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, 2024

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 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

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

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

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

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

As of June 28, 2024, 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: $13.9 million.

The number of shares of Registrant's Common Stock outstanding as of March 13, 2025 was 3,966,392.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2025 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, 2024, are incorporated by reference into Part III of this Report.

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

Table of Contents

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. You can identify these forward-looking statements by the fact they use 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 in connection with any discussion of future operating or financial performance. Certain forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts. 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. These statements relate to, among other things, 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.

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.

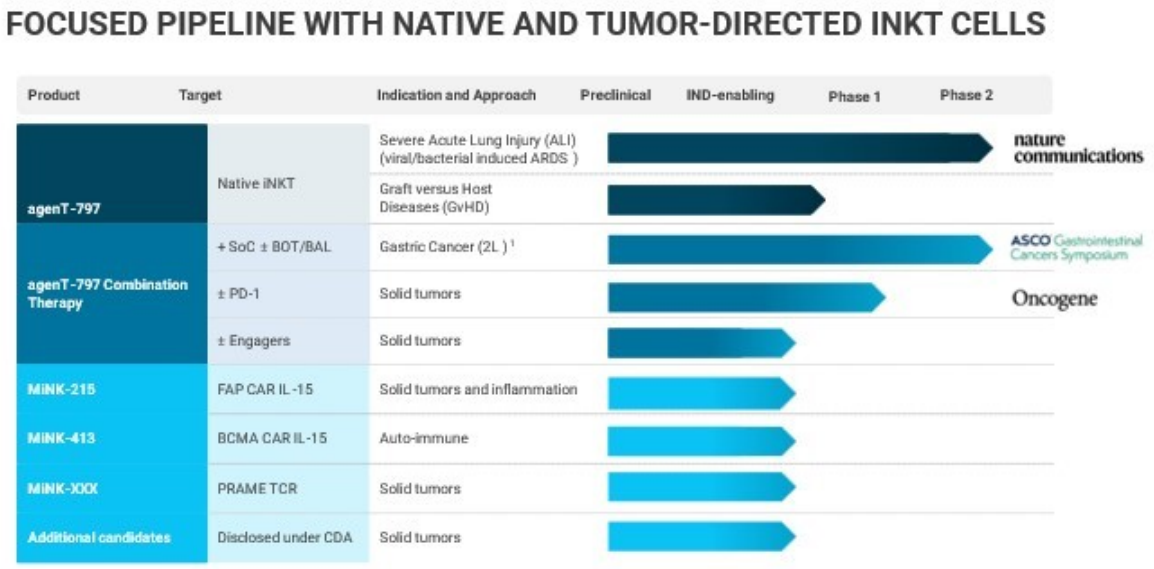
PART I

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. iNKT cells represent a distinct T cell population, combining durable memory responses with the rapid cytolytic capabilities of natural killer ("NK") cells. 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 to solid tumor cancers, acute respiratory distress (“ARDS”) and other severe immune-related diseases, such as 2L gastric cancer, and graft-versus-host disease ("GvHD"). Our discovery efforts are focused applying our proprietary technologies to build a broad pipeline of engineered iNKT cells, including TCRs, CAR-INKTS (such as, MiNK-215, FAP-CAR-iNKT and MiNK-413. BCMA-CAR-iNKT), and engager technology.

The following table summarizes our current product development pipeline:



[1]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. Our Phase 1 clinical trial has enrolled 34 patients and is evaluating agenT-797 in refractory solid tumor cancers, as a monotherapy and in combination with anti-PD-1 checkpoint inhibitors, pembrolizumab and nivolumab. Encouraging early activity was seen with agenT-797 monotherapy and combination, with reductions in target and non-target lesions and disease stabilization, which included a durable partial response in a PD-1 refractory gastric cancer patient. AgenT-797 also showed long-term persistence (detected in the periphery for up to 6 months), which was independent of human leukocyte antigen ("HLA") matching and in absence of lymphodepletion. These data were presented at Society of Immunotherapy for Cancer (“SITC”) in 2024. The data demonstrated agenT-797 alone or in combination with anti-PD-1 (nivo or pembro) elicited durable disease control in the majority of heavily pretreated patients. In addition, the presentation showed preclinical data of agenT-797 combined with bispecific engagers targeting antigens such as MUC16, HER2, Claudin 18.2, and DLL3. AgenT-797 promoted an increased T-cell activation, efficient tumor cell killing, and reduced exhaustion and myeloid cell activity. Further, a case study on the gastric cancer response was published in Oncogene in January 2024. Most recently, a Phase 2 investigator sponsored trial led by Dr. Yelena Janjigian at Memorial Sloan Kettering Cancer Center was launched and the first patient was dosed in February 2024. This study is evaluating the clinical safety and efficacy of the combination of agenT-797, Agenus Inc.'s ("Agenus") botensilimab (a novel fc-enhanced CTLA-4 inhibitor) plus balstilimab (anti-PD-1) with ramucirumab and paclitaxel for patients with previously treated, advanced esophageal, gastric, or gastro-esophageal junction ("GEJ") adenocarcinoma. The study aims to enroll around 38 patients with advanced, unresectable, or metastatic forms of these cancers who have experienced disease progression after initial treatment. A poster presentation at the American Society of Clinical Oncology Gastrointestinal Cancers ("ASCO GI") Symposium in January 2025 highlighted this study. Initial results are expected in 2025.

With the unique circumstances presented by the COVID-19 pandemic, we initiated a Phase 1 clinical trial evaluating agenT-797 for the treatment of moderate to severe viral acute respiratory distress syndrome (ARDS), a condition lacking approved therapies. The U.S. Food and Drug Administration ("FDA") has emphasized the importance of this indication, providing clear guidance on development approaches and specifying relevant patient populations. In a cohort of 21 mechanically ventilated patients, overall survival exceeded 70%, with an 80% survival rate observed specifically among patients (n=5) undergoing veno-venous extracorporeal membrane oxygenation ("VV ECMO"). These findings demonstrated a notable improvement compared to a 10% survival rate observed in the contemporaneous in-hospital control group. Comprehensive results from this study were published in Nature Communications in February 2024. Additionally, detailed clinical data highlighting translational and mechanistic insights from a complex severe ARDS case treated with agenT-797 were presented at the American Thoracic Society ("ATS") Annual Meeting in May 2024. Earlier data focused specifically on VV ECMO patients were also presented at the ATS Annual Meeting in 2023. Moving forward, we plan to advance agenT-797 for viral ARDS in an externally funded, large-scale platform trial.

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. Data were reported at the 2023 American Society of Gene and Cell Therapy Annual Meeting. At the American Association for Cancer Research ("AACR") 2024 Annual Meeting, MiNK 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.

We have achieved notable strides in the delivery of allogeneic iNKT cells, successfully treating nearly 100 patients across various immune-related diseases, including severe viral acute respiratory distress syndrome and solid tumor cancers. Moreover, our efforts have led to significant insights into the crucial mechanisms driving the activity of allo-iNKTs. With our vertically integrated capabilities and experienced leadership team, we remain fully dedicated to pioneering accessible and transformative cell therapy solutions to make a significant impact in the healthcare sector.

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:

- Advance agenT-797, native iNKT cells, in cancer, including solid tumors, as monotherapy and in combination with checkpoint antibodies.
- Validate broad applicability of iNKT cells through our opportunistic development of agenT-797 in severe viral acute respiratory distress syndrome, and other immune related diseases such as GvHD.
- Apply our proprietary technologies to build a broad pipeline of engineered iNKT cells, starting with MiNK-215, FAP-CAR-iNKT, with IND enabling activities actively underway.
- Continue to scale up our in-house manufacturing processes and build our capability to cost-efficiently optimize speed, control, flexibility and scalability.
- Selectively explore additional strategic partnerships that can enhance the potential of our iNKT cell product candidates and combination therapies. We appreciate that there may be significant potential over time to enhance the efficacy and addressable population of our products through combination of our iNKT cells with other classes of therapeutics. In October 2024, we entered into a research collaboration with Autonomous Therapeutics, aimed at effectively targeting and treating metastatic tumors. This collaboration will leverage Autonomous' precision encrypted RNA™ (encRNA) technology and MiNK's innovative iNKT cell therapies, MiNK-215 and agenT-797. The companies will evaluate these technologies in state-of-the-art metastatic solid tumor models. In December 2023, we entered into a collaboration agreement with Immunoscape to discover and develop next-generation T-cell receptor ("TCR") therapies against novel targets in solid tumors. The collaboration aims to accelerate the development of TCR-based therapies against novel targets in T cells, iNKT cells, and other modalities, potentially offering new therapeutic approaches for diverse cancer indications. In September 2021,we entered into an Intellectual Property Assignment and License Agreement with Agenus (the "Agenus License Agreement"), which provides us with access to Agenus therapeutic candidates and adjuvants for use in our development activities, subject to rights retained by Agenus. We continue to explore further potential collaborations with third parties, either to bring in access to products or expertise to advance the development and further differentiate of our pipeline. Furthermore, if therapeutics areas of interest reveal themselves beyond our core areas of focus we may look to partner with appropriately qualified partners.

Our Approach to Cell Therapy – iNKT Cells

Engineered CAR-T cells have revolutionized treatment for B-cell malignancies but face significant practical, logistical, and toxicity limitations, prompting interest in alternative immune cells like NK cells, γδ T cells, and macrophages. Our approach harnesses iNKT cells, a unique subset combining durable memory of adaptive immunity with rapid cytolytic features of innate immunity, offering advantages over conventional therapies.

Mechanistically, we have observed that agenT-797:

- Homes to tumors;
- Activates dendritic cells (signalers that help the immune system recognize tumor cells);
- Kills M2 macrophages (immunosuppressive cells that constrain the body's ability to fight tumors);
- Restores tumor killing capacity of exhausted T cells;
- Persists beyond our measurement period of 35 days;
- Are activated by CD1d, the key ligand for the invariant TCR, and by stress ligands for potent tumor killing;
- Can secrete a wide array of inflammatory cytokines to clear infections and tumors;
- Recruit and activate NK and T cells to regulate the immune response; and
- Dampen inflammatory donor T cell activity to naturally suppress 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 Features of iNKT Cells

Combine Features of Innate and Adaptive Immunity

iNKT cells uniquely combine TCR-mediated and NK-receptor-mediated mechanisms, enabling direct tumor targeting and powerful orchestration of the immune response within the TME. They directly eliminate immunosuppressive myeloid cells and activate NK and T cells, setting them apart from other innate lymphocytes.

Potent Anti-Tumor Activity

iNKT cells are primarily tissue-resident, ideal for homing in on solid tumors. They express an invariant TCR recognizing CD1d, a molecule widely expressed on tumors. This recognition enables rapid cytokine release and potent tumor-killing activity. Preclinical and clinical studies demonstrate iNKT cells' ability to home directly to tumors, target diverse ligands (CD1d, NKG2D), and effectively modify the TME.

Naturally Suited for Allogeneic Therapy

iNKT cells inherently suppress GvHD, eliminating the need for gene editing and reducing associated toxicity. Higher iNKT cell counts after hematopoietic stem cell transplantation correlate with decreased GvHD risk.

Enhanced Tolerability

iNKT cells' tissue-resident properties may enable better engraftment with reduced or no lymphodepletion, improving patient quality of life and maintaining a healthier immune system, vital for long-term cancer control.

Scalable and Efficient Manufacturing

Our proprietary process allows exponential expansion (>10,000-fold) of iNKT cells while preserving their full functional capabilities, immunomodulatory effects, and metabolic fitness, providing a scalable therapeutic solution.

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. 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, offering powerful tumor-killing properties of NK cells combined with durable memory capabilities of T cells, along with the ability 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: Established the safety, tolerability, and immune-modulatory effects of allogeneic iNKT cells in various cancer types and ARDS.

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 produces 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 cGMP manufacturing process ensures 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

agenT-797, our allogeneic, native iNKT cell therapy, is our most advanced product candidate and is currently in clinical development across multiple different trials and indications, constituting a pipeline within a single product. 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 – ARDS Secondary to Infectious Disease (i.e. COVID-19, Influenza)

In preclinical models, iNKT cells have been shown to promote viral clearance and increase secondary anti-viral responses, offering the potential to control inflammation and limit lung tissue damage resulting from ARDS secondary to infectious disease in humans. We completed a Phase 1/2 clinical trial of agenT-797 for the treatment of ARDS secondary to COVID-19, which was initiated during the height of the COVID-19 pandemic, and we subsequently expanded the trial to investigate viral ARDS secondary to other life-threatening infectious diseases, such as influenza In a cohort of 21 patients with mechanical ventilation, the survival rates from this study exceeded 70%, with a 80% survival rate among those patients (5) on VV ECMO. These data compared favorably to the 10% survival rate in the in-hospital control group at the same time. In addition to survival benefit, we demonstrated that we can dose the cells to 1x109 cells/dose with no related cytokine release syndrome or neurotoxicity and importantly, observed signals that the cells may prevent secondary infections.

agenT-797 – GvHD

iNKT cells have the potential to provide the following benefits in relation to GvHD: (1) promoting engraftment success; (2) mitigating or suppressing GvHD; and (3) promoting durable responses in patients with cancer. Our near-term plans are to advance the administration of allogeneic iNKT cells in patients undergoing HSCT to enable a successful engraftment and prevention/suppression of acute GvHD. HSCT is a well-established treatment for more than 50,000 adults and children with malignancies, autoimmune conditions and other serious diseases. The most common life-threatening complication, which occurs in approximately 50% of HSCTs, is graft failure and GvHD driven by immunocompetent T cells in the graft recognizing host tissues. Current pre-conditioning

therapies such as cytotoxic chemotherapies produce inferior responses in patients over 65 years old. Furthermore, failure to engraft and downstream GvHD are associated with cancer recurrence or death.

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 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. We have entered into a collaboration agreement with Immunoscape to discover and develop next-generation TCR therapies against novel targets in solid tumors.

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 and greatly de-risk 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 reduces hands-on time and optimizes personnel usage and facility qualification and validation processes. Our proprietary reagents and process 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, 2024, we own three issued U.S. patents and 15 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 two 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 two 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 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 an applicant for marketing approval 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, and particularly the immuno-oncology field, is characterized by rapidly advancing and changing technologies with intense competition. Cell therapy is one of the most active areas for the discovery and clinical development of new anti-cancer therapies. It involves the delivery of immune cells to the site of the tumor to mediate killing. We face substantial competition from many different entities, including large pharmaceutical companies, small and midsize biotechnology companies, and academic research institutions. These competitors are focused on engineering multiple immune cell types including NK cells, αb T cells and gd T cells, in addition to iNKT cells. These products are both autologous and allogeneic (i.e., derived from a healthy donor) in nature and are unmodified or genetically engineered to target ligands with CARs or TCRs. Several companies are also using induced pluripotent stem cells as an allogeneic cell source, which could theoretically have enhanced scalability. Other modalities such as bispecific antibodies, antibody drug conjugates, as well as novel immuno-oncology antibodies, are also capable of enabling infiltration of immune cells to the site of the tumor. For example, many bispecific approaches simultaneously bind one immune cell antigen and one tumor cell antigen, thereby redirecting a patient's endogenous NK or T cells to the site of a tumor.

Key competitor companies developing autologous CAR-T or TCR cell therapies include, but are not limited to, Bristol-Myers Squibb Company (Celgene/Juno Therapeutics), Gilead Sciences, Inc. (Kite Pharma), Johnson & Johnson, Novartis AG, AstraZeneca and BioNTech.

Key competitors developing iNKT cell therapies include Arovella Therapeutics (previously known as Suda Pharmaceuticals), Appia Bio, Inc., Brightpath Biotherapeutics and Ambicion Co. We are also aware of competitors advancing glycolipid formulations or small molecules designed to activate endogenous iNKT cells, including Portage Biotech LLC, Abivax SA and Gri Bio.

Key competitors developing allogeneic T cell therapies include, but are not limited to, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Cellectis S.A., Celyad Oncology SA, CRISPR Therapeutics AG, Poseida Therapeutics, Inc. and Precision BioSciences, Inc.

Key competitors in the NK cell therapy space include, but are not limited to, Celularity, Inc, Fate Therapeutics, Inc., Gamida Cell, Glycostem Therapeutics B.V., Nkarta, Inc., Artiva Biotherapeutics, Sanofi and Takeda Pharmaceutical Company Limited.

Other key competitors in the gd T cell therapy space include, but are not limited to, Adicet Bio, Inc., GammaDelta Therapeutics Limited, In8bio, Inc. and TC BioPharm Limited.

Many of our competitors have initiated clinical trials for solid tumors, hematological malignancies and autoimmune indications, 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. Competitors may compete with us in hiring scientific and management personnel, establishing clinical trial sites, recruiting patients for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Many of our current or potential competitors have significantly greater financial, technical, and human resources, as well as more expertise in research and development, manufacturing, conducting clinical trials and commercializing and marketing approved products. Early-stage companies may also prove to be significant competitors, either alone or through collaborative arrangements with large established companies. Our commercial opportunity could be reduced if our competitors develop and commercialize products that are safer, more effective, more convenient or less expensive. Our competitors also may obtain regulatory approval more rapidly than we may obtain approval for ours, which could result in them establishing a dominant market position.

Human Capital Resources and Employees

As of February 28, 2025, we had 23 full-time employees, 52% 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.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties. 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.
- Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and its financial condition and results of operations.
- 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 regulatory approval for it.
- Allogeneic iNKT cells represent a novel approaches to immunotherapy, which may result in significant challenges to the development, regulatory 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 regulatory approval.
- Serious adverse events, undesirable side effects or unexpected characteristics caused by our product candidates could delay or prevent regulatory 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.
- We may not be able to submit INDs or the foreign equivalent to commence additional clinical trials for cell therapies on the timeframes we expect.
- 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 regulatory 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.

Risks Related to Our Relationship with Agenus

- We may experience difficulty in separating our resources from Agenus.
- Agenus owns a majority 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.

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.

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 $10.8 million and $22.5 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $144.2 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.

We have initiated three Phase 1 clinical trials for our lead product candidate, agenT-797, 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 medicine or medicines 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 medicines 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 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, 2024, our cash balance was $4.6 million. We expect that our cash as of December 31, 2024, plus anticipated funding from corporate transactions, 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 and have operated as a majority-owned subsidiary of Agenus since that time. 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 three Phase 1 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 clinical trials, including large-scale, pivotal clinical trials; obtain marketing approvals; manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf; or conduct sales and marketing activities necessary for successful commercialization. It takes many years to develop a new medicine 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.

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

We regularly maintain cash balances at third-party financial institutions, such as Silicon Valley Bank ("SVB"), in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limit. In March 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. Although all depositors of SVB retained access to all of their money, including funds held in uninsured deposit accounts, if another depository institution that holds our cash or cash equivalents is subject to other adverse conditions in the financial or credit markets, it could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

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 regulatory approval for it.

We cannot guarantee that agenT-797 will be safe and effective, 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, regulatory approvals and cGMP manufacturing, we have not previously completed any clinical trials or submitted a BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that agenT-797 will be successful in clinical trials or receive regulatory approval. The FDA and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize agenT-797 and materially adversely affect our business, financial condition, results of operations and growth prospects.

Furthermore, because agenT-797 is our most advanced product candidate and our only product candidate in a clinical trial, 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.

We intend to develop our product candidates both as monotherapy and potentially as combination therapy, a common form of cancer treatment, with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the combination therapy used with our

product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with any product candidate we develop for our combination therapy, we may be unable to obtain approval of or market our product candidates.

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 an 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 products 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 regulatory 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.

We are very early in our development efforts and only have one product candidate in early stage clinical development. It will be many years before we commercialize a product candidate, if ever.

We are very early in our development efforts. Our future success depends heavily on the successful development of our product candidates. Currently, with the exception of agenT-797, which is in three Phase 1 clinical trials, all of our other product candidates are in preclinical development or in discovery. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product and we may never be able to develop or commercialize a marketable product.

Commercialization of our product candidates will require additional preclinical and/or clinical development; regulatory and marketing approval in multiple jurisdictions, including by the FDA and the European Medicines Agency (“EMA”); obtaining manufacturing

supply, capacity and expertise; building of a commercial organization; and significant marketing efforts. The success of product candidates we may identify and develop will depend on many factors, including the following:

- sufficiency of our financial and other resources to complete the necessary preclinical studies, IND-enabling studies and clinical trials;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers for clinical supply and commercial manufacturing and, where applicable, commercial manufacturing capabilities;
- successful development of our internal manufacturing processes and transfer to larger-scale facilities operated by either a contract manufacturing organization ("CMO") or by us;
- obtaining and maintaining patent, trade secret and other intellectual property protection and non-patent exclusivity for our medicines;
- launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile of the medicines following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- supplying the products at a price that is acceptable to the pricing or reimbursement authorities in different countries.

If we do not successfully achieve one or more of these activities in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we may develop, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Our business is highly dependent on our iNKT cell platform, and our product candidates will require significant additional testing before we can seek regulatory approval. We may not be successful in our efforts to identify and develop additional product candidates. Additional product candidates include, but are not limited to, iNKT cell products genetically engineered to express CARs and other modifications that are designed to enhance safety and efficacy. They may also include combinations with other drug substances such as small molecules and immuno-oncology antibodies. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates based on our iNKT cell platform. All of our product development programs are still in clinical research or in the preclinical stage of development. The process for obtaining marketing approval for any candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval, if at all.

There is no guarantee that the results obtained in current Phase 1 and anticipated clinical trials for agenT-797 will be sufficient for us to plan one or more pivotal clinical trials and obtain regulatory approval or marketing authorization, or that preclinical development of our other product candidates or agenT-797 in other indications will be successful.

Our research programs may also fail to identify additional potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates may be shown to have harmful side effects in preclinical *in vitro* experiments or animal model studies, they may not show promising signals of therapeutic effect in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable or unlikely to receive marketing approval. In addition, although we believe our iNKT cell platform will allow us to expand our portfolio of product candidates beyond our current product candidates, we have not yet successfully developed any product candidate and our ability to expand our portfolio may never materialize.

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

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 regulatory approval of the product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

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 prove 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, there have been no observations of 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.

If in the future we are unable to demonstrate that any of the above adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we may develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations and prospects significantly.

Additionally, if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a 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 other cell therapies, including autologous CAR-T cell therapies. 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 conduct additional clinical trials;
- 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.

The data produced in our clinical trials of agenT-797 is at an early stage and future data may not show responses in patients treated or support continued development. In addition, the results ultimately obtained from our preclinical studies or other clinical trials for agenT-797 or any of our other product candidates may not be predictive of future results.

In February 2024, we published data from our clinical trial for ARDS secondary to COVID-19; such interim data, and any future interim data from clinical trials that we may conduct, including the clinical trials for agenT-797 for the treatment of cancer and, potentially, other life-threatening infectious diseases, are 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. We cannot provide any assurance that additional data will be provided frequently or that data updates will be available at any particular time. Furthermore, while patients with who have

been treated with our product candidates may have a positive response, there can be no assurance that their progress or recovery will be sustained.

Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. Negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

In addition, the results of any preclinical studies of agenT-797 or for our other product candidates may not be predictive of the results of clinical trials. For example, preclinical models as applied to cell therapy in oncology do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks and may not provide adequate guidance as to appropriate dose or administration regimen of a given therapy.

We may not be able to submit INDs or the foreign equivalent outside of the United States to commence additional clinical trials for cell therapies on the timeframes we expect, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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 medicines for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA 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, the EMA 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 medicine 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 medicines;
- 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 medicines 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 medicines 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 regulatory 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 regulatory 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 regulatory 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.

The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. Some countries require approval of the sale price of a medicine 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 medicine in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine 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 medicines successfully also will depend in part on the extent to which reimbursement for these medicines 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 medicine 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.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, the EMA 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 medicine 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 medicines, 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 medicine 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 medicines 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 medicines from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize any medicines we may develop, and our overall financial condition.

If we are unable to successfully identify patients who are likely to benefit from therapy with any product candidates we develop, or experience significant delays in doing so, we may not realize the full commercial potential of any medicines we may develop.

Our success may depend, in part, on our ability to identify patients who are likely to benefit from therapy with any medicines we may develop. If we, or any third parties that we engage to assist us, are unable to successfully identify such patients, or experience delays in doing so, then:

- our ability to develop any product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and
- we may not realize the full commercial potential of any product candidates we develop that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines.

Any product candidates we develop may require use of a companion diagnostic to identify patients who are likely to benefit from therapy. If safe and effective use of any of the product candidates we may develop depends on a companion diagnostic, we may not receive marketing approval, or marketing approval may be delayed, if we are unable to or are delayed in developing, identifying or obtaining regulatory approval or clearance for the companion diagnostic product for use with our product candidate. Identifying a manufacturer of the companion diagnostic and entering into an agreement with the manufacturer could also delay the development of our product candidates.

As a result of these factors, we may be unable to successfully develop and realize the commercial potential of any product candidates we may identify and develop, and our business, financial condition, results of operations and prospects would be materially adversely affected.

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

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

In addition, the FDA, the EMA 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, the EMA 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

If our ongoing clinical trials of agenT-797 or any of our future trials fail to demonstrate safety and efficacy to our satisfaction and the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

We and our collaborators, if any, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates we may identify and develop, including:

- delays in reaching a consensus with regulators on trial design;
- regulators, institutional review boards (“IRBs”), or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching or failing to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations ("CROs") and clinical trial sites;
- clinical trials of any product candidates we may develop may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development or research programs;
- difficulty in designing well-controlled clinical trials due to ethical considerations which may render it inappropriate to conduct a trial with a control arm that can be effectively compared to a treatment arm;
- difficulty in designing clinical trials and selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the number of patients required for clinical trials of any product candidates we may develop may be larger than we anticipate, enrollment of suitable participants in these clinical trials may be delayed or slower than we anticipate or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs or independent ethics committees may require that we or our investigators suspend or terminate clinical research or clinical trials of any product candidates we may develop for various reasons, including noncompliance with regulatory requirements, a finding of undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks or after an inspection of our clinical trial operations or trial sites;
- the cost of clinical trials of any product candidates we may develop may be greater than we anticipate;
- the supply or quality of any product candidates we may develop or other materials necessary to conduct clinical trials of any product candidates we may develop may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of any product candidates we may develop to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with any product candidates we may develop that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, or additional administrative burdens associated with foreign regulatory schemes; or
- failure of ourselves or any third-party manufacturers, contractors or suppliers to comply with regulatory requirements, maintain adequate quality controls or be able to provide sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates.

If we experience delays in the initiation, enrollment or completion of any preclinical study or clinical trial of our product candidates, or if any preclinical studies or clinical trials of our product candidates are canceled, the commercial prospects of our product candidates may be materially adversely affected, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs and slow down our product candidate development and approval process.

If we or our collaborators are required to conduct additional clinical trials or other testing of any product candidates we may develop beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of any product candidates we may develop, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

- be delayed in obtaining marketing approval for any such product candidates we may develop or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a REMS or through modification to an existing REMS;
- be sued; or
- experience damage to our reputation.

Product development costs will also increase if we or our collaborators experience delays in clinical trials or other testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates we may develop, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize any product candidates we may develop, any of which may harm 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 regulatory 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, the EMA 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 regulatory approval of any product candidates we may develop may be delayed. Moreover, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as any product candidates we may develop, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

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.

As COVID-19 vaccination rates have increased in the general population, fewer patients have been hospitalized with ARDS secondary to COVID-19, which has slowed our ability to enroll patients in our clinical trial for ARDS secondary to COVID-19. We are preparing a protocol to expand this trial to include ARDS secondary to other life-threatening infectious diseases, including influenza.

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.

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 regulatory 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 and the EMA. 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, the EMA 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, the EMA 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 regulatory 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.

Even if we complete the necessary trials for agenT-797 or any other product candidates we may develop, the marketing approval process is expensive, time-consuming and uncertain. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Any product candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, import, export and distribution, are subject to comprehensive regulation by the FDA, the EMA and other regulatory authorities in the United States and by comparable authorities in other countries or jurisdictions. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biological product candidate's safety, purity and potency. Securing regulatory approval also requires the submission of extensive information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Regulatory authorities may also approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. Regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments as described above, which could render the approved medicine not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed and our ability to generate revenues will be materially impaired.

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 regulatory 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 medicines in any jurisdiction, which would materially impair our ability to generate revenue.

Even if we, or any collaborators we may have, obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our product candidates could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our product candidates, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, facility registration and drug listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition and prospects.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

The FDA, the EMA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, the EMA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we market our medicines for off-label use, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the FDCA and other statutes, including the False Claims Act, and equivalent legislation in other countries relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state and other countries' health care fraud and abuse laws and state consumer protection laws. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

In addition, later discovery of previously unknown problems with our medicines, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various negative consequences, including:

- restrictions on such medicines, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution or disgorgement of profits or revenue;
- restrictions on future procurements with governmental authorities;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;

- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we may develop and adversely affect our business, financial condition, results of operations and prospects.

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.

Certain federal and state healthcare laws and regulations pertaining to product promotion, fraud and abuse, privacy and price reporting and payment constrain the activities of pharmaceutical companies and their interactions with healthcare providers, third-party payors and patients. Those laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called “federal sunshine” law under the Healthcare Reform Act, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services within the U.S. Department of Health and Human Services for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback, anti-bribery and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws also require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

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.

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 we may develop and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been and continue to be ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of any product candidates that we may develop, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Although we cannot predict what healthcare or other reform efforts will be successful, such efforts may result in more rigorous coverage criteria, in additional downward pressure on the price that we, or our future collaborators, may receive for any approved products or in other consequences that may adversely affect our ability to achieve or maintain profitability.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the Healthcare Reform Act and the ongoing efforts to modify or repeal that legislation, as well as to implement new reforms. The Healthcare Reform Act substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. There are, and may continue to be judicial challenges to the various reform efforts. We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

Federal and state governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, waivers from Medicaid drug rebate law requirements, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The private sector has also sought to control healthcare costs by limiting coverage or reimbursement or requiring discounts and rebates on products. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-containment measures could significantly decrease the available coverage and the price we might establish for our potential products, which would have an adverse effect on our net revenues and operating results.

We may seek fast track, breakthrough or regenerative medicine advanced therapy designation by the FDA for product candidates but may be unable to obtain such designations. Even if such a designation is granted, it may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval.

FDA's fast track, breakthrough and regenerative medicine advanced therapy ("RMAT") programs are intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA fast track designation. A product candidate may be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A product candidate may receive RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. While we may seek fast track, breakthrough and/or RMAT designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track, breakthrough or RMAT designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw fast track, breakthrough

or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track, breakthrough and/or RMAT designation alone do not guarantee qualification for the FDA's priority review procedures.

We may seek priority review designation by the FDA, but we may not be able to obtain such designation and, even if obtained, priority review may not lead to a faster regulatory review or approval process and, in any event, would not assure FDA approval of any product candidates we may develop.

If the FDA determines that a product candidate is intended to treat a serious disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of such disease or condition, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review a marketing application is six months from filing of the application, rather than the standard review period of ten months. We may request priority review for certain of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may disagree and decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

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 or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan product candidates by the EMA in the European Union. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for another product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

The FDA's standards for granting orphan drug exclusivity in the cell-based immunotherapies context are unclear and evolving. In order for the FDA to grant orphan drug exclusivity to one of our product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease 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 candidate available for the disease or condition will be recovered from sales of the product in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product candidate for the same condition if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA's policies related to orphan drug exclusivity, including for adoptive cell therapies, are subject to ongoing evaluation. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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, the EMA 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, the EMA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter 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, and our clinical trials or regulatory approvals could be suspended, 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.

In addition, we may be subject to privacy and security laws in the various 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. The July 2020 invalidation by the Court of Justice of the European Union of the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States, has led to increased scrutiny on data transfers from the EEA to the United States generally and may increase our costs of compliance with data privacy legislation. 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. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. 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 and Cambridge, UK facilities 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 majority of our common stock and will be able to exert control over specific matters subject to stockholder approval.

Agenus beneficially owns approximately 55% of our outstanding common stock. Therefore, Agenus has the ability to substantially influence us through this ownership position. For example, Agenus may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. 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 controlling stockholder for an extended period of time or indefinitely. Even if Agenus were to control less than a majority of the voting power of our outstanding common stock, it may be able to influence the outcome of our corporate actions so long as it owns a significant portion of our common stock.

We are a "controlled company" within the meaning of the applicable rules of Nasdaq and, as a result, qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Agenus controls a majority of the voting power of our outstanding common stock. As a result, we are a "controlled company" within the meaning of the Nasdaq corporate governance requirements. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the board of directors consists of independent directors;
- for an annual performance evaluation of the nominating and corporate governance and compensation committees;
- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We use these exemptions and may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements.

If Agenus sells a controlling interest in our company to a third party in a private transaction, you may not realize a change of control premium on shares of our common stock, and we may become subject to the control of a presently unknown third party. In

addition, Agenus may 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 in a privately negotiated transaction, which, if sufficient in size, could result in a change of control of our company.

Agenus' ability to sell its shares of our common stock privately, with no requirement for a concurrent offer to be made to acquire your shares of our common stock, could prevent you from realizing any change of control premium on your shares of our common stock that may otherwise accrue to Agenus on its private sale of our common stock. Additionally, if Agenus privately sells its significant equity interest in our company, we may become subject to the control 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 controlling 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. Such sales may not be subject to the volume, manner of sale, holding period and other limitations of Rule 144 and, therefore, 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. 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.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials for agenT-797 is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA, EMA and other regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. In the United States, we also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If third-party investigators do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by third parties, we could be required to repeat, extend the duration of or increase the size of any preclinical studies or clinical trials we conduct and this could significantly delay commercialization and require greater expenditures.

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 medicines 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.

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

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations and prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture any product candidates we may develop, we may incur added costs and delays in identifying and qualifying any such replacement.

If we utilize third parties to manufacture any product candidates or medicines we may develop, it may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

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 regulatory 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, the EMA 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 regulatory 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 may 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 regulatory 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.

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.

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.

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, only became effective in March 2013. 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. Generally, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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.

Our internal computer systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure, accident and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our proprietary information or other disruptions. For example, the loss of clinical trial data from ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

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. 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 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.

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.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. We also plan to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act of 2002 (“SOX Section 404”), which will require annual management assessment of the effectiveness of our internal control over financial reporting. While we continue to outsource our finance and accounting personnel, we have begun recruiting additional finance and accounting personnel with certain skill sets that we need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors’ perceptions that our

internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our common stock price.

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. 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, 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. 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.

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.

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 amended and restated by-laws also provide 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 regulatory 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 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 are currently evaluating 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.

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, New York, NY and Cambridge, United Kingdom. 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, 2025, there were approximately 161 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.

Overview

MiNK Therapeutics, Inc. ("we," "us," "our," or "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 ("NK") 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 ("GvHD"). Our proprietary platform is designed to facilitate scalable and reproducible manufacturing for off-the-shelf delivery. As such, we believe that our approach represents a highly versatile application for therapeutic development in cancer and immune diseases. We are leveraging our platform and manufacturing capabilities to develop a wholly owned or exclusively licensed pipeline of both native and engineered iNKT cells.

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 and an Intellectual Property Assignment and License Agreement with Agenus Inc. ("Agenus"). Under the Amended and Restated Intercompany Services 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. iNKTs are a potent class of immune cells and serve as master regulators of immune response, possessing the killing power of NK cells and the memory of T-cells. Our proprietary manufacturing platform enables the infusion of these cells in billion-fold quantities, equipping the immune system to combat cancer and other life-threatening diseases. We have successfully established and launched in-house iNKT cell manufacturing and product release capacity, capable of supplying over 5,000 doses annually through a U.S. Food and Drug Administration ("FDA")-cleared, scalable, fully closed, and automated process.

Our clinical development of agenT-797 is advancing in multiple therapeutic areas of significant unmet needs. These include a Phase 2 trial in 2L gastric cancer and viral acute respiratory distress syndrome ("ARDS") in populations of patients where there are critical gaps in current treatment options.

In solid cancers, we completed a Phase 1 clinical trial of agenT-797 in solid tumor cancers, both as a monotherapy and in combination with anti-PD-1 checkpoint inhibitors pembrolizumab and nivolumab. The trial demonstrated durable clinical benefits with a tolerable safety profile across various heavily pre-treated solid tumors, including non-small cell lung cancer ("NSCLC"), testicular cancer, and gastric cancer. Notably, the median progression-free survival exceeded six months, with approximately 30% of patients experiencing durable disease stabilization, even in cancers refractory to prior therapies such as pembrolizumab and nivolumab. Building on these results, a randomized, Phase 2 investigator-sponsored trial led by Dr. Yelena Janjigian at Memorial Sloan Kettering Cancer Center is actively enrolling. This trial aims to evaluate the clinical safety and efficacy of the combination of agenT-797, botensilimab (a novel Fc-enhanced CTLA-4 inhibitor), balstilimab (anti-PD-1), ramucirumab, and paclitaxel in patients with previously treated, advanced esophageal, gastric, or gastroesophageal junction adenocarcinoma. The study, which is expected to enroll approximately 38 patients with advanced, unresectable, or metastatic forms of these cancers, is a priority program for us. Encouraging activity was observed with agenT-797 in both monotherapy and combination settings, with durable responses and disease stabilization, as presented at the American Association for Cancer Research ("AACR") and more recently at the Society for Immunotherapy of Cancer ("SITC") conference in November 2023.

In inflammatory diseases, we have completed a phase 1 study of agenT-797 in viral ARDS, leveraging the unique anti-inflammatory properties of iNKT cells. Results from our Phase 1 study were published in Nature Communications and presented at the American Thoracic Society International Conference over the past two years. We reported an encouraging survival benefit of 75%, compared to approximately 10-22% in an in-hospital control group and time-matched data from the Centers for Disease Control and Prevention. In a cohort of 21 patients on mechanical ventilation, survival rates exceeded 70%, with an 80% survival rate among those on venovenous extracorporeal membrane oxygenation. In addition to a survival benefit, agenT-797 improved lung function and significantly reduced

inflammation and secondary infections, which are major contributors to comorbidity and mortality in intensive care units. Given the lack of approved therapies for ARDS, we plan to advance agenT-797 in viral ARDS through strategic collaborations and non-dilutive external financing into a randomized Phase 2 trial.

Our pipeline is advancing next-generation allogeneic, engineered iNKT programs. Our two most advanced engineered programs are (1) MiNK-215, an IL-15 armored tumor stromal targeting FAP-CAR-iNKT and (2) MiNK-413, an IL-15 armored CAR-iNKT program targeting BCMA 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 has demonstrated efficacy in NSCLC and melanoma preclinical models, promoting curative responses, eliminating tumor burden in the lungs, and enhancing tumor specific CD8+ T cell infiltration through tumor stroma. These data and programs were presented at AACR in 2024, International Cancer Immunotherapy Conference in 2023, SITC in 2023, and the American Society of Cell and Gene Therapy in 2023. Most recently, preclinical data from MiNK-215 in microsatellite stability colorectal cancer liver metastases were presented at AACR 2024. This presentation highlighted MiNK-215's potent anti-tumor activity, immune activation, and tumor stroma remodeling against this difficult-to-treat solid tumor setting. Investigational new drug ("IND") enabling activities are underway we expect to submit an IND to the FDA in 2025.

In December 2023, we announced a collaboration with ImmunoScape, Inc. ("ImmunoScape") to discover and develop next-generation T-cell receptor therapies against novel targets in solid tumors. We will combine our unique, proprietary library of T cell antigens with ImmunoScape's platform for rapid discovery of novel T cell receptors. ImmunoScape's unique Deep Immunomics platform enables high-throughput and sensitive screening of T cells against relevant tumor targets for the rapid discovery of rare, therapeutically-relevant T-cell receptors ("TCRs"). We have a proprietary library of phospho-peptide neoantigens derived from a wide range of solid tumors and hematologic malignancies. In this collaborative effort, ImmunoScape will leverage its capabilities in multiplex antigen screening and in-depth T cell profiling to identify relevant TCRs targeting the library of phospho-peptide antigens. We will further characterize these tumor-specific TCRs, leveraging our proprietary capabilities to analyze and select TCR candidates for optimal tumor targeting. Any intellectual property resulting from the arrangement would be jointly owned by the parties.

Our research and development expenses for the years ended December 31, 2024 and 2023 were $6.3 million and $15.5 million, respectively. We have incurred losses since our inception. As of December 31, 2024, we had an accumulated deficit of $144.2 million.

Historical Results of Operations

For the Year Ended December 31, 2024 Compared to the Year Ended December 31, 2023

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 59% to $6.3 million for the year ended December 31, 2024 from $15.5 million for the year ended December 31, 2023. This decrease is primarily due to a $1.8 million gain recorded from the forgiveness of certain previously recorded liabilities in 2024, decreased costs associated with both the timing of our clinical trials and pre-clinical activities, and 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 decreased 42% to $4.3 million for the year ended December 31, 2024 from $7.4 million for the year ended December 31, 2023. This decrease is primarily due to decreased personnel costs, mainly due to decreased share based compensation expense and decreased headcount.

Other income (expense), net

Other income increased $0.3 million for the year ended December 31, 2024, from de minimis expense for the year ended December 31, 2023 to income of $0.3 million for the year ended December 31, 2024, due primarily 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 decreased $291,000 for the year ended December 31, 2024, from income of $463,000 for the year ended December 31, 2023 to income of $173,000 for the year ended December 31, 2024, primarily due to decreased interest earned on our money market funds and interest expense accrued under 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, 2024	2023
Payroll and personnel costs	$ 4,634,647	$ 6,814,210
Professional fees	1,353,448	5,283,439
Forgiveness of liability	(1,788,204)	—
Allocated services	517,861	500,280
Materials and other	1,618,323	2,892,068
Total	$ 6,336,075	$ 15,489,997

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 $144.2 million as of December 31, 2024. 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.

We have a Note outstanding as of December 31, 2024 of $5.0 million in principal plus accrued and unpaid interest of approximately $79,000. The Note provides that we 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 described in the Note, at Agenus' election, we must pay the principal amount outstanding and any unpaid interest, either in full or in the form of equity securities.

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, 2024 was $4.6 million. We believe that our cash and cash equivalents balance, plus anticipated funding from corporate transactions, 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, 2024 and 2023 was $9.6 million and $15.8 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 (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) 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.

This item is not required for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, 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 18, 2025

MiNK THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET

	December 31, 2024	December 31, 2023
ASSETS		
Cash and cash equivalents	$ 4,577,040	$ 3,367,229
Prepaid expenses	246,600	53,111
Other current assets	164,244	177,964
Total current assets	4,987,884	3,598,304
Equipment, net of accumulated depreciation of $524,639 and $495,638 as of December 31, 2024 and 2023, respectively	732,929	953,977
Total assets	$ 5,720,813	$ 4,552,281
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Accounts payable	2,728,212	3,911,973
Accrued liabilities	1,873,561	5,037,361
Other current liabilities	2,357,903	2,453,251
Total current liabilities	6,959,676	11,402,585
Related party note	4,924,612	—
Other long-term liabilities	—	48,072
Due to related parties	13,422,407	11,157,073
Commitments and contingencies		
Stockholders' deficit		
Common stock, par value $0.00001 per share, 150,000,000 shares authorized, 3,963,045 and 3,459,910 shares issued and outstanding as of December 31, 2024 and 2023, respectively	40	35
Additional paid-in capital	125,227,389	115,772,396
Accumulated other comprehensive loss	(631,576)	(430,947)
Accumulated deficit	(144,181,735)	(133,396,933)
Total stockholders' deficit	(19,585,882)	(18,055,449)
Total liabilities and stockholders' deficit	$ 5,720,813	$ 4,552,281

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,	
	2024	2023
Operating expenses:		
Research and development	$ 6,336,075	$ 15,489,997
General and administrative	4,314,164	7,431,108
Change in fair value of related party note	638,046	—
Operating loss	(11,288,285)	(22,921,105)
Other income (expense), net:		
Interest income, net	172,568	463,256
Other income (expense), net	330,915	(10)
Net loss	(10,784,802)	(22,457,859)
Per common share data:		
Basic and diluted net loss per common share	$ (2.86)	$ (6.54)
Weighted average number of common shares outstanding	3,773,326	3,435,994
Other comprehensive loss		
Foreign currency translation loss	(200,629)	(138,479)
Comprehensive loss	$ (10,985,431)	$ (22,596,338)

See accompanying notes to consolidated financial statements.

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

	Common Stock			Treasury Stock				
	Number of shares	Par Value	Additional Paid-In Capital	Number of shares	Amount	Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 2022	3,385,642	$ 34	$ 110,830,205	—	$ —	$ (292,468)	$ (110,939,074)	$ (401,303)
Net Loss	—	—	—	—	—	—	(22,457,859)	(22,457,859)
Other comprehensive loss	—	—	—	—	—	(138,479)	—	(138,479)
Vesting of nonvested shares	17,519	—	—	—	—	—	—	—
Exercise of stock options and employee share purchases	14,452	—	70,466	—	—	—	—	70,466
Share retirement	(19)	—	0	—	—	—	—	0
Issuance of shares for services	2,520	—	30,000	—	—	—	—	30,000
Grant and recognition of stock options	—	—	3,698,436	—	—	—	—	3,698,436
Recognition of parent stock options	—	—	131,930	—	—	—	—	131,930
Issuance of shares for employee bonuses	60,383	1	1,011,361	(20,587)	(477,639)	—	—	533,723
Retirement of treasury shares	(20,587)	—	(2)	20,587	477,639	—	—	477,637
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	—	—	—	—	—	—	—
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)

See accompanying notes to consolidated financial statements.

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

	For the Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (10,784,802)	$ (22,457,859)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	215,437	204,617
Share-based compensation	1,810,226	3,860,366
Gain on deconsolidation	(185,351)	—
Gain on forgiveness of liability	(1,788,204)	(266,780)
Change in fair value of related party note	638,046	—
Interest accrued on related party note	79,444	—
Changes in operating assets and liabilities:		
Prepaid expenses	(194,173)	245,589
Accounts payable	(1,182,414)	(1,917,557)
Accrued liabilities and other current liabilities	(393,771)	2,025,124
Other operating assets and liabilities	2,230,086	2,543,988
Net cash used in operating activities	(9,555,476)	(15,762,512)
Cash flows from investing activities:		
Purchases of equipment	—	(73,561)
Net cash used in investing activities	—	(73,561)
Cash flows from financing activities:		
Proceeds from issuance of related party note	5,000,000	—
Proceeds from sale of shares in private placement	5,800,000	—
Purchase of treasury shares to satisfy tax withholdings	—	(477,639)
Proceeds from employee stock purchases and option exercises	19,986	70,466
Net cash provided by (used in) financing activities	10,819,986	(407,173)
Effect of exchange rate changes on cash	(54,699)	(25,250)
Net increase (decrease) in cash	1,209,811	(16,268,496)
Cash, beginning of period	3,367,229	19,635,725
Cash, end of period	$ 4,577,040	$ 3,367,229
Supplemental cash flow information:		
Cash paid for interest	$ 13,135	$ 27,509
Supplemental disclosures - non-cash activities:		
Insurance financing agreement	$ 172,000	$ 109,000
Issuance of stock options for payment of certain employee bonuses	1,031,908	—
Issuance of related party note (Note 10)	792,878	—
Issuance of common stock, $0.00001 par value, for payment of employee bonuses	—	1,011,360
Issuance of common stock, $0.00001 par value, in connection with payment for services	—	30,000

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 cells.

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, 2024, MiNK had an accumulated deficit of $144.2 million and cash and cash equivalents of $4.6 million. MiNK believes that its cash and cash equivalents balance, plus anticipated funding from corporate transactions, 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 15 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 $215,000 and $205,000, for the years ended December 31, 2024 and 2023, 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 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, 2024.

(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, 2024 and 2023.

(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, 2024 and 2023, as they would be anti-dilutive:

	2024	2023
Stock options	895,002	694,571
Nonvested shares	80,646	78,950

(m) Recent Accounting Pronouncements

Recently Issued and Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 requires incremental annual and quarterly disclosures about segment measures of profit or loss as well as significant segment expenditures. It also requires public entities with a single reportable segment to provide all segment disclosures required by the amendments and all existing segment disclosures in Topic 280. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. The Company adopted the standard in the year ended December 31, 2024. The adoption of this standard resulted in increased disclosures, including significant segment expenditures, in the notes to its consolidated financial statements.

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. For the Company, 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, 2024 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, 2024 and 2023 (in thousands):

	December 31, 2024		December 31, 2023	
	Cost	Estimated Fair Value	Cost	Estimated Fair Value
Institutional money market funds	$ 4,212	$ 4,212	$ 2,899	$ 2,899

(4) Equipment

Equipment, net, consisted of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Equipment	$ 1,258	$ 1,450
Less accumulated depreciation	(525)	(496)
Equipment, net	$ 733	$ 954

(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 2020 through 2023. With few exceptions, the Company is no longer subject to U.S. Federal state, and foreign examinations by tax authorities for the tax year 2020. However, net operating losses from 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, 2024, the Company had available net operating loss carryforwards of $58.5 million for Federal and state income tax purposes, which are available to offset future Federal and state taxable income, if any. $58.3 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 $18.5 million generated in the United Kingdom and $9.1 million in Belgium. 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 IRC Section 174. The capitalized expenses are amortized over a 5-year period for domestic expenses and a 15-year period for foreign expenses. We have included the impact of this provision, which results in additional deferred tax assets of approximately $7.0 and $6.5 million as of December 31, 2024 and 2023 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, 2024 and 2023 are presented below (in thousands).

	December 31,	
	2024	2023
Deferred tax assets:		
U.S. Federal and state net operating loss carryforwards	$ 15,819	$ 13,804
Foreign net operating loss carryforwards	7,310	7,819
Research and development tax credits	341	341
Share-based compensation	346	269
Capitalized research expenses	6,967	6,515
Other	180	926
Total deferred tax assets	30,963	29,674
Less: valuation allowance	(30,963)	(29,674)
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 $1.3 million and $7.0 million during the years ended December 31, 2024 and 2023, respectively.

Income tax benefit was nil for the years ended December 31, 2024 and 2023. 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,	
	2024	2023
Computed "expected" Federal tax benefit	$ (2,265)	$ (4,716)
(Increase) reduction in income taxes benefit resulting from:		
Change in valuation allowance	1,436	5,987
Foreign income inclusion	295	(21)
State and local income benefit, net of Federal income tax benefit	(434)	(1,693)
Permanent differences	1,004	840
Other, net	(36)	(397)
Income tax benefit	$ —	$ —

(6) Accrued Liabilities

Accrued liabilities consist of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Payroll	$ 718	$ 1,831
Professional fees	374	398
Research services	191	302
Contract manufacturing costs	591	2,430
Other	—	76
Total	$ 1,874	$ 5,037

The above contract manufacturing costs balance as of December 31, 2024 reflects the forgiveness of certain previously recorded liabilities during the year ended December 31, 2024. The associated reversal of previously recorded expense was recognized as a reduction to research and development expense.

(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.

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.

(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, 2024, 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 will automatically increase on January 1st of each year from 2025 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. In both January 2023 and 2024, the 2021 Plan share pool increased by approximately 140,000 shares. As of December 31, 2024, there were approximately 1.0 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 135,000 shares reserved for issuance under the ESPP, plus an automatic annual increase on January 1st of each year from 2025 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.

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:

	2024	2023
Expected volatility	93%	92%
Expected term in years	6	6
Risk-free interest rate	4.3%	3.6%
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 2024 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	694,571	$ 20.30		
Granted	214,087	8.73		
Exercised	(7,423)	0.91		
Forfeited	(5,505)	3.38		
Expired	(728)	22.75		
Outstanding at December 31, 2024	895,002	17.70	6.98	$ 1,398,784
Vested or expected to vest at December 31, 2024	895,002	17.70	6.98	$ 1,398,784
Exercisable at December 31, 2024	634,757	$ 14.60	6.71	$ 1,398,784

The weighted average grant-date fair values of options granted during the years ended December 31, 2024 and 2023, was $6.86 and $17.80, respectively. During both 2024 and 2023, 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 2024 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, 2024 (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, 2024, determined on the dates of exercise, was approximately $63,000.

As of December 31, 2024, there was $2.3 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 1.1 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 2024 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2023	78,950	$ 11.81
Granted	31,869	8.57
Vested	(30,173)	9.83
Forfeited	—	—
Outstanding at December 31, 2024	80,646	$ 11.25

As of December 31, 2024, there was $0.7 million of unrecognized share-based compensation expense related to these non-vested shares which will be recognized over a weighted average period of 3.7 years. The total intrinsic value of shares vested during the year ended December 31, 2024 was $275,000.

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, 2024 and 2023, 7,423 shares and 10,518 shares, respectively, were issued as a result of stock option exercises. During the years ended December 31, 2024 and 2023, 30,173 shares and 17,519 shares, respectively, were issued as a result of the vesting of non-vested stock. During the years ended December 31, 2024 and 2023, 1,539 shares and 3,934 shares, respectively, were issued under the ESPP. Additionally, during the year ended December 31, 2023, 60,383 shares were issued as payment for certain employee bonuses, with 20,587 of those shares being withheld to cover taxes, resulting in a net share issuance of 39,796 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, 2024 and 2023, was as follows (in thousands):

	2024	2023
Research and development	$ 904	$ 541
General and administrative	1,938	3,289
Total share-based compensation expense	$ 2,842	$ 3,830

(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 $2.3 million as of both December 31, 2024 and December 31, 2023, 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 $2.3 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 $1.1 and $1.0 million for the years ended December 31, 2024 and 2023, respectively, is included in Operating expenses in the Company's statement of operations and comprehensive loss and Due to related parties, of $13.4 million as of December 31, 2024, in the Company's consolidated balance sheet. Agenus has agreed to not require repayment of this balance for the foreseeable future.

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, 2024, the Note had a principal balance of $5.0 million, an accrued and unpaid interest balance of $79,444 and an effective interest rate of 15.0%.

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 January 2023 Dr. Buell was granted an option to acquire 37,500 shares of Agenus common stock that vest over a period of four years, in June 2024 she was granted an option to acquire 37,500 shares of Agenus common stock that vest over a period of three years and in November 2024 Dr. Buell was granted an option to acquire 300,000 shares of Agenus common stock that vest after one year. Dr. Buell receives no additional compensation as an Agenus board member.

Effective April 12, 2022, the Company entered into a Master Services Agreement with Atlant Clinical Ltd. ("Atlant"), a subsidiary of Agenus, to provide clinical trial support services to the Company, including an eTMF platform, medical monitoring and data manager services. The Company's Audit and Finance Committee approved the engagement under its related-party transactions policy for up to $250,000 in services. As of December 31, 2024, the Company had entered into work orders with Atlant totaling approximately $193,000, plus out of pocket expenses which are to pass through to Company at cost. For the years ended December 31, 2024 and 2023, approximately $23,000 and $30,500 related to these services is included in "Research and development" expense in the Company's consolidated statements of operations.

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, 2024 and 2023, and continues to do so. In the years ended December 31, 2024 and 2023, the Company expensed Wolf Greenfield fees totaling approximately $168,000 and $225,000, 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, 2024 was $4.8 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, 2024 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, 2024 was recorded in "Operating expenses" in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

(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, 2024 and 2023, the Company expensed $156,000 and $172,000, 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, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Operating expenses:		
External expenses	$ (2,452)	$ (9,885)
Payroll related expenses	(5,217)	(8,211)
Other operating expenses	(3,619)	(4,825)
Operating loss	(11,288)	(22,921)
Other income (expense):		
Interest expense	(93)	(28)
Interest income	265	491
Other income	331	—
Net loss	$ (10,785)	$ (22,458)

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

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 a reverse stock split of its issued and outstanding common stock at a ratio of 1-for-10 (the "Reverse Stock Split"). On January 17, 2025, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to our 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

During 2024 the Company received notices from Nasdaq notifying the Company of its non-compliance with The Nasdaq Capital Market under Nasdaq Listing Rules 5550(a)(2) (the Minimum Bid Price Rule) and 5550(b)(2) (the Minimum Value of Listed Securities Rule, collectively the "Rules").

In January 2025 the Company executed a Reverse Stock Split and in February 2025 received letters from Nasdaq notifying the Company it had regained compliance with the Rules and that it complies with the requirements for continued listing.

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 Chief 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) promulgated under the Exchange Act. Based on this evaluation, our Chief 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). Under the supervision and with the participation of our management, including our Chief 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, 2024.

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 was no change 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, 2024 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, 2024, none of our directors or executive officers adopted or terminated a "Rule 10b5-1 trading arrangement" 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.

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, 2024.

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, 2024.

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, 2024.

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, 2024.

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, 2024.

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	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	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).
10.2	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).
10.3+	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).
10.4+	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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	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).

10.11+	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).
10.12+	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).
10.13+	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).
10.14+	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).
10.15+	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).
10.16+	Executive Employment Agreement between the Registrant and Marc van Dijk, dated March 2, 2022 (Incorporated by reference to Exhibit 10.17 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	Master Services Agreement between the Registrant and Atlant Clinical Ltd., dated April 12, 2022 (Incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022 (File No. 001-40908) filed on March 24, 2023).
10.18	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).
10.19	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.
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.
+ 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, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

MiNK Therapeutics, Inc.

Date: March 18, 2025

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, as amended, 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 18, 2025
/s/ Christine M. Klaskin **Christine M. Klaskin**	Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2025
/s/ Garo H. Armen, Ph.D. **Garo H. Armen, Ph.D.**	Chairman of the Board of Directors	March 18, 2025
/s/ Peter Behner **Peter Behner**	Director	March 18, 2025
/s/ Brian Corvese **Brian Corvese**	Director	March 18, 2025
/s/ Robert Kadlec, M.D. **Robert Kadlec, M.D.**	Director	March 18, 2025
/s/ Barbara Ryan **Barbara Ryan**	Director	March 18, 2025
/s/ Ulf Wiinberg **Ulf Wiinberg**	Director	March 18, 2025

Exhibit 19.1

MiNK Therapeutics, Inc.

Securities Trading Policy

This Securities Trading Policy (this **"Policy")** describes the requirements that MiNK Therapeutics, Inc. and its subsidiaries (collectively, the "**Company"** or **"MiNK"**) have adopted regarding the trading, and causing the trading of, the Company's securities.

I. PURPOSE

MiNK is committed to complying with all relevant laws and regulations pertaining to the listing, trading and disclosure obligations arising from any transactions involving its securities. This Policy sets forth the requirements for MiNK, as well as its directors, officers, employees, consultants with access to confidential Company information, and their respective immediate family members (collectively, **"Covered Persons")** to comply with such laws and regulations.

The insider trading laws of the United States ("**U.S.**") prohibit buying or selling a company's securities by certain persons while they are aware of material, nonpublic information about that company. It may also violate U.S. securities laws to disclose material, non-public information (deliberately or inadvertently) to another person (including your family member) if that person either buys or sells securities while aware of the information disclosed or passes that information to a third party who does. Providing advice regarding a company's stock while aware of material, non-public information regarding that company may also violate civil and criminal U.S. securities laws and must be avoided.

II. APPLICABILITY

This Policy applies to all trading or other transactions in (i) the Company's securities, including common stock, options and any other securities that the Company may issue, such as preferred stock, notes, bonds and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company and (ii) the securities of certain other companies, including common stock, options and other securities issued by those companies as well as derivative securities relating to any of those companies' securities where MiNK has access to confidential information related to such other companies.

This Policy applies to all Covered Persons, with additional trading restrictions that apply to Company directors, officers, employees at the level of Vice President or above, and additional employees who may from time to time be identified by the

General Counsel based on their position, responsibilities or their actual or potential access to material information (collectively, "**Company Insiders**"). The General Counsel will inform you if you are deemed to be a Company Insider.

III. DEFINITIONS

Material. Information is "material" if a reasonable investor would consider it significant in a decision to buy, hold or sell securities. Put another way, information that could reasonably be expected to affect the price of a security, either positively or negatively, is material.

Common examples of information that will frequently be regarded as material are information relating to:

- earnings or losses that are inconsistent with the expectations of the investment community;
- projections of future earnings or losses or other earnings guidance;
- proposals, plans or agreements, even if preliminary in nature, involving a proposed merger, acquisition, strategic alliance, licensing agreement or sale of part of the Company's business;
- impending securities offerings by the Company;
- changes in management or the board of directors;
- cybersecurity risks and incidents, including vulnerabilities and breaches;
- results of clinical trials, collaborations, licenses or matters related to the status of clinical trials (e.g., enrollment);
- new products or significant discoveries;
- negotiations regarding an important license, distribution agreement, or joint venture;
- pending action from governmental agencies, including the Food and Drug Administration ("**FDA**"), other relevant regulatory agency actions;
- a proposed stock split or stock dividend;
- impending financial problems;
- changes in the status of any of the Company's activities which may have an adverse or favorable impact on the Company's business; or
- actual or threatened litigation with the potential to have a meaningful impact on the business, or governmental investigations or major developments in such matters.

Other types of information may also be material; no complete list can be provided. If you have questions regarding the materiality of information, it is best to check with the General Counsel before undertaking any activity in the Company's securities.

Nonpublic. Information is "nonpublic" or "inside information" if it has not been disseminated in a manner making it available to investors generally. To show that information is public, it may be necessary to point to some fact that establishes that the information has become publicly available, such as the filing of a report with the SEC, the distribution of a press release through a widely disseminated news or wire service, or by other means that are reasonably designed to provide broad public access. Before a person who possesses material, nonpublic information can trade, there also must be adequate time for the market as a whole to absorb the information that has been disclosed. As a general rule, if you know of material, nonpublic information about the Company, you should not engage in any stock transactions before the second business day after the day on which the information is publicly announced. If the information relates to the Company's financial performance, you should wait until the second business day after the Company publishes its annual or quarterly earnings report. If you are not sure whether information is considered public, you should check with the General Counsel or assume that the information is nonpublic and treat it as confidential.

IV. COVERED PERSONS CANNOT TRADE OR CAUSE TRADING OF COMPANY SECURITIES WHILE IN POSESSIONS OF MATERIAL, NON-PUBLIC INFORMATION:

A. Covered Persons may not purchase or sell, or offer to purchase or sell, any Company security, whether or not issued by the Company, while in possession of material nonpublic information about the Company.

B. Covered Persons who know of any material nonpublic information about the Company may not communicate that information to ("**tip"**) any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

C. Covered Persons may not purchase or sell any security of any other publicly traded company while in possession of material nonpublic information that was obtained in the course of his or her involvement with the Company. Covered Persons who know of any such material nonpublic information cannot communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

V. SPECIAL RESTRICTIONS APPLICABLE TO COMPANY INSIDERS

A. **Pre-Clearance by General Counsel for Company Insider Transactions.** In all instances, no Company Insider may trade in Company securities unless the trade has been approved by the General Counsel in accordance with the procedures set forth below. The General Counsel will review and either approve or prohibit all proposed trades by Company Insiders. The General Counsel may consult with the

Company's other executive officers and/or outside legal counsel and will receive approval for his/her own trades from the Company's Chief Executive Officer.

***Procedures*.** No Company Insider may trade in Company securities until:

- The Company Insider has notified in writing (including by email) the General Counsel of the amount and nature of the proposed trade(s). In order to provide adequate time for the preparation of any required reports under Section 16 of the Exchange Act, a request to trade must be received by the General Counsel at least two (2) business days prior to the intended trade date; and

- The General Counsel or his/her designee has approved the trade(s) in writing.

***Completion of Trades*.** After receiving written clearance to engage in a trade by the General Counsel, a Company Insider must complete the proposed trade within five (5) business days or make a new trading request.

Post-Trade Reporting. Any transactions in the Company's securities by a Company director or executive officer (including transactions effected pursuant to a Rule 10b5-1 Plan (as defined below)) must be reported in writing (including by email) to the General Counsel on the same day such a transaction occurs specifying the number of shares purchased or sold, the price per share, and the date the trade was executed (not settled). A written report directly from the individual's broker to the General Counsel will be deemed compliance with this reporting requirement. Compliance with this provision is imperative given the requirement of Section 16 of the Exchange Act requiring certain persons report changes in ownership of Company securities within two (2) business days. The sanctions for noncompliance with this reporting deadline include mandatory disclosure in the Company's proxy statement for the next annual meeting of stockholders, as well as possible civil or criminal sanctions for chronic or egregious violators.

B. <u>Blackout Periods</u>

All Company Insiders are prohibited from trading in the Company's securities during blackout periods as defined below.

From time to time when material nonpublic information regarding the Company (such as negotiation of mergers, acquisitions or dispositions, investigation and assessment of cybersecurity incidents or new product developments) may be pending and not yet publicly disclosed may necessitate a so-called "blackout period" during which Company Insiders are prohibited from trading in the Company's securities. While such material nonpublic information is pending, the Company may impose a blanket prohibition on any trading in the Company's

securities. The General Counsel will notify Company Insiders of such blackout period, as necessary.

It is a violation of this Policy for any individual, subject to any blackout period, to make any transaction in the market (purchase or sale) during such blackout period. Individuals who are subject to a blackout period should not make any transaction in the market until either (i) the individuals have been notified by the General Counsel that the blackout period has been lifted, or (ii) the second business day after the Company issues a press release or SEC filing announcing the news that was the subject of the blackout period.

Company Insiders are also prohibited from entering into hedging arrangements with respect to Company securities, such as collars, swaps, and exchange funds, or trading in derivative securities tied to the price of Company securities, including put options, call options, and futures contracts, in each case, without the prior consent of the Company's board of directors.

C. Trading Window

Company Insiders are permitted to trade in the Company's securities when no blackout period is in effect. Generally, this means that Company Insiders can trade (subject to the pre-clearance requirement noted above) during the period beginning two business days after the nonpublic information was publicly disclosed. Even during an open trading window, a Company Insider who is in possession of any material nonpublic information **may not** trade in the Company's securities until the information has been made publicly available (via the appropriate SEC filing and/or press release) or is no longer material. In addition, the Company may close this trading window if a special blackout period is imposed and will re-open the trading window once the blackout period has ended.

VI. TRANSACTIONS NOT INVOLVING A PURCHASE OR SALE

Bona fide gifts of securities are not transactions subject to this policy, unless the person making the gift has reason to believe that the recipient intends to sell the Company's securities at a time when the transferor is aware of material, nonpublic information or the person making the gift is subject to the trading restrictions specified under the heading, "Blackout Periods" of this policy and the sale by the recipient of the Company's securities would be expected to occur during such a "blackout period."

Further, transactions in mutual funds that are invested in Company securities are not transactions subject to this policy.

VII. SPECIAL AND PROHIBITED TRANSACTIONS APPLICABLE TO COVERED PERSONS

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if Covered Persons (you) engage in certain types of transactions. Therefore, it is the Company's policy that you may not engage in any of the following transactions, or should otherwise consider the Company's preferences as described below:

A. **Short Sales.** Short sales of Company securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company securities are prohibited. In addition, Section 16(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") prohibits officers and directors from engaging in short sales. (Short sales arising from certain types of hedging transactions are governed by the paragraph below captioned "Hedging Transactions.")

B. **Publicly-Traded Options.** Given the relatively short term of publicly-traded options, transactions in options may create the appearance that you are trading based on material nonpublic information and focus your attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options or other derivative securities, on an exchange or in any other organized market, are prohibited by this policy. (Options positions arising from certain types of hedging transactions are governed by the next paragraph below.)

C. **Hedging Transactions.** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, put and call options, collars and exchange funds. Such transactions may permit you to continue to own Company securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, you may no longer have the same objectives as the Company's other shareholders. Therefore, the Company strongly discourages you from engaging in such transactions. Any person wishing to enter into such an arrangement must first submit the proposed transaction for approval to the General Counsel. Any request for pre-clearance of a hedging or similar arrangement must be submitted to the General Counsel at least two weeks prior to the proposed execution of documents evidencing the proposed transaction and must set forth a justification for the proposed transaction.

D. **Margin Accounts and Pledge Securities.** Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's

consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledger is aware of material non-public information or otherwise is not permitted to trade in Company securities, you are prohibited form holding Company securities in a margin account or otherwise pledging Company securities as collateral for a loan.

E. **Standing and Limit Orders.** Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans, as described below) create heightened risks for Company Insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a director, officer or other employee is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on Company securities other than pursuant to Rule 10b5-1 Plans. If a person subject to this policy determines that they must use a standing order or limit order, the order should be limited to short duration and should otherwise comply with the restrictions and procedures outlined below under the section "Special Restrictions Applicable to Company Insiders" above.

VIII. POST-TERMINATION TRANSACTIONS APPLICABLE TO COVERED PERSONS

This Policy continues to apply to your transactions in the Company's securities even after you have terminated employment or other services to the Company as follows: if you are aware of material, nonpublic information when your employment or service relationship terminates, you may not trade in the Company's securities until that information has become public or is no longer material. You may contact the General Counsel prior to and after you have terminated employment or your services to the Company regarding the trading of the Company's securities in compliance with this Policy.

X. EXCEPTIONS TO THIS POLICY

A. Exception for Pre-Approved Rule 10b5-1 Plans. Transactions effected pursuant to a Rule 10b5-1 Plan approved by the General Counsel prior to its effective date will not be subject to the Company's blackout periods or preclearance procedures, and Company Insiders are not required to seek preclearance for such transactions. Rule 10b5-1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans that meet certain requirements. A trading plan, arrangement or instruction that meets the requirements of Rule 10b5-1 (a "Rule 10b5-1 Plan") enables Company Insiders to

establish arrangements to trade in Company securities outside of the Company's trading windows, even when in possession of material, nonpublic information. If a Company Insider intends to trade pursuant to a Rule 10b5-1 Plan, such plan must:

- satisfy the requirements of Rule 10b5-1;
- be documented in writing;
- be established during a trading window when such Insider does not possess material, nonpublic information; and
- be pre-approved by the General Counsel.

Any deviation from, or alteration to, the specifications of an approved Rule 10b51 Plan (including, without limitation, the amount, price or timing of a purchase or sale) must be reported immediately to the General Counsel. Any modification of an Insider's prior Rule 10b5-1 Plan requires pre-approval by the General Counsel. A modification must occur during a trading window and while such Insider is not aware of material, nonpublic information.

The General Counsel may refuse to approve a Rule 10b5-1 Plan or any modification thereto as he or she deems appropriate including, without limitation, if he or she determines that such plan does not satisfy the requirements of Rule 10b5-1. The General Counsel may consult with the Company's external legal counsel before approving a Rule 10b5-1 Plan. If the General Counsel does not approve a Company Insider's Rule 10b5-1 Plan, such Company Insider must adhere to the pre-clearance procedures and blackout periods set forth above until such time as a Rule 10b5-1 Plan is approved.

B. **Stock Option Exercises.** This Policy does not apply to the exercise of a stock option acquired pursuant to a Company equity incentive plan or to a transaction in which a person has elected to have the Company withhold shares subject to an option award to satisfy tax withholding requirements. This policy does, however, apply to any sale of shares as part of a broker-assisted cashless exercise of an option or any other market sale for the purpose of generating the cash needed to pay the exercise price of or taxes associated with an option.

C. **Restricted Shares and Similar Awards**. This policy does not apply to the vesting of restricted shares, the settlement of restricted stock units or similar awards, or to a transaction in which there is an election to have the Company withhold shares to satisfy tax withholding requirements upon the vesting of any restricted shares or the vesting or settlement of any restricted stock unit. This policy does apply, however, to any market sale of Company securities received upon the settlement of any restricted stock unit or similar award.

D. **Employee Stock Purchase Plan ("ESPP").** This Policy does not apply to periodic purchases through automatic payroll contributions under a ESPP, if such plan exists, that are made as the result of an election made at the beginning of the

purchase period. This policy would apply, however, to an initial decision to participate/enroll in ESPP or a decision to increase the level of contribution in a subsequent purchase period. It would also apply to any sales of shares purchased under the ESPP.

E. 401(k) Plan. This Policy does not apply to purchases of Company securities in the Company's 401(k) plan as a result of periodic contributions made pursuant to payroll deduction. The policy does apply, however, to initial elections to participate, and increases or decreases in the level of participation, in a Company stock fund and transfers in or out of a Company stock fund (including in connection with a plan loan).

XI. CONSEQUENCES OF VIOLATING THIS POLICY

Penalties for trading on or communicating material nonpublic information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties, and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

Legal Penalties. Federal law imposes serious penalties on those who, in violation of the law, either buy or sell securities while aware of material nonpublic information or pass the material nonpublic information to others who use it to buy or sell securities (known as "tipping"). Potential penalties for individual violators are:

- disgorgement of the profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of such violation, have purchased or sold, as applicable, securities of the same class;
- civil penalties of up to $1,000,000 per violation or three times the amount of the profit gained or loss avoided;
- a criminal fine of up to $5,000,000 (no matter how small the profit); and
- a jail term of up to 20 years.

In addition, the Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties of up to the greater of $1,275,000 or three times the profit made or loss avoided, as well as a criminal penalty of up to $25 million if the Company failed to take appropriate steps to prevent such trading, and could under certain circumstances be subject to private lawsuits based on the misconduct.

Company Sanctions. In view of the seriousness of this matter, the Company may discipline any person who violates this Policy as appropriate, including dismissal

for cause. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Policy has been violated. The Company may determine that specific conduct violates this Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

Any of these consequences, and even an investigation that does not result in prosecution, can tarnish your reputation and irreparably damage you and the Company.

XII. REPORTING VIOLATIONS

If you violate this policy or any federal or state laws governing Company Insider trading, or know of any such violation by any Covered Person, you must report the violation immediately to the General Counsel (compliance@minktherapeutics.com), or anonymously to 855-855-782-0439 and website is minktherapeutics.ethicspoint.com. If the conduct in question involves the General Counsel, or if you do not feel that you can discuss the matter with the General Counsel, you may raise the matter with another member of senior management or chair of the Audit Committee of the Board of Directors.

XIII. COMPANY ASSISTANCE

Anyone with questions about specific transactions may obtain additional guidance from the General Counsel at compliance@minktherapeutics.com. Ultimately, the responsibility for adhering to this policy and avoiding unlawful transactions rests with the individual Company Insider or other parties that are subject to this Policy.

XIV. ACKNOWLEDGEMENT AND CERTIFICATION

All Covered Persons are required to read and certify acknowledgment to this Policy annually.

Exhibit 21.1

List of Subsidiaries of MiNK Therapeutics, Inc.

Name of Subsidiary	**Jurisdiction of Organization**
AgenTus Therapeutics Limited	England and Wales
AgenTus Therapeutics SA	Belgium

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-268143 and 333-281522) on Form S-3 and registration statements (Nos. 333-266170, 333-273906 and 333-281519) on Form S-8 of our report dated March 18, 2025, with respect to the consolidated financial statements of MiNK Therapeutics, Inc.

/s/ KPMG LLP

Boston, Massachusetts
March 18, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Jennifer S. Buell, certify that:

1. I have reviewed this Annual Report on Form 10-K of MiNK Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2025

By: /s/ Jennifer S. Buell, Ph.D.

Jennifer S. Buell, Ph.D.
President, Chief Executive Officer and Principal Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Christine M. Klaskin, certify that:

1. I have reviewed this Annual Report on Form 10-K of MiNK Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2025

By: /s/ Christine M. Klaskin
Christine M. Klaskin
Treasurer and Principal Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of MiNK Therapeutics, Inc. (the "Company") for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 18, 2025

By: /s/ Jennifer S. Buell, Ph.D.

Jennifer S. Buell, Ph.D.
President, Chief Executive Officer and Principal Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of MiNK Therapeutics, Inc. (the "Company") for the period ending December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 18, 2025

By: /s/ Christine M. Klaskin

Christine M. Klaskin
Treasurer and Principal Financial Officer