971.

As of December 31, 2025, there was $1.4 million of unrecognized share-based compensation expense related to stock options granted to employees, consultants and directors which, if all milestones are achieved on outstanding performance based awards, will be recognized over a weighted average period of 2.5 years. For awards with performance conditions, expense is recognized if the achievement of underlying performance conditions is deemed probable.

A summary of non-vested stock activity for 2025 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	80,646	$ 11.25
Granted	69,533	12.57
Vested	(71,480)	11.99
Forfeited	(833)	22.10
Outstanding at December 31, 2025	77,866	$ 11.63

As of December 31, 2025, there was $0.6 million of unrecognized share-based compensation expense related to these non-vested shares which will be recognized over a weighted average period of 2.8 years. The total intrinsic value of shares vested during the year ended December 31, 2025 was $801,257.

The Company issues new shares upon option exercises the vesting of non-vested stock and purchases under the ESPP. During the years ended December 31, 2025 and 2024, 96,885 shares and 7,423 shares, respectively, were issued as a result of stock option exercises. During the years ended December 31, 2025 and 2024, 36,068 shares and 30,173 shares, respectively, were issued as a result of the vesting of non-vested stock. During the years ended December 31, 2025 and 2024, 209 shares and 1,539 shares, respectively, were issued under the ESPP. Additionally, during the year ended December 31, 2025, 35,412 shares were issued as payment for

certain employee bonuses, with 11,286 of those shares being withheld to cover taxes, resulting in a net share issuance of 24,126 shares.

Stock based compensation expense also includes expense related to awards granted to employees of the Company from the Agenus 2019 Equity Incentive Plan. The impact on the Company's results of operations from share-based compensation for the year ended December 31, 2025 and 2024, was as follows (in thousands):

	2025	2024
Research and development	$ 339	$ 904
General and administrative	2,313	1,938
Total share-based compensation expense	$ 2,652	$ 2,842

(9) Research and Development Agreement

In December 2018, the Company entered into an agreement with the Belgium Walloon Region Government ("Walloon Region") in which the Walloon Region agreed to provide a grant of €1.3 million and a repayable advance of €8.3 million for the development of one of the Company's research programs. During 2020, the Company discontinued research efforts related to this program.

Other current liabilities of $2.5 million and $2.3 million, as of December 31, 2025 and 2024, respectively, represent the remaining amount of the advance received.

In 2022, the Company received notice that the Walloon Region had obtained a default judgment seeking repayment of approximately $2.5 million of the advance based upon the Company allegedly not providing required notification that research and operations in the region were discontinued.

(10) Related Party Transactions

Until the completion of its IPO, the Company relied on Agenus for all of its working capital requirements. For the periods presented, certain of the Company's operations were fully integrated with Agenus, including, but not limited to, corporate functions such as finance, human resources, information technology and legal functions. The Company's consolidated financial statements reflect all costs of doing business related to these operations.

In September 2021, the Company entered into an Intellectual Property Assignment and License Agreement with Agenus (the "New Assignment and License Agreement"), upon which the prior intercompany agreement between Agenus and MiNK was terminated. Pursuant to the New Assignment and License Agreement, Agenus assigned to the Company certain patent rights and know-how related to its iNKT cell platform, product candidates and other patents and know-how related to its business. In addition to the patent rights assigned to the Company by Agenus, the Company also received an exclusive, royalty-free, sublicensable license to research, develop, manufacture and commercialize certain licensed technology in the field. The New Assignment and License Agreement further provides for the Company to grant Agenus a field-limited, non-exclusive, royalty-free license under the assigned patent rights, subject to MiNK's discretion and provided such access would not reasonably result in a disruption of planned MiNK activities. Agenus has also agreed to provide the Company with Agenus' biological material upon written request in order for the Company to use such material in its development activities of a combination therapy. Agenus may withhold the transfer of biological material, including, but not limited to, checkpoint modulating antibodies, for various reasons, including if such transfer would reasonably result in a disruption of planned Agenus activities. For any materials Agenus does share with the Company, the parties have agreed to enter into a separate agreement governing the transfer and providing for joint ownership of the data. Agenus has agreed that during the full term of the New Assignment and License Agreement, and for three years thereafter, it will not develop, manufacture or commercialize an iNKT cell therapy, directly or indirectly by transferring such technology. The Company has the sole responsibility to develop, manufacture and commercialize products under this New Assignment and License Agreement. The Company may terminate the New Assignment and License Agreement without cause upon 90 days' prior written notice to Agenus. Either party may terminate if they believe there has been a material breach which has not been cured within 90 days (or 45 days for breach of payment obligations) of receiving such notice.

Effective April 1, 2022, the Company entered into an Amended and Restated Intercompany Services Agreement (the "New Intercompany Agreement") with Agenus, which amended and restated the Intercompany General & Administrative Agreement between the Company and Agenus dated September 10, 2021 (the "Prior Intercompany Agreement"). Under the New Intercompany Agreement, Agenus provides the Company with certain general and administrative support, including, without limitation, financial, facilities management, human resources and information technology administrative support (the "Agenus Services"), and the Company and Agenus provide each other with certain research and development services (the "R&D Services") and other support services, including legal and regulatory support (the "Shared Services"). The Company is required to pay 10% of Agenus' costs

related to the Agenus Services, and the costs of R&D Services are based upon pass-through costs related to such services plus an allocation of the costs of the employees performing the services. No payment will be due from either party for the Shared Services, provided that the services provided by each party are proportional in scope and volume. The Company is also entitled to use Agenus' business offices and laboratory space and equipment (inclusive of a cGMP site) in exchange for the Company contributing a proportionate payment for the use of such facilities and equipment, and the Company will be covered by certain Agenus insurance policies, subject to certain conditions, including the Company paying the cost of such coverage. Either party may terminate the New Intercompany Agreement upon 60 days' prior written notice and individual services upon 30 days' prior written notice.

Allocated Agenus services primarily include payroll related expenses, facility costs, insurance and stock-based compensation, and are included in the accompanying financial statements based on certain estimates and allocations described above. Under the Prior Intercompany Agreement, the allocation methods primarily included time devoted to activities and headcount-based allocations. Agenus business services and occupancy costs were allocated to the Company based on the Company's headcount as a percentage of Agenus' and the Company was required to pay 105% of Agenus' costs for these business services and occupancy costs. Research services were charged between the entities based on hours recorded by Agenus employees as time spent on specific projects, applied to hourly wage rates, and the Company paid 110% of Agenus' costs for these research services. As such, these allocations may not be indicative of the actual amounts that would have been recorded had the Company operated as an independent, publicly traded company for the periods presented.

Allocation of Agenus Services, net, of $0.9 and $1.1 million for the years ended December 31, 2025 and 2024, respectively, is included in Operating expenses in the Company's statement of operations and comprehensive loss and Due to related parties, of $15.4 million as of December 31, 2025, in the Company's consolidated balance sheet. Agenus has agreed to not require repayment of this balance for the foreseeable future. The payable does not carry a stated interest rate and the Company has determined that interest is not required to be imputed because the amount due is commensurate with the value of the services received.

On February 12, 2024, the Company and Agenus entered into a Convertible Promissory Note Purchase Agreement pursuant to which the Company issued to Agenus a convertible promissory note in the principal amount of up to $5.0 million. The Purchase Agreement sets forth the terms and conditions, including representations and warranties, for the Company's issuance and sale of the Note to Agenus.

The Note carries an annual rate of interest rate of 2% (the "Interest Rate") that accrues from the date funds are paid or advanced by Agenus to the Company. Interest shall accrue and not be payable until converted or paid in connection with the repayment in full of the principal amount of the Note. The Note provides that the Company will pay Agenus on demand the principal amount outstanding, together with any unpaid interest, on or after January 1, 2026. In the event of a qualified financing event, as defined in the Note, the outstanding principal amount of the Note plus accrued and unpaid interest shall, at Agenus' election, either be paid in full or converted into equity shares equal to the quotient obtained by dividing (i) the amount due on the date of conversion by (ii) 80% of the per share price of the equity securities sold in the qualified financing. Upon a change of control, the Company will pay Agenus an amount equal to (i) 1.5 times the principal then outstanding under the Note and (ii) the amount of accrued interest then outstanding immediately prior to the closing of such change of control.

In March 2024, MiNK received $5.0 million from Agenus and the Note was fully drawn. As of December 31, 2025, the Note had a principal balance of $5.0 million, an accrued and unpaid interest balance of $179,444 and an effective interest rate of 15.0%. In January 2026, the Note was repaid in full.

In January 2023, the Company's Chief Executive Officer ("CEO" or "Dr. Buell"), became an employee of Agenus in the role of Chairman of the Executive Council, and she was appointed to the Agenus Board of Directors in June 2024. As an employee of Agenus, Dr. Buell is paid $150,000 annually. In June 2024 Dr. Buell was granted an option to acquire 37,500 shares of Agenus common stock that vest over a period of three years, in November 2024 she was granted an option to acquire 300,000 shares of Agenus common stock that vest after one year, and in June 2025 Dr. Buell was granted an option to acquire 6,750 shares of Agenus common stock that vest over a period of three years. Dr. Buell receives no additional compensation as an Agenus board member.

Dr. Buell's spouse is a partner in the law firm of Wolf, Greenfield & Sachs, P.C. ("Wolf Greenfield"), which provided legal services to the Company during the years ended December 31, 2025 and 2024, and continues to do so. In the years ended December 31, 2025 and 2024, the Company expensed Wolf Greenfield fees totaling approximately $300,000 and $168,000, respectively. Dr. Buell's spouse does not receive direct compensation from the fees paid to Wolf Greenfield by the Company and the fees paid by the Company to Wolf Greenfield in the period were an insignificant amount of Wolf Greenfield's revenues. The Company's Audit and Finance Committee approved these services under its related-party transactions policy.

(11) Fair Value Measurement

The Company measures the Note at fair value. The fair value of the Note at December 31, 2025 was $5.0 million, using a scenario based present value methodology that was derived by evaluating the nature and terms of the Note and considering the prevailing economic and market conditions at the balance sheet date, some of which are considered Level 2 inputs under the fair value measurements standard. As of December 31, 2025 the Note had a principal balance of $5.0 million. The initial difference between the determined fair value at the issuance of the Note and the proceeds received was recorded as additional paid-in capital at the date of issuance. The subsequent difference between the fair value of the Note at issuance and the fair value of the Note as of December 31, 2025 was recorded in "Operating expenses" in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2025.

(12) Contingencies

The Company may currently be, or may become, a party to legal proceedings. While the Company currently believes that the ultimate outcome of any of these proceedings will not have a material adverse effect on its financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty.

(13) Benefit Plans

The Company's employees are eligible to participate in the Agenus Inc. 401(k) Savings Plan in the United States and a defined contribution Group Personal Pension Plan in the United Kingdom (the "Plans") for all eligible employees, as defined in the Plans. Participants may contribute a portion of their compensation, subject to a maximum annual amount, as established by the applicable taxing authority. Each participant is fully vested in his or her contributions and related earnings and losses. For the years ended December 31, 2025 and 2024, the Company expensed $93,000 and $156,000, respectively, related to the discretionary contribution to the Plans.

(14) Segments

MiNK is managed and operated as one business segment. The Company does not operate separate lines of business with respect to any of its product candidates or geographic locations. MiNK's single reportable segment is focused on the discovery, development and manufacturing of allogeneic, off-the-shelf, iNKT cell therapies to treat cancer and other immune-mediated diseases.

MiNK's CEO serves as its Chief Operating Decision Maker ("CODM") and is responsible for reviewing company performance and making decisions regarding resource allocation. The Company's CODM evaluates company performance based on net loss, as included in the Consolidated Statements of Operations and Comprehensive Loss, ensuring resource allocation decisions support company goals. The measure of segment assets is total assets, as included in the Consolidated Balance Sheets. Refer to the consolidated financial statements for other financial information regarding the Company's single reportable segment.

The following table presents selected financial information related to the Company's single reportable segment for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Operating expenses:		
External expenses	$ (4,456)	$ (2,452)
Payroll related expenses	(4,237)	(5,217)
Other operating expenses	(3,949)	(3,619)
Operating loss	(12,642)	(11,288)
Other income (expense):		
Interest expense	(110)	(93)
Interest income	290	265
Other income	(32)	331
Net loss	$ (12,494)	$ (10,785)

In the table above, "Other operating expenses" includes items such as the allocation of Agenus Services, depreciation and amortization expense, stock-based compensation expense, fair value adjustments and expenses related to certain foreign subsidiaries.

(15) Subsequent Events

In January 2026, in accordance with the terms of the Note agreement, the Company repaid Agenus approximately $5.2 million, representing the full principal and accrued interest balance of the Note.

During the period of January 1, 2026 through March 27, 2026, the Company sold approximately 193,000 shares of its common stock under the Sales Agreement, receiving net proceeds of approximately $3.0 million.

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

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were functioning effectively as of the end of the period covered by this Annual Report on Form 10-K to provide reasonable assurance that the Company can meet its disclosure obligations.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

As a non-accelerated filer and an emerging growth company, management's assessment of internal control over financial reporting was not subject to attestation by our independent registered public accounting firm.

Changes in Internal Control Over Financial Reporting

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

Item 9B. Other Information.

Trading Plans of Our Directors and Officers

During the quarter ended December 31, 2025, none of our directors or officers (as defined in Rule 16(a)-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" and/or "non-Rule 10b5-1 trading arrangement," as each item is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2025.

We have adopted a written code of conduct that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions. A current copy of the code is posted in the "Investor & Media" section of our website under "Corporate Governance," which is located at investor.minktherapeutics.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our code of conduct, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified in the preceding sentence. The information contained on our website is not incorporated by reference into this Form 10-K. We granted no waivers under our code of conduct in 2025.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) The consolidated financial statements are listed under Item 8 of this Annual Report on Form 10-K.

(2) The financial statement schedules required under this Item and Item 8 are omitted because they are not applicable, or the required information is shown in the consolidated financial statements or the footnotes thereto.

(3) Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40908) filed on October 20, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MiNK Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40908) filed on January 21, 2025).
3.3	Amended and Restated By-laws (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40908) filed on October 20, 2021).
4.1	Specimen stock certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
4.2	Form of Convertible Promissory Note by and between the Registrant and Agenus Inc., dated February 12, 2024 (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-40908) filed on March 21, 2024).
4.3	Description of Securities (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-40908) filed on March 18, 2022).
10.1	At Market Issuance Sales Agreement, dated as of July15, 2025, between MiNK Therapeutics, Inc. and B. Riley Securities, Inc. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K (File No. 001-40908) filed on July 15, 2025).
10.2	Intellectual Property Assignment and License Agreement, by and between Agenus Inc. and MiNK Therapeutics, Inc., dated September 10, 2021 (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503) filed on September 14, 2021).
10.3	Amended and Restated Intercompany Services Agreement, by and between Agenus Inc. and MiNK Therapeutics, Inc., dated August 2, 2022 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 (File No. 001-40908) filed on August 15, 2022).
10.4+	MiNK Therapeutics, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
10.5+	MiNK Therapeutics, Inc. 2021 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
10.6+	MiNK Therapeutics, Inc. 2021 Cash Incentive Plan (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
10.7+	Form of Restricted Stock Unit Agreement under the MiNK Therapeutics, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
10.8+	Form of Non-Statutory Stock Option Agreement under the MiNK Therapeutics, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
10.9+	Form of Incentive Stock Option Agreement under the MiNK Therapeutics, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).

10.10+	AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503) filed on September 14, 2021).
10.11+	Form of Restricted Stock Award Agreement under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503) filed on September 14, 2021).
10.12+	Form of Non-Qualified Stock Option Award Agreement for Employees under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503) filed on September 14, 2021).
10.13+	Form of Non-Qualified Stock Option Award Agreement for Non-Employees under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503) filed on September 14, 2021).
10.14+	Form of Incentive Stock Option Award Agreement under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503) filed on September 14, 2021).
10.15+	Form of Indemnification Agreement, to be entered into by and between the Registrant and each of its directors and officers (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-259503), as amended, filed on October 12, 2021).
10.16+	Executive Employment Agreement between the Registrant and Jennifer Buell, dated March 3, 2022 (Incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 (File No. 001-40908) filed on March 18, 2022).
10.17	Convertible Promissory Note Purchase Agreement by and between the Registrant and Agenus Inc., dated February 12, 2024 (Incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-40908) filed on March 21, 2024).
10.18	Stock Purchase Agreement, by and between MiNK Therapeutics, Inc. and the investor named therein, dated May 13, 2024 (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 (File No. 001-40908) filed on August 13, 2024).
19.1	Insider Trading Policy (Incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024 (File No. 001-40908) filed on March 18, 2025)
21.1*	Subsidiaries of MiNK Therapeutics, Inc.
23.1*	Consent of KPMG LLP, 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.
97.1	Policy for Recoupment of Executive Incentive Compensation in the Event of an Accounting Restatement (Incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023 (File No. 001-40908) filed on March 21, 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 With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan.

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, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

MiNK Therapeutics, Inc.

Date: March 31, 2026

By: /s/ Jennifer S. Buell, Ph.D.
Jennifer S. Buell, Ph.D.
President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Jennifer S. Buell, Ph.D. **Jennifer S. Buell, Ph.D.**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2026
/s/ Melissa Orilall **Melissa Orilall**	Principal Financial Officer	March 31, 2026
/s/ Austin Charette **Austin Charette**	Principal Accounting Officer	March 31, 2026
/s/ Garo H. Armen, Ph.D. **Garo H. Armen, Ph.D.**	Chairman of the Board of Directors	March 31, 2026
/s/ Peter Behner **Peter Behner**	Director	March 31, 2026
/s/ Brian Corvese **Brian Corvese**	Director	March 31, 2026
/s/ John Holcomb, M.D. **John Holcomb, M.D.**	Director	March 31, 2026
/s/ Barbara Ryan **Barbara Ryan**	Director	March 31, 2026
/s/ Ulf Wiinberg **Ulf Wiinberg**	Director	March 31, 2026