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This is a confidential draft submission to the United States Securities and Exchange Commission on January 22, 2021 under the Securities Act of 1933, as amended.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AgenTus Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**2836**	**82-2142067**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

3 Forbes Road
Lexington, MA 02421
781-674-4550
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Garo H. Armen, Ph.D.
President and Chairman of the Board of Directors
3 Forbes Road
Lexington, MA 02421
781-674-4550
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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New York, NY 10018
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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1)**	**Amount of registration fee(2)**
Common Stock, par value $0.00001 per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.
(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Explanatory Note

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are not required to file our financial information for the fiscal year ended December 31, 2018 or for the nine months ended September 30, 2020 and 2019 because we expect to file our financial information for the fiscal year ended December 31, 2020 in our registration statement when it is publicly filed. While the financial information for the fiscal year ended December 31, 2018 and for the nine months ended September 30, 2020 and 2019 is otherwise required by Regulation S-X, it will not be required to be included in the Form S-1 filing at the time of the contemplated offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated , 2021

Preliminary prospectus

shares

AgenTus Therapeutics, Inc.

Common stock

This is an initial public offering of shares of common stock of AgenTus Therapeutics, Inc. We are selling shares of our common stock. The initial public offering price is expected to be between $ and $ per share.

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "AGTS."

We are an "emerging growth company" and "smaller reporting company" under applicable federal securities laws and will be subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company and Smaller Reporting Company."

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to AgenTus Therapeutics, Inc., before expenses	$	$

(1) See "Underwriting" for additional disclosure regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock from us at the initial public offering price, less underwriting discounts and commissions.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 13 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about , 2021.

Mizuho Securities

, 2021.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Industry Terms

“Adoptive cell therapy”	A therapy that involves the infusion of new immune cells into a patient with the intent to treat a disease.
“Allogeneic cell therapy”	A therapy that involves the infusion of cells derived from healthy donors into a patient with the intent to treat a disease.
“Autologous cell therapy”	A therapy that involves the re-infusion of a patient’s own cells with the intent to treat a disease.
“Leukapheresis”	A procedure in which white blood cells are separated from a sample of blood.
“Lymphodepletion”	A chemotherapy regimen that aims to reduce a patient’s immune response to the cell therapy treatment and make room for new cells.
“PTT”	Phosphopeptide tumor targets are portions of certain proteins that present at the cell surface to the immune system in the context of human leukocyte antigen class 1 molecules.

Trademarks

We use AgenTus®, T-Rx™, CARDIS™, INTELLIGENT iNKT™ and other marks as trademarks in the United States and/or in other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may be listed without the ®, SM and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names.

Market and Industry Data

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management’s estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this prospectus is reliable. Management’s estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates.

Prospectus Summary

This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making any investment decision. Unless the context otherwise requires, the terms "AgenTus," the "Company," "we," "us" and "our" relate to AgenTus Therapeutics, Inc., together with its consolidated subsidiaries.

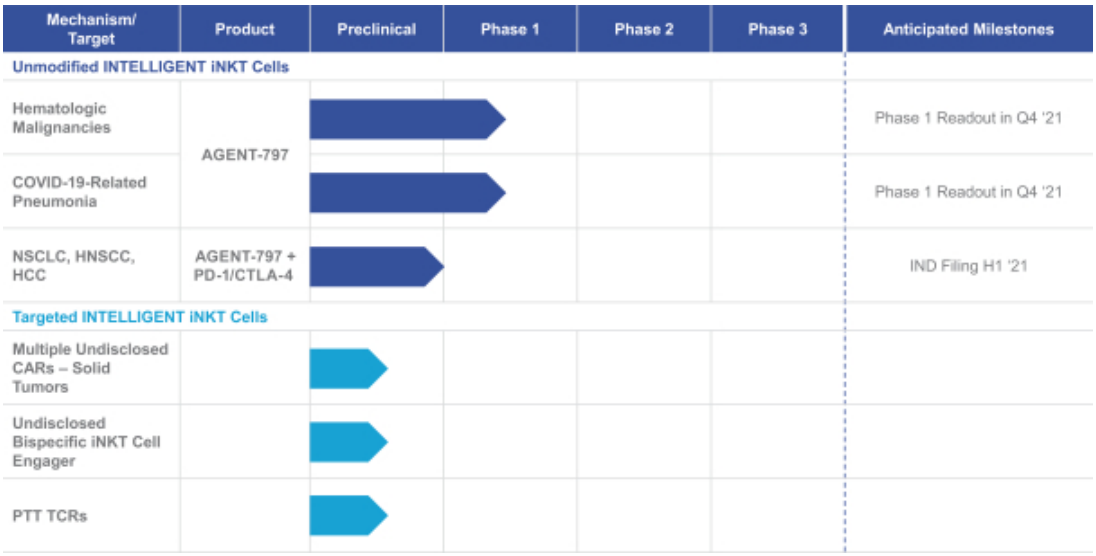
Overview

We are a clinical stage biopharmaceutical company developing allogeneic invariant natural killer T (iNKT) cell therapies to treat cancer and other life-threatening illnesses. Our iNKT cells, which we refer to as INTELLIGENT iNKT™ cells, are designed to have the innate capacity to home to the site of diseased tissue, including cancer, and recruit key components of the immune system to fight disease. iNKT cells combine properties of both T and natural killer (NK) cells and tune their response based on individual elements of the tumor or disease microenvironment. Our development pipeline includes off-the-shelf iNKT cell product candidates to treat hematologic and solid tumors. We believe these product candidates have the potential to help us treat a significantly larger patient population than is currently served by autologous chimeric antigen receptor T (CAR-T) cell therapy.

Our platform is designed to facilitate scalable iNKT cell manufacturing, novel cancer target identification and engineering for precision targeting and functional enhancement. Through our collaboration with our parent company, Agenus Inc. (Agenus), we have developed an iNKT cell engineering and targeting platform built on Agenus' antibody engineering capabilities. This includes novel proprietary technologies for chimeric antigen receptors (CARs), T cell receptors (TCRs) and bispecific iNKT cell-engagers. We believe Agenus' portfolio of novel clinical immuno-oncology antibodies provides a differentiated opportunity for development of combination therapies. Agenus has a wide library of immuno-oncology antibodies that will be available to us through the collaboration, and we intend to initially focus on two of Agenus' assets, zalifrelimab and balstilimab. We also have access to Agenus' QS-21 Stimulon™ adjuvant, which we believe can be used as part of a combination therapy with iNKT cells to further augment a patient's own immune response.

We intend to leverage our iNKT cell manufacturing capabilities to enable efficient, scalable and reproducible batches of our INTELLIGENT iNKT cells for off-the-shelf delivery. Our manufacturing process is designed to improve the persistence of iNKT cells for sustained activity after administration.

The following table summarizes our current product development pipeline:



Our most advanced product candidate is AGENT-797, an allogeneic unmodified INTELLIGENT iNKT cell therapy derived from healthy donors. In January 2021, we intend to commence a Phase 1 clinical trial of AGENT-797 for hematologic malignancies, including multiple myeloma and B cell lymphoma. We selected multiple myeloma (which also expresses CD1d, a key TCR ligand for iNKT cells) and other B cell malignancies as the initial cancer indications for the Phase 1 clinical trial for AGENT-797 because iNKT cells effectively home to the bone marrow, and we believe marrow-invading hematologic malignancies represent promising tumor indications. We also believe that our INTELLIGENT iNKT cells have the potential to persist and function in the absence of lymphodepletion. An allogeneic cell therapy that does not require prior lymphodepletion would have the potential to significantly lower the treatment burden for patients and prevent further deterioration of their immune systems. We believe that our proven ability to purify and expand the iNKT cells in AGENT-797 offers the opportunity to treat more than 100 patients per batch. We currently expect to report data from this Phase 1 clinical trial in the fourth quarter of 2021.

Strategy

Rapidly advance our lead product candidate, AGENT-797, through clinical development. We currently expect to report data from our Phase 1 clinical trials in the fourth quarter of 2021. Should the data support it, we intend to continue rapidly advancing AGENT-797 through clinical development.

Continue to collaborate with Agenus to develop immuno-oncology combination therapies. We intend to continue collaborating with Agenus to develop combination therapies that can join our INTELLIGENT iNKT cell product candidates with the products and product candidates in Agenus' immuno-oncology portfolio. We believe this collaboration will be aided by Agenus' extensive library of immuno-oncology antibodies. For example, we intend to investigate enhancement of the intrinsic bone marrow and tumor homing and killing properties of iNKT cells through co-administration of synthetic glycolipid CD1d ligands and immuno-oncology antibodies from the Agenus portfolio. We anticipate filing an investigational new drug (IND) application for such a combination therapy in the first half of 2021.

Leverage our scalable, cost-efficient manufacturing footprint. We and Agenus have developed and intend to leverage our efficient and scalable manufacturing capabilities for our INTELLIGENT iNKT cells. This manufacturing process uses healthy, donor-derived peripheral blood mononuclear cells (PBMCs) collected by apheresis, which eliminates a key supply bottleneck compared to autologous cell therapies. We believe that this manufacturing process has the potential to allow our product candidates to be developed and, if approved, made available in a significantly more cost-efficient manner for payors and patients.

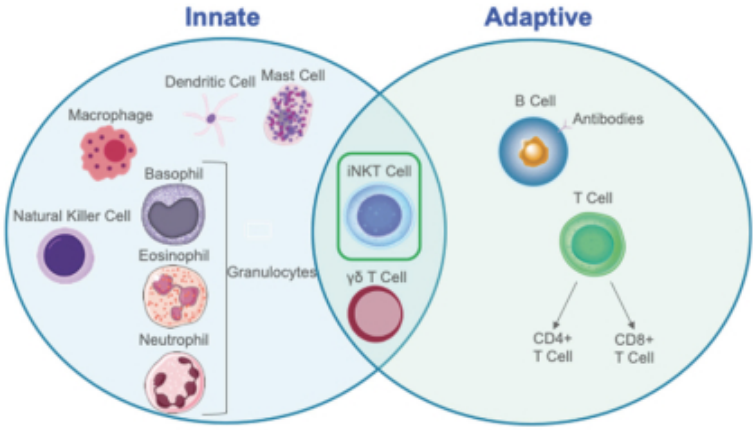
Apply our novel iNKT cell and proprietary CAR, TCR and bispecific iNKT cell-engager engineering platforms to build a broad pipeline of product candidates and combination therapies in additional indications. We have several programs for allogeneic off-the-shelf iNKT cell product candidates with enhanced tumor targeting in preclinical research. We intend to continue using the ability to target iNKT cells, specifically via CARs, TCRs or redirecting bispecific antibodies, to expand our current product pipeline. We believe our proprietary CAR generation platform is capable of discovering and engineering single-chain variable fragment (ScFv) and ligand-based CARs to any surface-expressed tumor antigen. Direct functional selection from a pooled library results in a high number of functional leads, while fully human ScFv libraries impart a lower risk of immunogenicity. Our platform to discover and optimize highly functional TCRs is designed to target any intracellular antigen, peptide or ligand. We believe our pipeline expansion will be aided by our access to a large portfolio of proprietary neo-antigen targets that can be utilized to generate neo-antigen-specific cell therapy products.

Selectively explore strategic partnerships that can maximize the potential of our iNKT cell product candidates and combination therapies. We intend to continue to evaluate iNKT cell technologies in our platform that have the potential to enhance or expand our product candidates and intend to monitor for others that provide a differentiated cell therapy engineering or manufacturing platform. We intend to also evaluate additional opportunities for strategic partnerships that can enhance the development of our existing programs or allow us to expand into new indications. We may also seek to differentiate our platform through in-licensing additional product candidates or technology platforms.

Background on Adoptive Cell Therapy

Immunity, T Cells and iNKT Cells

The immune system is a complex network of soluble factors and cellular components that defends the body against infection and cancer, with two lines of defense: innate immunity and adaptive immunity. Innate immunity is the first immunological mechanism for combating an invading pathogen or diseased cell. It is a rapid immune response, occurring within minutes or hours after infection or cell stress, and has no immunological memory. Adaptive immunity is antigen-dependent and antigen-specific. Though the onset of the adaptive immune response takes days in comparison to innate immunity that only takes minutes or hours, it has the capacity for memory, which enables the host to mount a more rapid and efficient immune response upon subsequent re-exposure to the same pathogen. T cells are key to the adaptive immune response to cancer and infections, and through expression of specific TCRs they recognize antigens displayed on the surface of diseased target cells. Innate-like T cells include natural killer T (NKT) cells and gd T cells.



Immuno-Oncology and Adoptive Cell Therapy

Immuno-oncology has revolutionized cancer treatment by harnessing and redirecting a patient's own immune system to target malignant cells. Immuno-oncology antibodies, such as anti-PD-1 and anti-CTLA-4, are used to modulate and activate a patient's existing immune system, with positive responses in certain previously untreatable patients.

Limitations of Autologous CAR-T Cell Therapy

We believe the limited adoption of autologous CAR-T cell therapies can be traced to several key challenges, most notably the limited number of accessible indications, the high cost of treatment and safety and relapse concerns.

Limited Indications

Adoptive cell therapy for cancer involves the addition of new anti-cancer immune cells to a patient's immune system to directly and effectively, target tumors, rather than relying on the patient's immune system alone. Clinical trials of adoptive cell therapy for cancer initially centered on autologous T cells, and in 2017, the FDA approved the first autologous CAR-T cells therapies, Kymriah® and Yescarta®, for the treatment of select B cell cancers.

CAR-T cell therapies to date have been limited to a subset of hematologic B cell malignancies that are CD19 positive. These CD19 positive B cell malignancies together have an annual incidence rate that represents less than 5% of all newly diagnosed cancers. Furthermore, current approvals are only for relapsed or refractory cases that have limited therapy options due to the higher hurdle for targeting specific extracellular antigens for other tumor types, including all solid tumors. Other leukemia/lymphoma indications and solid tumors are not adequately addressed by current marketed CAR-T cell therapies.

High Cost of Treatment

Autologous CAR-T cell therapy is extremely expensive for payors and patients. Such therapies are priced between $373,000 and $475,000 per treatment. In addition, because of the frequency of severe adverse events associated with current CAR-T cell therapy, inpatient treatment is required, which can add approximately $500,000 in hospital and adjunctive costs per treatment.

Current marketed autologous CAR-T cell therapies are “vein-to-vein” procedures, where the initial cells used for product manufacture are taken from the patient, shipped to the manufacturing location, processed, shipped back, and infused into the same patient as treatment. Complex, dedicated logistics and infrastructure are required to maintain a strict chain of custody and identity from leukapheresis to manufacturing and delivery, which limit the ability to scale and add significant process cost.

Patients who have previously gone through chemotherapy or hematopoietic stem cell transplantation often have damaged or exhausted T cells. Exhausted T cells may not proliferate well during manufacturing or may ultimately have insufficient potency after administration, resulting in incomplete responses or early relapse after administration. Due to manufacturing time and failure, patients can experience disease progression or even die while waiting for the CAR-T cell therapy.

Safety and Relapse Concerns

Safety and relapse rates have also been concerns related to current CAR-T cell therapies. For the first approved CAR-T cell therapies, severe or life-threatening cytokine release syndrome (CRS) was observed in 13% to 49% of patients treated in pivotal clinical trials. CRS, a systemic inflammatory response caused by the cytokines released by infused CAR-T cells, can lead to widespread irreversible organ dysfunction. CRS is the most common type of toxicity caused by CAR-T cells.

Many CAR-T cell therapy relapses are also caused by antigen-negative escape, in which the tumor evolves such that it no longer expresses the target antigen due to intrinsic tumor heterogeneity and immune-editing of the tumor by the therapy. Rare tumor cells that do not express the target are not killed by the therapy, which leads to relapses.

Our Solution: Allogeneic iNKT Cell Therapy

We believe allogeneic iNKT cell therapy has the potential to address many of the key limitations of existing CAR-T cell therapies. We believe these advantages can lead to more patients in the treatment pool and can significantly broaden utilization.

Potential Advantages of Allogeneic iNKT Cell Therapy Compared to Current CAR-T Cell Therapy

Broad Potential Indications

Due to their specific set of intrinsic properties, we believe allogeneic iNKT cells can be utilized in a wide array of disease indications. This includes the B cell malignancies targeted by the first-generation autologous CAR-T products, as well as additional leukemia/lymphoma indications. It also includes solid tumors, which represent significant challenges beyond those presented by B cell malignancies and largely beyond what a first generation autologous CAR-T product can meet.

More Favorable Cost Profile

The “vein-to-vein” nature of autologous CAR-T cell therapies involves substantial logistical planning and cost and has a high risk of product failure. Allogeneic iNKT cell therapy does not require individual, per-patient preparation of clinical grade product on demand. This makes it a “shelf-to-vein” procedure, because it does not require the use of the patients own cells as a starting point to manufacture the treatment. This reduces complexity and cost and also reduces the risk of batch failure impacting patient treatment.

More Favorable Safety and Relapse Rate Profile

Very few serious adverse events have been observed in previous trials using autologous iNKT cells, including only one Grade 3 adverse event out of 33 patients. Notably, no CRS has been observed. We expect that our INTELLIGENT iNKT cells will have a higher level of batch homogeneity and consistency than the autologous iNKT cells used in the clinic to date, which we believe will translate into a similarly favorable, or even improved, safety profile.

In addition, we believe that the use of iNKT cells may offer further benefit over other allogeneic approaches by potentially reducing or eliminating the need for lymphodepletion. Contrary to T cells, we believe that iNKT cells, due to their natural tissue-homing properties, may need less, or no, prior lymphodepletion. An effective allogeneic iNKT cell-based treatment requiring low or no prior lymphodepletion has the potential to offer enormous benefits, clinically as well as economically.

Finally, we believe rate of relapse is likely to be reduced using iNKT cell therapy. Targeted allogeneic iNKT cell therapy can produce many off-the-shelf batches of cells, including against different targets, because the amount of donor cells is not a limiting factor and batches are produced and released ahead of time. This enables the simultaneous targeting of multiple antigens and the ability to adaptively re-dose cells against a different target as the disease progresses.

Key Features of Our INTELLIGENT iNKT Cells

We have set forth below several of the key features of iNKT cells.

Combine Key Features of Innate and Adaptive Immunity

iNKT cells offer significant advantages compared to other allogeneic cell types as they can directly attack tumor cells through both TCR-mediated as well as NK-receptor-mediated mechanisms. In addition to their direct cancer targeting and killing properties, iNKT cells are also powerful orchestrators of the immune responses within the tumor microenvironment (TME).

Potent Cancer Killing

iNKT cells are largely tissue-resident, and a small percentage (less than 1% of circulating T cells) are present in the blood. They have the capacity to mount strong anti-tumor responses both directly and by activating other immune cells, potentiating endogenous NK cells and T cells within the TME.

Naturally Suited for Allogeneic Approaches

Host versus Graft (HvG) response, which governs the rejection of the infused cells by a patient's immune system, and Graft versus Host Disease (GvHD), which is caused by conventional donor αb T-cells present in the graft (e.g. organ-, allogeneic bone marrow transplant or cell therapy) attacking healthy tissue in the recipient, are significant risk factors in organ and allogeneic bone marrow transplants. iNKT cells can be generated in a way that minimizes the potential for HvG response of the infused cells by the host immune system. Additionally, in both clinical and preclinical studies, iNKT cells have been observed to not cause, and to actually actively suppress, GvHD, lowering the safety risks associated with other allogeneic stem cells.

Ability to Tune Activity in Patients

A key distinguishing feature of iNKT cells is their invariant TCR, which can function as a built-in on- and off-switch to provide the opportunity to control the activity of iNKT cells in patients. iNKT cells can be primed for anti-tumor activity using the activating lipid ligand α-Galactosyl-Ceramide (α-GalCer), which

stimulates iNKT cell production of large amounts of cytokines, undergo clonal expansion, and subsequently recruit and activate NK cells, neutrophils, macrophages, dendritic cells (DCs), B cells and T cells for sustained anti-tumor response.

Unlike many other types of cells, iNKT cells express a differentiated receptor in the form of the invariant TCR that functions as a built-in safety switch by allowing for highly specific targeted elimination of iNKT cells with an antibody, if needed. In the event of a serious adverse event or other safety concerns, iNKT cells can be eliminated using an invariant TCR antibody without killing healthy immune cells.

Enhanced Tolerability

We believe that allogeneic iNKT cells may engraft better than other allogeneic cell types and thus require less lymphodepletion. Whereas we believe we will not need high dose lymphodepletion for allogeneic iNKT cells to persist and be effective, we intend to investigate whether varying doses of certain lymphodepletion drugs may further enhance the clinical efficacy of allogeneic iNKT cell therapy while minimizing side effects.

Manufacturing Efficiency and Reliability

Our manufacturing process uses healthy, donor-derived PBMCs collected by apheresis, which eliminates a key supply bottleneck compared to autologous cell therapies. We expect manufacturing costs for iNKT cells to be significantly lower than the estimated manufacturing costs for autologous cell therapies.

Allogeneic cell product batch production also provides the opportunity for more rigorous quality control and release of consistent cell-product by producing large numbers of doses per manufacturing run for both non-engineered and engineered products. Using healthy donor cells as the starting material eliminates the risk that such cells will be exhausted, or damaged, from prior chemotherapy or hematopoietic stem cell transplantation. Advance manufacturing also reduces the risk of batch failure, as every manufacturing run of cells can be more rigorously validated prior to release.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial 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.
- Our short operating history, and the fact that we have not operated as a standalone public company, may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Our business is highly dependent on our INTELLIGENT iNKT cell platform. 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 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.
- 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, or limit the commercial potential of, the product candidates, or result in significant negative consequences following any potential marketing approval.

- The resources Agenus provides us may not be sufficient for us to operate as a standalone company, and we may experience difficulty in separating our resources from Agenus.
- Agenus will continue to own a significant percentage of our common stock after this offering and will be able to exert significant control over 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.
- We contract with third parties for the manufacture of materials for our research programs, preclinical studies and clinical trials and expect to do so for commercialization of any product candidates that we may develop. 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.
- 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, development and commercialization efforts.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see “Risk Factors.”

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (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 this 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 $1.07 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.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We will continue to be a smaller reporting company after this offering until the last day of the fiscal year in which (i) the market value of our stock held by non-affiliates equaled or exceeded $250.0 million as of the prior June 30th and (ii) our annual revenue equaled or exceeded $100.0 million during the such completed fiscal year the market value of our stock held by non-affiliates equaled or exceeded $700.0 million as of the prior June 30th. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Implications of Being a Controlled Company

We are presently a "controlled company" under the Nasdaq Marketplace Rules because Agenus controls a majority of the voting power of our outstanding common stock. As a controlled company, we are entitled to rely on certain exemptions to Nasdaq's corporate governance requirements, including the requirement (i) that a majority of the board of directors consist of independent directors, (ii) to have a governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iii) to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iv) that the compensation committee consider certain independence factors when engaging legal counsel and other committee advisors and (v) for an annual performance evaluation of the governance and compensation committees. We expect to continue to be a controlled company following this offering and for the foreseeable future.

Our Corporate Information

We were incorporated as AgenTus Biosciences Inc. in Delaware in July 2017. We changed our name to AgenTus Therapeutics, Inc. in October 2017. Our principal executive offices are located at 3 Forbes Road, Lexington, MA 02421, and our telephone number is 781-674-4550. Our website is www.agentustherapeutics.com. Information contained on, or that can be accessed through, our website is not part of this prospectus.

The Offering	
Common stock offered by us	shares.
Common stock to be outstanding after this offering	shares (shares if the underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares of common stock from us	We have granted the underwriters an option to purchase up to an aggregate of additional shares of common stock from us at the initial public offering price, less underwriting discounts and commissions, for a period of 30 days after the date of this prospectus.
Use of proceeds	We estimate that our net proceeds from the sale of our common stock in this offering will be approximately $, or $ if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows: (1) approximately $ million to fund the development of AGENT-797 through completion of our planned Phase 1 clinical trial for the treatment of patients with COVID-19-related pneumonia; (2) approximately $ million to fund the IND submission and development of AGENT-797 through completion of our planned Phase 1 clinical trial for the treatment of patients with multiple myeloma and B cell lymphoma; (3) approximately $ million to fund our planned development of our combination study of AGENT-797 with PD-1/CTLA-4 checkpoint inhibitors for the treatment of patients with non-small cell lung cancer, head and neck squamous cell carcinoma and hepatocellular carcinoma; (4) approximately $ million to fund our process validation and manufacturing batches for AGENT-797; and (5) the remainder for working capital and other general corporate purposes, which includes funding for additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company. See "Use of Proceeds."
Risk Factors	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	"AGTS"

The number of shares of common stock to be outstanding following this offering is based on 8,687,500 shares of common stock outstanding as of December 31, 2020. This amount excludes:

- 975,000 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2020 having a weighted average exercise price of $0.017 per share;
- 337,500 shares of common stock available for future issuance under our 2018 Equity Incentive Plan (the 2018 Plan), as of December 31, 2020;
- shares of common stock reserved for issuance under our 2021 Equity Incentive Plan (the 2021 Plan), which will become effective in connection with this offering; and
- shares of common stock reserved for issuance under our 2021 Employee Stock Purchase Plan (the 2021 ESPP), which will become effective in connection with this offering.

Unless otherwise noted, the information in this prospectus assumes:

- a 1-for- reverse stock split effected on , 2021;
- the automatic conversion of all outstanding convertible notes into an aggregate of shares of common stock immediately prior to the closing of this offering;
- no exercise of the outstanding stock options described above;
- no issuance of warrants on or after , 2021;
- no exercise by the underwriters of their option to purchase additional shares; and
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated by-laws upon the closing of this offering.

Summary Consolidated Financial Data

In the tables below, we provide you with our summary financial data for the periods indicated. You should read the following summary financial data together with our consolidated financial statements and the related notes appearing elsewhere in this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2020 and 2019 from our audited financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period.

	For the Years ended December 31,	
	2020	2019
Summary of Operations Data:		
Revenue	$	$ 689,626
Operating Expenses:		
Research and development expense		19,654,135
General and administrative expense		3,828,040
Change in fair value of convertible affiliated note		(508,071)
Operating loss		(22,284,478)
Other expense, net		(1,517,704)
Net loss		(23,802,182)
Net loss per common share, basic and diluted	$	$ (2.75)
Weighted average number of common shares outstanding, basic and diluted		8,645,000
Pro Forma weighted average common shares outstanding, basic and diluted (unaudited)		
Pro Forma net loss per share, basic and diluted (unaudited)		

	As of December 31,		
	2020	Pro Forma (1)	Pro Forma as adjusted (2)
Condensed Consolidated Balance Sheet Data:			
Cash			
Total assets			
Current liabilities			
Convertible affiliated note			
Other long-term liabilities			
Total stockholders' (deficit) equity			

(1) The pro forma balance sheet data give effect to the conversion of our convertible affiliated note based on .

(2) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total assets, and shareholders' (deficit) equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our consolidated financial statements and related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. We have devoted substantially all of our efforts and financial resources in building our INTELLIGENT iNKT cell platform, identifying our current product candidates, conducting preclinical development and initiating clinical trials of AGENT-797. Our net loss was $23.8 million and $ million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of $ 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 from our current research programs;
- seek to develop our INTELLIGENT 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;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent 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;
- acquire or in-license product candidates, intellectual property and technologies; and
- operate as a standalone public company.

We have only recently initiated a Phase 1 clinical trial 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 U.S. Food and Drug Administration (FDA) or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations and, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We will need substantial 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 our 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, upon the closing of this offering, we expect to incur additional 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 to date has been through Agenus. As of December 31, 2020, our cash balance was $ million. We estimate that the net proceeds of this offering will be approximately $ million, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We expect that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for . 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, including purchasers of common stock in this offering, 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, and the fact that we have not operated as a standalone public 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 our services agreement. We have only recently initiated a Phase 1 clinical trial 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 operating history.

Our limited 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. Our very short history as an operating company makes 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. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

There is substantial doubt about our ability to continue as a going concern.

A history of operating losses and negative cash flows from operations combined with our anticipated use of cash to fund operations raises substantial doubt about our ability to continue as a going concern.

Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities or to raise additional capital to finance our operations.

There is no assurance that we will succeed in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

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 (the CARES 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. If we undergo an ownership change in connection with or after this offering, our ability to use our NOLs could be further limited. For these reasons, we may not be able to use a material portion of our NOLs, even if we attain profitability.

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 current Good Manufacturing Processes (cGMP) manufacturing, we have not previously completed any clinical trials or submitted a Biologics License Application (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 trial of AGENT-797 encounters 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 INTELLIGENT 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 investigational new drug (IND) applications 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 a Phase 1 clinical trial, 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 INTELLIGENT 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, TCRs 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 INTELLIGENT iNKT cell platform. All of our product development programs are still

in the research or preclinical stage of development or early stage clinical trials. 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 INTELLIGENT 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 not completed a clinical trial for any of our product candidates. Moreover, there have been only a limited number of clinical trials involving the use of allogeneic 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 (CRS), peripheral neuropathies and adverse events linked to lymphodepleting chemotherapy regimens used in the field prior to administration of cell therapy products. We have also observed a serious adverse event of cardiac arrest in our ongoing AGENT-797 trial in patients with COVID-19 requiring mechanical ventilation and with moderate-to-severe acute respiratory distress syndrome, which was determined by the study investigator to be unrelated to AGENT-797. 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 Risk Evaluation and Mitigation Strategy (REMS), to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. The FDA has required REMS programs for 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 prospectus.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. We have chosen to focus initially on AGENT-797 for the treatment of hematologic malignancies and COVID-19-related pneumonia, and on other product candidates that are in preclinical development. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

The data produced in our clinical trial 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 of preclinical studies for AGENT-797 or any of our other product candidates may not be predictive of future results.

Our Phase 1 clinical trial of AGENT-797 for COVID-19-related pneumonia commenced in October 2020 and we intend to commence a Phase 1 clinical trial of AGENT-797 for hematologic malignancies in January 2021. We do not know at this stage whether patient response data from such trials will be favorable, and initial success in clinical trials may not be indicative of results obtained when such trials are completed. Interim data from clinical trials that we may conduct, including the clinical trials for AGENT-797 in hematologic malignancies and in COVID-19-related pneumonia, 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.

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 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. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

Progression of our product candidates, including AGENT-797, in indications other than cancer and COVID-19-related pneumonia, will depend on the results obtained in preclinical programs. To obtain FDA or other regulatory authority approval to market a new biological product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the EMA or other 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.

Commencing clinical trials in the United States is subject to acceptance by the FDA of INDs and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests, the start of certain of our proposed clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence a clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other jurisdictions, including the European Union.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or

more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in-vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, because standards for preclinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre-IND proposal, the FDA may not accept the IND submission as presented, in which case patient enrollment would be placed on partial or complete hold and treatment of enrolled patients could be discontinued while the product candidate is re-evaluated. Even if clinical trials do begin for our preclinical programs, our clinical trials or development efforts may not be successful.

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.

Our company does not have a sales or marketing infrastructure and has 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.

For example, key competitors developing autologous CAR-T cell therapies include, but are not limited to, Autolus Therapeutics plc, Bristol-Myers Squibb Company (Celgene/Juno Therapeutics), bluebird bio, Inc., Gilead Sciences, Inc. (Kite Pharma), GlaxoSmithKline plc, Immatics N.V., Janssen Pharmaceutica N.V., Novartis AG and Tmunity Therapeutics Inc. Key competitors developing allogeneic T cell therapies include, but are not limited to, Adaptimmune Therapeutics plc, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Cellectis S.A., Celularity, Inc., Celyad Oncology SA, CRISPR Therapeutics AG, Poseida Therapeutics, Inc., Precision BioSciences, Inc. and Takeda Pharmaceutical Company Limited.

Other key competitors include, in the NK cell therapy space, Astellas Pharma Inc., Fate Therapeutics, Inc., Glycostem Therapeutics B.V., Kiadis Pharma N.V., NantKwest, Inc., Nkarta, Inc.; and in the gd T cell therapy space, Adicet Bio, Inc. and GammaDelta Therapeutics Limited. Kuur Therapeutics Limited is a key competitor developing allogeneic cell therapies in the iNKT cell therapy space.

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 the market opportunities for any product candidates we may develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer. We must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth.

We focus our research and product development on treatments for cancer and other life threatening diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with the product candidates we may develop, or may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

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 trial 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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable. For example, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities in response to the COVID-19 pandemic. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions. 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 trial 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.

A decline in the prevalence of COVID-19, such as upon the achievement of herd immunity, will decrease our ability to enroll patients in our clinical trial for COVID-19-related pneumonia.

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 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.

On June 23, 2016, the United Kingdom electorate voted in favor of leaving the European Union, commonly referred to as “Brexit.” The United Kingdom formally left the European Union on January 31, 2020 and a transition period, during which European Union pharmaceutical law remained applicable to the United Kingdom ended on December 31, 2020. Since the regulatory framework for pharmaceutical products in the United Kingdom relating to quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit will materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. Over time the United Kingdom is likely to develop its own legislation that diverges from that in the European Union, but at this time the impact of Brexit remains uncertain and could have an adverse impact on our business.

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 Federal Food, Drug, and Cosmetic Act (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.

The change in presidential administration may dramatically shift the approach to regulatory reform in the United States, making it difficult to predict the effect on the FDA's regulatory oversight and implementation priorities. Any change in regulatory approach has the potential to negatively impact our business.

During the Trump Administration numerous actions, including the issuance of a number of executive orders, were taken that affected the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking or issuances of guidance. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. For fiscal years 2018 and beyond, the executive order required agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and on February 2, 2017, the administration indicated that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. While the Biden Administration is likely to retract such policies and promote more active regulatory and administrative action by agencies, including the FDA, it is unclear exactly how the Biden Administration will structure its priorities, particularly with regard to FDA's oversight, approval, review and regulation of novel biological products. Any change in regulation or regulatory approach, whether it impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course or expand the FDA's regulatory discretion, has the potential to negatively impact our business.

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. Modifications to the Healthcare Reform Act have been implemented under the Trump Administration and additional modifications or repeal may occur. Health care reforms have also been implemented in the wake of the COVID-19 pandemic, such as the expansion in Medicare coverage of telehealth services. There may be additional reforms promulgated by the Biden Administration as, for example, President Biden advocated for action to address the high cost of drugs during his campaign. 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.

Risks Related to Our Relationship with Agenus

The resources Agenus provides us may not be sufficient for us to operate as a standalone company, and we may experience difficulty in separating our resources from Agenus.

Because our operations have not been fully separated from Agenus in the past, we may have difficulty doing so. We will need to acquire resources in addition to, and eventually in lieu of, those provided by Agenus to our company, and may also face difficulty in separating our resources from Agenus' resources and integrating newly acquired resources into our business. In addition, Agenus may prioritize its own research, development, manufacturing and other needs ahead of the services Agenus has agreed to provide us. Agenus employees who conduct services for us may prioritize Agenus' interests over our interests, or Agenus employees we rely upon to provide certain services may leave Agenus. 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.

We will need to replicate or replace certain functions, systems and infrastructure to which we will no longer have the same access after this 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.

Agenus currently performs or supports many important corporate functions for our company. Following this offering, many of these services will be governed by a new services agreement with Agenus. Because our services agreement will be negotiated in the context of a parent-subsidiary relationship, the terms of the agreement, including the fees charged for the services, may be higher or lower than those that would be agreed to by parties bargaining at arm's length for similar services.

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 our services agreement. Additionally, after the 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 following this offering.

Additionally, the historical financial information included in this prospectus does not reflect the results we would have achieved as a standalone public company during the periods presented, and may not be a reliable indicator of our future results.

Agenus will continue to own a significant percentage of our common stock and will be able to exert significant control over matters subject to stockholder approval.

Agenus and its officers and directors currently own over 90% of our common stock and will continue to own a significant percentage of our common stock after this offering is completed. Upon the closing of this offering, Agenus will beneficially own approximately % of the voting power of our outstanding common stock, or approximately % if the underwriters exercise their option to purchase additional common stock from us in full. Therefore, even after this offering, Agenus will have 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 expect to be a "controlled company" within the meaning of the applicable rules of Nasdaq and, as a result, will 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.

Upon the closing of this offering, Agenus will continue to control a majority of the voting power of our outstanding common stock. As a result, we expect to be 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 intend to use these exemptions upon the closing of this offering and we 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.

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.

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. (President and Chairman of the Board), Jennifer S. Buell, Ph.D. (Interim Chief Executive Officer), Brian Corvese (Director) and Ulf Wiinberg (Director) are all officers and/ or directors of Agenus. Additionally, Patrick N. Jordan (Chief Operating Officer) is the son of Agenus director Wadih Jordan. 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 trial 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 have designed the ongoing clinical trial for AGENT-797, and will design any future clinical trials for our product candidates, independent investigators at New York-Presbyterian/Weill Cornell Medical Center are conducting our clinical trial for AGENT-797 in COVID-19-related pneumonia, 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 materials for our research programs, preclinical studies and clinical trials and expect to do so for commercialization of any product candidates that we may develop. 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 do not have any manufacturing facilities at the present time. We currently rely on third-party manufacturers for the manufacture of our materials for preclinical studies and clinical trials. We do not have a long-term supply agreement with any of the third-party manufacturers, and we purchase our required supply on a purchase order basis. Additionally, we are in the process of transferring our manufacturing to a CMO, and we may experience delays or other difficulties associated with such a transition.

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 manufacturer 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.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any product candidates we may develop pose numerous risks to us, including the following:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates we may develop if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

- Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines.
- Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates we may develop.
- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement 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 several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

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 our owned or 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 owned and licensed patent rights. With respect to both in-licensed and owned 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 owned and in-licensed patents and patent applications are, and may in the future be, co-owned by us 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 patent rights and proprietary technology from third parties that are important or necessary to the development 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 are 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 do 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. 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 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 licensors, including Agenus, 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 patents 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 in-licensed patents and patent applications may not provide sufficient protection of our cell-based immunotherapies, our product candidates and our future product candidates or result in any competitive advantage.

We have in-licensed from Agenus a number of U.S. patents and patent applications that claim cell-based immunotherapies. We have filed provisional patent applications or Patent Cooperation Treaty, or PCT, applications intended to specifically protect our cell-based immunotherapies and uses with respect to treatment of particular diseases and conditions, but we do not currently own any U.S. patents. 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.

Our in-licensed patents and patent applications contain composition of matter claims directed to our product candidates, as well as method claims directed to the use of such product candidates in various therapies. 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 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 owned or in-licensed 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 owned or 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 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 or the patents and patent applications we in-license 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 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 licensors are aware, but which we or our 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 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 owned patent applications and 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 patents 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 in-licensed patents and 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 in-licensed 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 or in-license currently or in the future. Upon the expiration of our current in-licensed 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 Agenus and others 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 agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or broaden what we believe to be the scope of the licensor’s rights to our intellectual property and technology, or increase what we believe to be our financial or other obligations under the relevant 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.

We currently have rights to intellectual property, through licenses from third parties, including Agenus, to identify and develop product candidates, and we expect to seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. 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 owned and in-licensed, and other third-party, intellectual property and proprietary rights 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 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 future patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our 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 owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our 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 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 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. Patent term extension (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 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 trade secrets, 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 and trade secret protection, 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 trade secrets or 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, including our trade secrets, and we may not be

able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable.

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, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might have for this type of misconduct may not result in an adequate remedy. In addition, trade secrets 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, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

In addition, some courts inside and outside the United States are sometimes less or not willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 may own 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 in-licensed 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, 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 owned or in-licensed patents, or parts of our owned or in-licensed patents;
- 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 owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- 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 owned or in-licensed issued patents 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 owned or in-licensed 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 Legal Compliance Matters

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.

We are exposed to the risk of fraud or other misconduct by our employees, consultants, and commercial partners, and, if we commence clinical trials, 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 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 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 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 shareholder. 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 trade secrets or other 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. In July 2020, the United States government charged a pair of Chinese hackers working on behalf of China's intelligence service in relation to the hacking of U.S.-based biotechnology companies researching COVID-19 vaccines.

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.

The continuing outbreak of COVID-19 in the United States and other countries may adversely affect our business and that of our suppliers, CROs or other third parties relevant to our business.

The COVID-19 pandemic is impacting worldwide economic activity, particularly economic activity in the United States, and poses the risk that we or our employees, contractors, suppliers, or other partners may be prevented or delayed from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The continued prevalence of COVID-19 and the measures taken by the governments of countries affected could disrupt our supply chain and manufacturing, cause diversion of healthcare resources away from the conduct of preclinical and clinical trial matters to focus on pandemic concerns, limit travel in a manner that interrupts key trial activities, such as trial site initiations and monitoring, delay regulatory filings with regulatory agencies in affected areas or adversely affect our ability to obtain regulatory approvals. These disruptions could also affect other facets of our business, including but not limited to:

- our ability to recruit employees from outside of the United States;
- the ability of our employees to travel between our facilities in the United States and the United Kingdom;
- the ability of our CROs to conduct preclinical studies in countries outside of the United States;
- our ability to import materials from outside of the United States; and
- our ability to export materials to our CROs and other third-parties located outside of the United States.

The COVID-19 pandemic and mitigation measures also may have an adverse impact on global economic conditions, which could adversely impact our business, financial condition or results of operations. Additionally, the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past as a result of the COVID-19 outbreak could have an adverse effect on our ability to access capital and on the market price of our common stock.

In March 2020, we put in place a number of protective measures in response to the COVID-19 pandemic. These measures include cancelling all commercial business travel, requesting employees to limit non-essential personal travel, asking some employees to self-quarantine at home, adjusting our facilities janitorial and sanitary policies, encouraging employees to work from home to the extent their job function enables them to do so, staggering the working hours of employees that are unable to perform their duties remotely and reconfiguring our facilities for physical distancing. We are revisiting these measures on a regular basis as the pandemic evolves, and we are likely to take additional action as we learn more and as instruction is provided by national, state and local governmental agencies. These measures have resulted, and any future actions are likely to result, in a disruption to our business. Our employees are also impacted by the closures of their children's schools for lengthy periods of time. For instance, in Massachusetts, all public and private elementary and secondary schools were closed for the duration of the 2019-2020 academic year, leaving many of our employees with no choice but to work from home while also caring for their children, which caused a loss in employee productivity. We expect this state of affairs to continue for the duration of the pandemic. In addition, in March 2020, the United States government announced that it would suspend air travel between the United States and parts of Europe for a 30-day period and subsequently revised this suspension to include the United Kingdom, where we have an office and employees. Starting in July 2020, the European Union banned entry by travelers from the United States, and, at present, the United Kingdom is requiring travelers from the United States self-quarantine for 10 days after arrival. In the event the governments in these jurisdictions further extend their shelter in place orders, travel bans or otherwise prohibit employees from going to work for a longer period of time, our business will be disrupted and our programs and timelines are likely to be delayed, depending on the ultimate length and severity of the mandate. Not all of our employees are able to perform their duties remotely.

Risks Related to this Offering and Ownership of Our Common Stock

We do not know whether a market will develop for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Before this offering, there was no public trading market for our common stock. If a market for our common stock does not develop or 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.

You will incur immediate and substantial dilution as a result of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $ per share, representing the difference between the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma net tangible book value per share after giving effect to this offering. Moreover, we issued options in the past that allow the holders to acquire common stock at prices significantly below the assumed initial public offering price. As of , 2021, there were shares subject to outstanding options with a weighted-average exercise price of $ per share. To the extent that these outstanding options are ultimately exercised or the underwriters exercise their option to purchase additional shares, you will incur further dilution. For a further description of the dilution you will experience immediately after this offering, see "Dilution."

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. After this offering, we will have shares of common stock outstanding, or shares if the underwriters exercise their option to purchase additional shares in full, in each case based on the shares of our common stock outstanding as of , 2021. Of these shares, the shares (or shares if the underwriters exercise their option to purchase additional shares in full) we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. 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 and the lock-up agreements described in the "Underwriting" section of this prospectus. 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. In connection with this offering, we intend to begin 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 will 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. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. 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 will become effective upon the closing of this 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;
- 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 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;
- specify that no stockholder is permitted 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 purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. 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;
- the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread;
- 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. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. 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.

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 in this offering 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 will incur increased costs as a result of operating as a standalone public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

We have historically operated our business as part of a public company. As a standalone public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we have not incurred historically. 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 becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will 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 obtain 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.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in "Use of Proceeds." Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- our ability to demonstrate, and the timing of, preclinical proof-of-concept *in-vivo* for multiple programs;
- our ability to advance any product candidates that we may develop and successfully complete clinical trials;
- our ability to quickly leverage our initial programs and to progress additional programs to create a clinical portfolio;
- the implementation of our strategic plans for our business, programs, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments related to our competitors and our industry;
- our ability to maintain our collaborative relationship with Agenus, as well as our ability to identify and enter into future license agreements and collaborations;
- regulatory developments in the United States and foreign countries;
- our ability to attract and retain key scientific and management personnel; and
- our use of proceeds from this offering, estimates of our expenses, capital requirements and needs for additional financing.

The forward-looking statements in this prospectus are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

Use of Proceeds

We estimate that the net proceeds to us from the sale of the shares of common stock in this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, based upon an assumed initial price to the public of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by approximately $, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of December 31, 2020, we had a cash balance of $. The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and to facilitate our access to the public equity markets.

We currently expect to use the net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities, as follows:

- approximately $ million to fund the development of AGENT-797 through completion of our planned Phase 1 clinical trial for the treatment of patients with COVID-19-related pneumonia;
- approximately $ million to fund the IND submission and development of AGENT-797 through completion of our planned Phase 1 clinical trial for the treatment of patients with multiple myeloma and B cell lymphoma;
- approximately $ million to fund our planned development of our combination study of AGENT-797 with PD-1/CTLA-4 checkpoint inhibitors for the treatment of patients with non-small cell lung cancer, head and neck squamous cell carcinoma and hepatocellular carcinoma;
- approximately $ million to fund our process validation and manufacturing batches for AGENT-797; and
- the remainder for working capital and other general corporate purposes, which includes funding for additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company.

We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

Capitalization

The following table summarizes our cash, cash equivalents and marketable securities and capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis, to reflect the effectiveness of our amended and restated certificate of incorporation; and
- on a pro forma as adjusted basis, to further reflect the sale and issuance by us of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses.

You should read the information in this table together with the consolidated financial statements and related notes to those statements, as well as the information set forth under the headings "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of December 31, 2020		
(in thousands, except per share amounts)	Actual	Pro forma	Pro forma as adjusted
Cash	$	$	$
Stockholders' equity:			
Common stock ($0.00001 par value; actual: 10,000,000 shares authorized, 8,687,500 shares issued and outstanding; pro forma: shares authorized, shares issued and shares outstanding; pro forma as adjusted: shares authorized, shares issued, and shares outstanding)			
Additional paid-in capital			
Accumulated deficit			
Total stockholders' (deficit) equity	$	$	$
Total capitalization	$	$	$

Each $1.00 increase (decrease) in the assumed initial price to the public of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash, cash equivalents, and marketable securities, additional paid-in capital, total stockholders' deficit and total capitalization on a pro forma as adjusted basis by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) each of cash, cash equivalents, and marketable securities, additional paid-in capital, total stockholders' deficit and total capitalization on a pro forma as adjusted basis by approximately $, assuming that the assumed initial price to the public remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial price to the public and other terms of this offering determined at pricing.

The outstanding share information in the table above excludes as of December 31, 2020:

- 975,000 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2020 having a weighted average exercise price of $0.017 per share;
- 337,500 shares of common stock available for future issuance under the 2018 Plan as of December 31, 2020;

- shares of common stock reserved for issuance under the 2021 Plan, which will become effective in connection with this offering; and
- shares of common stock reserved for issuance under the 2021 ESPP, which will become effective in connection with this offering.

Dilution

If you invest in our common stock in this offering, you will experience immediate and substantial dilution in the pro forma as adjusted net tangible book value of your shares of common stock. Dilution in pro forma as adjusted net tangible book value represents the difference between the assumed initial price to the public per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Net tangible book value (deficit) per share represents our total tangible assets, less total liabilities divided by the number of shares of outstanding common stock as of December 31, 2020, or 8,687,500 shares. The historical net tangible deficit of our common stock as of December 31, 2020 was $, or $ per share. Our pro forma net tangible book value as of December 31, 2020 was $, or $ per share.

After giving effect to our sale of shares of common stock in this offering at an assumed initial public offering price $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been approximately $, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders and an immediate dilution of $ per share to investors participating in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share		$
Historical net tangible deficit per share of common stock as of December 31, 2020	$	
Increase per share in net tangible book value per share of common stock attributable to pro forma adjustments		
Pro forma net tangible book value per share of common stock as of December 31, 2020		
Increase in net tangible book value per share of common stock attributable to this offering		
Pro forma as adjusted net tangible book value per share of common stock after this offering		
Dilution per share of common stock to new investors participating in this offering		$

Each $1.00 increase (decrease) in the assumed initial price to the public of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value by approximately $, or approximately $ per share, and increase (decrease) the dilution per share to investors participating in this offering by approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses. We may also increase or decrease the number of shares we are offering. An increase of 1,000,000 in the number of shares offered by us would increase the pro forma as adjusted net tangible book value by approximately $, or $ per share, and the dilution per share to investors participating in this offering would be $ per share, assuming that the assumed initial price to the public remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses. Similarly, a decrease of 1,000,000 shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value by approximately $, or $ per share, and the dilution per share to investors participating in this offering would be $ per share, assuming that the assumed initial price to the public remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial price to the public and other terms of this offering determined at pricing.

If the underwriters exercise in full their option to purchase additional shares of common stock from us in this offering, our pro forma as adjusted net tangible book value per share after the offering would be $, and the dilution per share to new investors would be $, in each case assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on the pro forma as adjusted basis as of December 31, 2020, the differences between the number of shares of common stock purchased from us, the total consideration paid to us in cash and the average price per share paid by existing stockholders and by investors participating in this offering. The table below excludes shares for which no cash consideration was received.

	Shares purchased		Total consideration		
	Number	Common Percent	Amount	Percent	Average price per share
Existing stockholders		%	$	%	$
New investors		%		%	$
Total		100%	$	100%	

In addition, if the underwriters' option to purchase additional shares is exercised in full, the number of shares held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding upon completion of this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to % of the total number of shares of common stock to be outstanding upon completion of the offering.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) total consideration paid by new investors by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares offered by us would increase (decrease) total consideration paid by new investors by $, assuming that the assumed initial price to the public remains the same.

The outstanding share information in the tables above excludes:

- 975,000 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2020 having a weighted average exercise price of $0.017 per share;
- 337,500 shares of common stock available for future issuance under the 2018 Plan as of December 31, 2020;
- shares of common stock reserved for issuance under the 2021 Plan, which will become effective in connection with this offering; and
- shares of common stock reserved for issuance under the 2021 ESPP, which will become effective in connection with this offering.

Furthermore, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. New investors will experience further dilution if any of our outstanding options are exercised, new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities for lower consideration per share than in this offering in the future.

Selected Financial Data

The following tables set forth, for the periods and as of the dates indicated, our selected historical financial data. We have derived the condensed consolidated statement of operations data for each of the years in the two-year period ended December 31, 2020 and the condensed consolidated balance sheet data set forth below as of December 31, 2020 and 2019, from our audited consolidated financial statements included elsewhere in this prospectus.

Our historical results are not necessarily indicative of the results that should be expected for any future period. You should read the selected condensed consolidated financial data in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," our consolidated financial statements, and the notes to our consolidated financial statements included elsewhere in this prospectus.

	For the Years ended December 31,	
	2020	2019
Condensed Consolidated Statement of Operations Data:		
Revenue	$	$ 689,626
Research and development expense		19,654,135
General and administrative expense		3,828,039
Net loss		(23,802,182)
Net loss per common share, basic and diluted	$	$ (2.75)
Weighted average number of common shares outstanding, basic and diluted		8,645,000

	As of December 31,	
	2020	2019
Condensed Consolidated Balance Sheet Data:		
Total assets	$	$ 1,308,919
Convertible affiliated note		26,790,402
Other long-term liabilities		3,433,376
Stockholders' deficit		(36,333,760)

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus.

Overview

We are a clinical stage biopharmaceutical company developing iNKT cell therapies to treat cancer and other life-threatening illnesses. Our INTELLIGENT iNKT cells are designed to have the innate capacity to home to the site of diseased tissue, including cancer, and recruit key components of the immune system to fight disease. iNKT cells combine properties of both T and NK cells and can also tune their response based on individual elements of the tumor or disease microenvironment. Our development pipeline includes off-the-shelf iNKT cell product candidates to treat hematologic and solid tumors. We believe these product candidates have the potential to help us treat a significantly larger patient population than is currently served by autologous CAR-T cell therapy.

Our business activities include product research and development, manufacturing, regulatory and clinical affairs, corporate finance and development, and support of our collaborations. Our product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Certain AgenTus operations are fully integrated with Agenus, including the regulatory and clinical affairs, finance, human resources and legal functions. We are party to an Intercompany License and Services Agreement under which (i) we were granted a non-exclusive, field-limited, nontransferable license to our intellectual property assets, (ii) Agenus is to perform research and business services to support our operations on a cost plus basis and (iii) we are to perform research services for Agenus, also on a cost plus basis.

In January 2021, we intend to commence a Phase 1 clinical trial of AGENT-797 for the treatment of hematologic malignancies, including multiple myeloma and B cell lymphoma. We commenced a Phase 1 clinical trial of AGENT-797 for the treatment of COVID-19-related pneumonia in October 2020. We currently expect to report data from both of these Phase 1 clinical trials in the fourth quarter of 2021. Should the data support it, we intend to rapidly continue advancing AGENT-797 through clinical development in both indications.

Our research and development expenses for the year ended December 31, 2019, were $19.7 million. We have incurred losses since our inception. As of December 31, 2019, we had an accumulated deficit of $36.5 million.

To date we have been reliant on Agenus to finance our operations. We expect to continue to incur operating losses and negative cash flows for the foreseeable future. Until we are successful in our efforts for capital infusion, and because the completion of such is not entirely within our control, a substantial doubt exists about our ability to continue as a going concern for a period of one year after the date of filing of these financial statements. Management continues to address our liquidity position and will adjust spending as needed in order to preserve liquidity. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities.

Historical Results of Operations

Year Ended December 31, 2019

Research and Development Programs

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions. 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 $36.5 million as of December 31, 2019. 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. To date, we have been reliant on Agenus to finance our operations. From our inception through December 31, 2019, we received funding of $25.3 million from Agenus.

As of December 31, 2019, we had a Convertible Note (the Note), outstanding of $25.3 million in principal plus accrued and unpaid interest of $2.0 million payable in cash or equity shares at Agenus' election upon certain triggering events described in the Note. In addition, we had $3.4 million in other long-term liabilities related to a repayable advance received for which the timing of settlement is uncertain.

Our cash balance at December 31, 2019 was $299,000. Until we are successful in our efforts for capital infusion, which is not entirely within our control, a substantial doubt exists about our ability to continue as a going concern for a period of one year after the date of filing of these financial statements. In addition, the ability of Agenus to continue to provide financial support is dependent on its ability to secure additional funding. Management continues to address our liquidity position and will adjust spending as needed in order to preserve liquidity. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities.

Net cash used in operating activities for the year ended December 31, 2019 was $14.9 million. 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 "Special Note Regarding Forward-Looking Statements" and the risks highlighted under "Risk Factors" of this prospectus.

Inflation

We believe that inflation has not had a material adverse effect on our business, results of operations or financial condition to date.

Off-Balance Sheet Arrangements

At December 31, 2019, we had no off-balance sheet arrangements.

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 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.

The following is not intended to represent all of our accounting policies. Our significant accounting policies are described in Note 2 of the notes to our consolidated financial statements contained elsewhere in this prospectus. In many cases, the accounting treatment of a particular transaction is dictated by U.S. generally accepted accounting principles, 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. We have identified the following as our critical accounting policy.

Fair Value Measurements

In accordance with the Fair Value Option subsection of Accounting Standards Codification (ASC) 825, *Financial Instruments - Overall*, we measure the Note at fair value. In accordance with ASC 820, *Fair Value Measurements and Disclosures*, we measure fair value based on a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. We measured the Note using a scenario based present value methodology which was derived by evaluating the nature and terms of each note and considering the prevailing economic and market conditions at the balance sheet date.

Recent Accounting Pronouncements

Refer to Note 2 to our consolidated financial statements included within this prospectus 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 this 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 $1.07 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.

Business

We are a clinical stage biopharmaceutical company developing allogeneic invariant natural killer T (iNKT) cell therapies to treat cancer and other life-threatening illnesses. Our iNKT cells, which we refer to as INTELLIGENT iNKT™ cells, are designed to have the innate capacity to home to the site of diseased tissue, including cancer, and recruit key components of the immune system to fight disease. iNKT cells combine properties of both T and natural killer (NK) cells and can also tune their response based on individual elements of the tumor or disease microenvironment. Our development pipeline includes off-the-shelf iNKT cell product candidates to treat hematologic and solid tumors. We believe these product candidates have the potential to help us treat a significantly larger patient population than is currently served by autologous CAR-T cell therapy.

Our platform is designed to facilitate scalable iNKT cell manufacturing, novel cancer target identification, and engineering for precision targeting and functional enhancement. Through our collaboration with our parent company, Agenus Inc. (Agenus), we have developed an iNKT cell engineering and targeting platform built on Agenus' antibody engineering capabilities. This includes novel proprietary technologies for CARs, TCRs and bispecific iNKT cell-engagers. We believe Agenus' portfolio of novel immuno-oncology antibodies provides a differentiated opportunity for development of combination therapies. We intend to leverage our iNKT cell manufacturing capabilities to enable efficient, scalable and reproducible batches of our INTELLIGENT iNKT cells for off-the-shelf delivery. Our manufacturing process is designed to improve the persistence of iNKT cells for sustained activity after administration.

The following table summarizes our current product development pipeline:

Mechanism/ Target	Product	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Unmodified INTELLIGENT iNKT Cells						
Hematologic Malignancies	AGENT-797					Phase 1 Readout in Q4 '21
COVID-19-Related Pneumonia						Phase 1 Readout in Q4 '21
NSCLC, HNSCC, HCC	AGENT-797 + PD-1/CTLA-4					IND Filing H1 '21
Targeted INTELLIGENT iNKT Cells						
Multiple Undisclosed CARs – Solid Tumors						
Undisclosed Bispecific iNKT Cell Engager						
PTT TCRs						

Our most advanced product candidate is AGENT-797, an allogeneic unmodified iNKT cell therapy derived from healthy donors. In January 2021, we intend to commence a Phase 1 clinical trial of AGENT-797 for hematologic malignancies, including multiple myeloma and B cell lymphoma. We selected multiple myeloma (which also expresses CD1d, a key TCR ligand for iNKT cells) and other B cell malignancies as the initial cancer indications for the Phase 1 clinical trial for AGENT-797 because iNKT cells effectively home to the bone marrow, and we believe marrow-invading hematologic malignancies represent promising tumor indications. We also believe that allogeneic unmodified iNKT cells have the potential to persist and function in the absence of lymphodepletion. An allogeneic cell therapy that does not require prior lymphodepletion would have the potential to significantly lower the treatment burden for patients and prevent further deterioration of their immune systems. We believe

that our proven ability to purify and expand the iNKT cells in AGENT-797 offers the opportunity to treat more than 100 patients per batch. We currently expect to report data from this Phase 1 clinical trial in the fourth quarter of 2021.

We also commenced a Phase 1 clinical trial of AGENT-797 for the treatment of COVID-19-related pneumonia in October 2020. We chose to pursue this indication due to the potential benefits of allogeneic immune cell therapy in treating COVID-19-related pneumonia, the magnitude of the public health burden of COVID-19 and the lack of existing therapeutic options for patients with severe COVID-19 symptoms. Patients hospitalized with COVID-19 admitted to the intensive care unit often have reduced and impaired innate and adaptive immune cells, with a majority of such patients developing acute respiratory distress syndrome. iNKT cells promote viral clearance and increase secondary anti-viral responses, offering the potential to control inflammation and limit lung tissue damage resulting from COVID-19-related pneumonia. We currently expect to report data from this trial in the fourth quarter of 2021.

We are developing other preclinical allogeneic off-the-shelf iNKT cell product candidates using iNKT cell tumor targeting and activation to expand the range of indications addressable with our INTELLIGENT iNKT cell therapies. We are utilizing our and Agenus' extensive antibody knowledge and proprietary mammalian display screening platforms for identification of CAR candidates that further enhance inherent iNKT cell capabilities for targeting solid tumors, an area not well served by current autologous CAR-T cell therapies. In addition, we are using our proprietary humanized iNKT-TCR binding antibodies to develop a portfolio of bispecific antibody-based iNKT cell engagers that we believe can further increase targeting and activation of iNKT cells for treatment of leukemia and lymphoma.

Our Strategy

Our goal is to develop and commercialize iNKT cell therapies to treat cancer and other life-threatening illnesses. Our strategy to achieve this mission is as follows:

Rapidly advance our lead product candidate, AGENT-797, through clinical development. We commenced a Phase 1 clinical trial of AGENT-797 for the treatment of COVID-19-related pneumonia in October 2020. We currently expect to report data from our Phase 1 clinical trials in the fourth quarter of 2021. Should the data support it, we intend to rapidly continue advancing AGENT-797 through clinical development and to pursue other indications of AGENT-797 in other life-threatening diseases and cancers.

Continue to collaborate with Agenus to develop immuno-oncology combination therapies. We intend to continue collaborating with Agenus to develop combination therapies that can join our INTELLIGENT iNKT cell product candidates with the products and product candidates in Agenus' immuno-oncology portfolio. We believe this collaboration will be aided by Agenus' extensive library of immuno-oncology antibodies. For example, we intend to investigate enhancement of the intrinsic bone marrow and tumor homing and killing properties of iNKT cells through co-administration of synthetic glycolipid CD1d ligands and immuno-oncology antibodies from the Agenus portfolio. We anticipate filing an investigational new drug (IND) application for such a combination therapy in the first half of 2021.

Leverage our scalable, cost-efficient manufacturing footprint. We and Agenus have developed and intend to leverage our efficient and scalable manufacturing capabilities for our INTELLIGENT iNKT cells. This manufacturing process uses healthy, donor-derived PBMCs collected by apheresis, which eliminates a key supply bottleneck compared to autologous cell therapies. We believe that this manufacturing process has the potential to allow our product candidates to be developed and, if approved, made available in a significantly more cost-efficient manner for payors and patients.

Apply our INTELLIGENT iNKT cell and proprietary CAR, TCR and bispecific iNKT cell-engager engineering platforms to build a broad pipeline of product candidates and combination therapies in

additional indications and potentially identify new disease targets. We have several programs for allogeneic off-the-shelf iNKT cell product candidates with enhanced tumor targeting in preclinical research. We intend to continue using the ability to target iNKT cells, specifically via CARs, TCRs or redirecting bispecific antibodies, to expand our current product pipeline. We believe our proprietary CAR generation platform is capable of discovering and engineering single-chain variable fragment (ScFv) and ligand-based CARs to any surface-expressed tumor antigen. Direct functional selection from a pooled library results in a high number of functional leads, while fully human ScFv libraries impart a lower risk of immunogenicity. Our platform to discover and optimize highly functional TCRs is designed to target any intracellular antigen, peptide or ligand. We believe our pipeline expansion will be aided by our access to a large portfolio of proprietary neo-antigen targets that can be utilized to generate neo-antigen-specific cell therapy products.

Selectively explore strategic partnerships that can maximize the potential of our INTELLIGENT iNKT cell product candidates and combination therapies. We intend to continue to evaluate iNKT cell technologies and platforms that have the potential to enhance or expand our product candidates and intend to monitor for others that provide a differentiated cell therapy engineering or manufacturing platform. We intend to also evaluate additional opportunities for strategic partnerships that can enhance the development of our existing programs or allow us to expand into new indications. We may also seek to differentiate our platform through in-licensing additional product candidates or technology platforms.

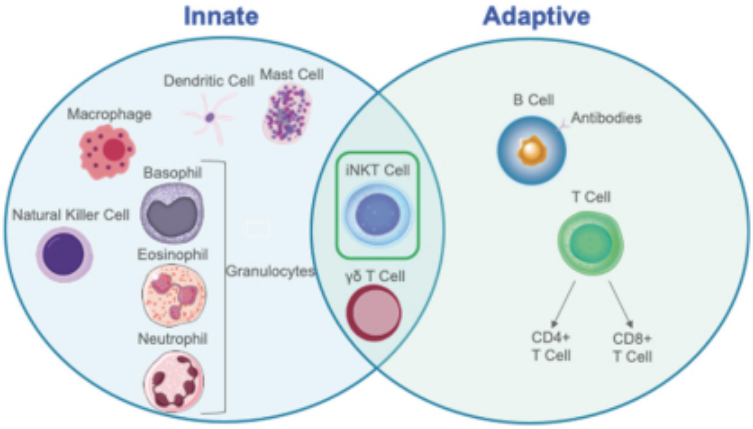
Background on Adoptive Cell Therapy

Immunity, T Cells and iNKT Cells

The immune system is a complex network of soluble factors and cellular components that defends the body against infection and cancer, with two lines of defense: innate immunity and adaptive immunity.

- Innate immunity is the first immunological mechanism for combating an invading pathogen or diseased cell. It is a rapid immune response, occurring within minutes or hours after infection or cell stress, and has no immunological memory. Innate immunity relies on swift recognition of molecular signatures common among pathogens and stressed or infected body cells by germline-encoded immunoreceptors. The cellular component of innate immunity is comprised of DCs, NK cells, macrophages, mast cells, neutrophils, basophils and eosinophils.
- Adaptive immunity is antigen-dependent and antigen-specific. Though the onset of the adaptive immune response takes days in comparison to innate immunity that only takes minutes or hours, it has the capacity for memory, which enables the host to mount a more rapid and efficient immune response upon subsequent re-exposure to the same pathogen. Adaptive immunity is mediated by B cells and T cells, where each individual cell expresses a specific receptor with the potential to recognize a specific pathogen- or cancer- derived antigen. Such receptors are tailor-made by sequential recombination of gene fragments, generating an extreme receptor diversity that could otherwise not be encoded in the genome. The ability of T cells to seek and destroy diseased cells has made them the prime focus in adoptive immunotherapy approaches.

T cells are key to the adaptive immune response to cancer and infections, and through expression of specific TCRs they recognize antigens displayed on the surface of diseased target cells. The diversity of TCRs arising from gene rearrangements allows TCRs to be generated against a virtually unlimited number of antigens. Though this system arose to target the unique peptide antigen repertoire of pathogens and cancers, it has evolved the capacity to generate and select receptors recognizing common stress- and infection-related molecules presented on the cell surface. This led to the evolution of specialized “innate-like” T cell populations which, akin to the cells of the innate immune system, detect molecular markers common among pathogens, infected cells, and cancer, such as lipids or metabolites. Such specialized innate-like T cells demonstrate additional innate characteristics underscoring their hybrid phenotype, such as the expression of innate immunoreceptors and the ability to rapidly respond to cell stress caused by cancer and infections. Innate-like T cells include natural killer T (NKT) cells and gd T cells.



NKT cells comprise a family of specialized innate-like T cells that recognize lipid antigens presented by the monomorphic major histocompatibility complex (MHC)-I-like CD1d molecule. NKT cells are divided into two distinct subsets: type I and type II.

- Type I NKT cells, also known as iNKT cells, use an invariant TCR α-chain and recognize the glycolipid α-GalCer, as well as other exogenous and endogenous glycolipids. iNKT cells recognize endogenous and bacterially-derived glycolipids presented by CD1d, but beyond a number of microbial glycolipids the specific stress-related endogenous glycolipids recognized by iNKT cells remain largely unknown. iNKT cells contribute to natural anti-tumor responses through their IFN-g-production and the subsequent activation of DCs, NK cells and cytotoxic T lymphocytes, and their presence within tumors correlates with favorable prognosis in multiple cancers.
- Type II NKT cells use an αb TCR repertoire that is more diverse than that of iNKT cells, and do not recognize α-GalCer. A major subset of type II NKT cells recognize self-lipid antigens, and therefore help maintain tolerance to self-antigen and prevent autoimmunity. In cancer, activated type II NKT cells are known to repress anti-tumor immunity both by abrogating iNKT cell activation and by promoting the immunoinhibitory activities of myeloid-derived suppressor cells.

Both types of NKT cells are potent immunoregulators, though often in opposing ways, with iNKT cells enhancing pro-inflammatory immunity and type II NKT cells mediating anti-inflammatory responses in general. We focus on the development of iNKT cell therapies for fighting cancer and other life-threatening diseases. iNKT cells have been explored clinically for nearly two decades, with a promising safety and activity profile.

iNKT cells reside predominantly in tissues, with a small fraction of the tissue-resident iNKT cells circulating in the blood. We have developed an efficient procedure for isolating of the blood-circulating fraction of iNKT cells, which forms the starting point of our manufacturing process.

Immuno-Oncology and Adoptive Cell Therapy

Immuno-oncology has revolutionized cancer treatment by harnessing and redirecting a patient's own immune system to target malignant cells. Immuno-oncology antibodies, such as anti-PD-1 and anti-CTLA-4, are used to modulate and activate a patient's existing immune system, with positive responses in certain previously untreatable patients. Despite advancements such as anti-CTLA-4 monoclonal antibody (mAb) Yervoy® (ipilimumab), approved by the FDA in 2011, followed by the anti-PD-1 antibodies Opdivo® (nivolumab) and Keytruda® (pembrolizumab) in 2014, and a library of different immuno-oncology modalities that have since been developed, including bispecific antibodies, agonistic antibodies and antibody drug conjugates. Checkpoint inhibitors are effective in only 15% to 40% of patients with responding cancer indications, leaving 60% to 85%

of such patients in need of more effective therapeutic options, in addition to those patients who relapse after checkpoint inhibitor therapy. Furthermore, many cancer patients have compromised immune systems that cannot be effectively activated by immuno-oncology antibodies alone.

Adoptive cell therapy for cancer involves the addition of new anti-cancer immune cells to a patient's immune system to directly and effectively target tumors, rather than relying on the patient's immune system alone. Clinical trials of adoptive cell therapy for cancer initially centered on autologous T cells, and in 2017, the FDA approved the first CAR-T cell therapies, Kymriah® and Yescarta®, for the treatment of select B cell cancers. Previously incurable refractory cancers can now reproducibly achieve durable remissions. However, existing commercial therapies are autologous and derived from a patient's own cells, which require a complex and individualized manufacturing and logistics process for every patient. Additionally, the vast majority of cancers still have no cell therapy option and multiple challenges restrict the wider adoption of autologous adoptive cell therapy, even in approved indications. As a result, adoptive cell therapy currently represents 3% of the overall sales of the immuno-oncology market. Immuno-oncology antibodies, which have efficacy in previously difficult-to-treat tumors as well as off-the-shelf dosing and significant label expansions, currently dominate the immuno-oncology market. Merck's anti-PD-1 monoclonal antibody, Keytruda®, accounted for over $11.0 billion of sales in 2019, while CAR-T cell therapy represented sales of approximately $730.0 million.

While the vast majority of cancers still have no cell therapy option, a new generation of allogeneic adoptive cell therapies that can selectively target both hematologic and solid tumors have the potential to significantly expand the treatable patient pool. Developing an allogeneic adoptive cell therapy for cancer may enable improved quality, scalability and patient access as compared to the currently available first-generation autologous CAR-T cell therapies. Research forecasts estimate that the T cell immunotherapy market will grow significantly if improvements and indication expansions can increase the potentially treatable patient pool, with a predicted 26-fold increase in market size in the next ten years. This expansion assumes that new products can be dosed off-the-shelf and will be less expensive than existing therapies, have better safety and tolerability, and persist for improved efficacy. With these improvements, the market for T cell immunotherapy is forecasted to generate sales of over $26.0 billion by 2030.

Limitations of Autologous CAR-T Cell Therapy

We believe the limited adoption of autologous CAR-T cell therapies can be traced to several key challenges, most notably the limited number of accessible indications, the high cost of treatment, and safety and relapse concerns.

Limited Indications

Autologous CAR-T cell therapies to date have been limited to a subset of hematologic B cell malignancies that are CD19 positive. CD19 is a molecule that is highly expressed on these tumors, but also on most normal B cells in the blood, which makes it more difficult to only target the cancerous cells. Specifically adult diffuse large B cell lymphoma, mantle cell lymphoma, and pediatric and young adult acute lymphocytic leukemia (ALL) are addressed by these therapies. These CD19 positive B cell malignancies together have an annual incidence rate that represents less than 5% of all newly diagnosed cancers. Furthermore, current approvals are only for relapse or refractory cases that have limited other effective therapy options due to the higher hurdle for targeting specific extracellular antigens for other tumor types, including all solid tumors. Since CD19-expressing normal B cells can be eliminated with minimal adverse events, this represented the simplest, most straightforward target for first generation CAR-T cell therapies. Many of the cell-therapies currently under development are targeting B cell malignancies, with the majority targeting CD19, and also an additional B cell target, B cell maturation antigen. Other leukemia/lymphoma indications and solid tumors are not adequately addressed by current marketed CAR-T cell therapies. Solid tumors are more difficult for T cells to get into, and also actively suppress T cell activity. This leaves large areas of unmet medical need.

High Cost of Treatment

Autologous CAR-T cell therapy is extremely expensive for payors and patients. For example, Kymriah®, Yescarta® and Tecartus™ are priced between $373,000 and $475,000 per cell therapy treatment alone. In addition, because of the frequency of severe adverse events associated with current marketed CAR-T cell therapies, inpatient treatment is required, which can add approximately $500,000 in hospital and adjunctive costs per treatment. We believe the high cost of treatment has resulted in restricted access by payors, both private and public, which is particularly acute in geographies with nationalized payor systems that have pharmacoeconomic benefit thresholds for reimbursement. In the United States, challenges in accessing CAR-T cell therapy have arisen because hospitals bear the cost burden of treatment, due to inadequate reimbursement rates for adjunctive management under Medicare.

Manufacturing and administration of CAR-T cell therapies contribute significantly to these high costs. Current marketed autologous CAR-T cell therapies are “vein-to-vein” procedures, where the initial cells used for product manufacture are taken from the patient, shipped to the manufacturing location, processed, shipped back, and infused into the same patient as treatment. Autologous CAR-T cell therapy is inherently individualized and labor-intensive, as only a single patient can be treated from a manufacturing run. Complex, dedicated logistics and infrastructure are required to maintain a strict chain of custody and identity from leukapheresis to manufacturing and delivery, which limit the ability to scale and add significant process cost. Autologous products have high manufacturing and supply chain costs, contributing to the high prices for current treatment options.

Autologous T cell product generation also takes an extended period of time. Due to the individualized manufacturing process, patients must wait approximately two to four weeks after leukapheresis to be treated, in addition to any delays due to insurance or payor authorization prior to treatment.

In addition, the obligatory use of a patient’s own T cells for product manufacture can result in products that do not meet specifications. Patients who have previously gone through chemotherapy or hematopoietic stem cell transplantation (HSCT) often have damaged or exhausted T cells. Exhausted T cells may not proliferate well during manufacturing or may ultimately have insufficient potency after administration, resulting in incomplete responses or early relapse. Due to manufacturing time and failure, patients can experience disease progression or even die while waiting for the CAR-T cell product to be administered. In the registrational trials for approved CAR-T cell therapies, approximately 8% to 34% of enrolled patients did not receive the T cells.

Costs are further increased for patients because treatment with approved CAR-T cell therapies is currently limited to a select number of certified hospitals due to safety, logistical and regulatory reasons under a Risk Evaluation and Mitigation Strategy (REMS) Program. This limited access may require some patients to pay to travel significant distances and stay for many weeks to access one of these hospitals.

Safety and Relapse Concerns

Safety and relapse rates have also been concerns related to current CAR-T cell therapies. For the first approved CAR-T cell therapies (Kymriah®, Yescarta® and Tecartus™), severe or life-threatening CRS was observed in 13% to 49% of patients treated in the respective pivotal clinical trials. CRS, a systemic inflammatory response caused by the cytokines released by infused CAR-T cells, can lead to widespread irreversible organ dysfunction. CRS is the most common type of toxicity caused by CAR-T cells. In addition, severe or life-threatening neurotoxicity was seen in 18% to 37% of patients. Several of the treatment-related side-effects are caused by the use of lymphodepleting drugs**.** Many first-generation autologous and allogeneic cell therapies require prior high-dose lymphodepletion to promote engraftment and persistence of the cell therapy product. This adds time before cell administration and can result in serious adverse events, including death. The regimen that is commonly used is based on a combination of fludarabine and cyclophosphamide and has a number of significant side effects, including severe neutropenia, anemia, thrombocytopenia, and immunosuppression, which increase the risk for infections and

secondary malignancies. In addition, peripheral neurotoxicity and fevers are frequently observed. The severity and frequency of these side effects adds to the treatment cost and limits the accessibility of current cell therapies to those patients that can tolerate such side effects.

Notwithstanding the significant adverse events, current generation autologous CAR-T cell therapies do have significant overall response rates (ORR) and complete response (CR) rates in patients with late line cancers (50% ORR and 32% CR for Kymriah®, 72% ORR and 51% CR for Yescarta®, 87% ORR and 62% CR for Tecartus™). Patients with ALL who have received CAR-T cell therapy have shown CR rates between 67% to 85%. However, as more follow-up data is released for these ALL patients, current CAR-T cell therapies still have one-year relapse rates of approximately 50%. For patients with B cell Non-Hodgkin's lymphoma (NHL) treated with CAR-T cell therapy in one study, the ORR was approximately 68%. The ORR for the patients with B cell NHL dropped to 42% on a 12-month follow-up. Thus, less than 50% of patients treated with CAR-T cell therapies for such cancers will have sustained remission at the end of one year and the remaining patients need another option to achieve a durable cure.

Many CAR-T cell therapy relapses are also caused by antigen-negative escape, in which the tumor evolves such that it no longer expresses the target antigen due to intrinsic tumor heterogeneity and immune-editing of the tumor by the therapy. Rare tumor cells that do not express the target are not killed by the therapy, which leads to relapses.

Our Solution: Allogeneic iNKT Cell Therapy

We believe allogeneic iNKT cell therapy has the potential to address many of the key limitations of existing CAR-T cell therapies. We believe our INTELLIGENT iNKT cells have advantages which can lead to more patients in the treatment pool and can significantly broaden utilization.

Potential Advantages of Allogeneic iNKT Cell Therapy Compared to Current CAR-T Cell Therapy

Broad Potential Indications

Due to their specific set of intrinsic properties, we believe allogeneic iNKT cells can be utilized in a wide array of disease indications. This includes the B cell malignancies targeted by the first-generation autologous CAR-T products, as well as additional leukemia/lymphoma indications. It also includes solid tumors, which represent significant challenges beyond those presented by B cell malignancies and largely beyond what a first generation autologous CAR-T product can meet. A key requirement in targeting solid tumors is that the newly infused cells must find their way into solid tumors. In addition, the precision required to target only cancer cells and not harm normal tissue is much greater than required for B cell malignancies because of the commonality of antigens on tumors and healthy tissue. iNKT cells naturally home to tissues such as bone marrow, lung and liver, and have demonstrated compelling clinical efficacy in solid tumor indications, such as head and neck squamous cell carcinoma (HNSCC). We believe that utilizing allogeneic iNKT cells will allow us to overcome many of the limitations of autologous product, including manufacture and treatment, and provide an excellent basis for the development of iNKT cell-based products for a wide set of hematologic and solid tumor indications as well as other life-threatening diseases.

More Favorable Cost Profile

The "vein-to-vein" nature of autologous CAR-T cell therapies involves substantial logistical planning and cost and has a high risk of product failure. Allogeneic iNKT cell therapy does not require individual, per-patient preparation of clinical grade product on demand. This makes it a "shelf-to-vein" procedure because it does not require the use of the patients own cells as a starting point to manufacture the treatment. This reduces complexity and cost and also reduces the risk of a single batch failure impacting patient treatment. iNKT cells have an intrinsic proliferative capacity that vastly exceeds that of conventional T

cells, enabling substantial and reproducible batch sizes. Hence, the manufacturing throughput capacity of iNKT cell therapy is typically greater than that of existing autologous CAR-T cell therapies. By spreading fixed manufacturing costs for one batch across a large number of resulting doses, the cost per dose produced is significantly lowered.

In addition, frozen storage also means that the product can be immediately made available for patient treatment without waiting for individual manufacturing, testing and shipping. Off-the-shelf administration at diagnosis or progression provides an immediate therapeutic option with comparable availability to traditional small molecules and biologics. Thus, although the complexity of the actual cell manufacturing process for iNKT cell therapy is comparable to autologous CAR-T cell therapy, the significant decrease in time pressure for apheresis and logistics requirements greatly streamline the overall process and therefore has the potential to reduce cost.

More Favorable Safety and Relapse Rate Profile

Very few serious adverse events have been observed in previous trials using autologous iNKT cells, including only one Grade 3 adverse event out of 33 patients. Notably, no CRS has been observed. We expect that our INTELLIGENT iNKT cells will have a higher level of batch homogeneity and consistency than the autologous iNKT cells used in the clinic to date, which we believe will translate into an at least similarly favorable or even improved safety profile. Homogeneity may also be able to mitigate risk of CRS as dosing can be more precisely tuned for an improved therapeutic index.

In addition, we believe that the use of iNKT cells may offer further benefit over other allogeneic approaches by potentially reducing or eliminating the need for lymphodepletion. Contrary to T cells, we believe that iNKT cells, due to their natural tissue-homing properties, may need less, or no, prior lymphodepletion. Long-term cancer survival requires, among other things, an intact and potent immune system, and high-dose lymphodepletion harms the patient's immune system, potentially compromising long-term tumor control. In addition to their cancer-killing ability, iNKT cells also are orchestrators of local immune responses in and around tumors, which can further benefit patients with an intact immune system. We intend to calibrate the need for, and level of, lymphodepletion required for maximal clinical efficacy in our clinical trials with the aim to maximize iNKT cell engraftment without severely impairing host immunity. An effective allogeneic iNKT cell-based treatment requiring low or no prior lymphodepletion has the potential to offer enormous benefits, clinically as well as economically.

Finally, we believe rate of relapse is likely to be reduced using iNKT cell therapy. Targeted allogeneic iNKT cell therapy can produce many off-the-shelf batches of cells, including against different targets, because the amount of donor cells is not a limiting factor and batches are produced and released ahead of time. This enables the simultaneous targeting of multiple antigens and the ability to adaptively re-dose cells against a different target as the disease progresses. The allogeneic approach can create tumor specific "cocktails" targeting multiple antigens to minimize chance of antigen-negative escape. The ability to re-dose with cells against newly evolved targets can also induce additional therapeutic responses. iNKT cells can be engineered to respond to a specific target, and can also be re-targeted by using soluble targeting adapters, such as bispecific iNKT cell engagers, that recognize both the invariant TCR on iNKT cells and a tumor target. Using this approach, iNKT cell engagers can essentially turn iNKT cells into "universal CARs" without the need for cell engineering, thereby reducing the risk of relapse. An important property of iNKT cells is the ability to tune the activity of the cells in patients: through administration of synthetic glycolipids such as α-GalCer, the activity of iNKT cells can be enhanced. This has been used with success in prior clinical trials and has proven safe and effective.

Key Features of iNKT Cells

We have set forth below several of the key features of allogeneic iNKT cell therapy.

Combine Key Features of Innate and Adaptive Immunity

iNKT cells offer significant advantages compared to other allogeneic cell types as they can directly attack tumor cells through both TCR-mediated as well as NK-receptor-mediated mechanisms. In addition to their direct cancer targeting and killing properties, iNKT cells are also powerful orchestrators of the immune responses within the tumor microenvironment (TME). iNKT cells directly attack suppressive myeloid cells in the TME and recruit and activate NK cells and T cells, a distinguishing feature not shared by other innate lymphocytes such as NK and gd T cells.

Potent Cancer Killing

iNKT cells are largely tissue-resident, and a small percentage (less than 1% of circulating T cells) are present in the blood. Like NK cells, they respond quickly with wide-ranging effector potential, and unlike αb T cells, they are purposefully selected to express a specific TCR that recognizes CD1d, a key monomorphic human leukocyte antigen (HLA)-related molecule expressed in a wide range of cancers. iNKT cells have the capacity to mount strong anti-tumor responses both directly and by activating other immune cells, potentiating endogenous NK cells and T cells within the TME. While NK cells have a similar advantage of allogeneic dosing without requiring gene editing, they are already plentiful within the body and lack the high level of immune-orchestrating capabilities displayed by iNKT cells. Given the ability to effectively recruit endogenous NK cells, we believe that infusion of iNKT cells will have a more significant clinical impact than infusion of additional allogeneic NK cells.

In preclinical and clinical studies, iNKT cells have been observed to travel to tumor tissues and target CD1d-, NKG2D-, and other NK-receptor ligands expressed on solid and liquid tumors to mediate tumor killing and modification of the TME. The invariant TCR can recognize glycolipids presented by CD1d, arming them with the ability to respond to lipid antigenic stimulation within minutes by secreting a wide variety of cytokines. NKG2D expressed on iNKT cells detects NKG2D tumor stress ligands. While CARs on T cells aim to replace endogenous TCR signaling, iNKT cells can utilize their naturally occurring invariant TCR to synergize with the CAR to achieve maximum anti-tumor efficacy. In addition, the range of NK cell receptors naturally expressed by iNKT cells further enhances their reactivity towards tumors. Examples of NK cell receptors expressed on iNKT cells are NKG2D, DNAM1 (CD226), and NKP46.

Naturally Suited for Allogeneic Approaches

There are two immunologic parameters that impact the success of adoptive cell therapy: acceptance of the newly infused organs/cells by the patient’s immune system and avoidance of the newly infused cells attacking the patient’s normal healthy tissues. The first has a key impact on persistence of the newly infused organs/cells, and the second has a key impact on safety. There are two terms that cover the clinical outcomes of these: Host versus Graft (HvG) response, which governs the rejection of the infused cells by the patient’s immune system, and Graft versus Host Disease (GvHD), which is caused by conventional donor αb T cells present in the graft (e.g. organ or allogeneic bone marrow transplant or cell therapy) attacking healthy tissue in the recipient. Both are significant risk factors in organ and allogeneic bone marrow transplants. Both HvG response and GvHD are critical parameters for an allogeneic cell therapy platform. Although allogeneic products also offer many potential advantages to currently available autologous CAR-T cell therapies, certain types of allogeneic cells may not be as well tolerated as autologous T cell therapy, which is derived from a patient’s own T cells and will not attack the patient’s own normal tissues. Allogeneic cell therapy derived from healthy donor T cells may view the patient’s tissues as foreign and attack it, resulting in GvHD, which can lead to major complications and even death. To reduce the risk of GvHD, conventional allogeneic donor T cells must be genetically engineered to inactivate their TCR, which is technically challenging, expensive and not always completely effective. To minimize GvHD risk,

researchers have turned to alternative human immune cell types as a basis for allogeneic cell therapy for cancer. The opportunity afforded by allogeneic adoptive cell therapy has motivated approaches using several cell types, including engineered αb T cells, NK cells and gd T cells.

In both clinical and preclinical studies, iNKT cells have been observed to not cause, and to actually actively suppress, GvHD, lowering the safety risks associated with other allogeneic immune cells. Higher iNKT cell counts following HSCT for acute leukemia correlates with lower risk for GvHD, and vice versa. Unlike conventional αb T cells, iNKT cells do not require gene editing of the TCR to eliminate risk of GvHD due to the monomorphic nature of the CD1d ligand of the iNKT cell TCR.

iNKT cells can also be generated in a way that minimizes the potential for HvG response of the infused cells by the host immune system. HvG rejection, though not a safety concern, can impact cell persistence, and thus therapeutic activity. To reduce the risk of HvG rejection, we develop iNKT cells using partial HLA-matching and can create a bank of different partially matched donor iNKT cell pools to accommodate patients with different HLAs.

Ability to Tune Activity in Patients

A key distinguishing feature of iNKT cells is their invariant TCR, which can function as a built-in on- and off-switch to provide the opportunity to control the activity of iNKT cells in patients. iNKT cells can be primed for anti-tumor activity using the activating lipid ligand α-GalCer, which stimulates iNKT cell production of large amounts of cytokines, undergo clonal expansion and subsequently recruit and activate NK cells, neutrophils, macrophages, DCs, B cells, and T cells for sustained anti-tumor response. The administration of α-GalCer to patients has been used in clinical trials conducted over the last two decades and has demonstrated to be safe. Activating iNKT cells using α-GalCer may enable significantly enhanced persistence and expansion, further reducing or eliminating the need for lymphodepletion prior to adoptive cell therapy administration. We currently have a supply of cGMP-grade α-GalCer that we believe will enable clinical application after initial dose escalation studies with allogeneic unmodified iNKT cells.

Unlike many other types of cells, iNKT cells express a differentiated receptor in the form of the invariant TCR that functions as a built-in safety switch by allowing for highly specific targeted elimination of iNKT cells with an antibody, if needed. Since the invariant TCR of CD1d-restricted iNKT cells is not polymorphic, the TCR expressed by iNKT cells is effectively the same in different individuals. In the event of a serious adverse event or other safety concerns, iNKT cells can be eliminated using an invariant TCR antibody without killing healthy immune cells.

Enhanced Tolerability

We believe reducing or eliminating lymphodepletion would significantly improve patients' quality of life, increase their ability and willingness to undergo treatment, and potentially increase long-term anti-tumor
immunity. We believe that allogeneic iNKT cells may engraft better than other allogeneic cell types and thus require less lymphodepletion.

Whereas we believe we will not need high dose lymphodepletion for allogeneic iNKT cells to persist and be effective, we intend to investigate whether varying doses of certain lymphodepletion drugs may further enhance the clinical efficacy of allogeneic iNKT cell therapy while minimizing side effects. At lower doses, the drugs used in lymphodepletion regimens can have positive effects that may improve the TME for cell therapy. These effects include alteration of tumor phenotype by decreasing production of certain metabolites, change in expression of costimulatory molecules on tumor cells, reducing regulatory T cells and damaging vascular endothelial cells. In addition, these drugs induce a greater availability of beneficial cytokines such as interleukin (IL)-2, IL-7, and IL-15. Most importantly, reduced or no lymphodepletion leaves the patient's immune system in a better condition. A healthy and intact immune system is a key requirement for long-term cancer control.

Manufacturing Efficiency and Reliability

We believe that the efficient and scalable manufacturing capabilities for iNKT cells provide strategic advantages over other cell types. Our manufacturing process uses healthy, donor-derived PBMCs collected by apheresis, which eliminates a key supply bottleneck compared to autologous cell therapies. The donor cells are processed using a proprietary combination of iNKT cell enrichment, α-GalCer mediated cell activation, and selective expansion, yielding highly pure iNKT cells essentially without potentially alloreactive T cells (contaminating conventional αb T cells). After robust testing to ensure product purity and potency, iNKT cells are cryopreserved for distribution and storage. CAR targeted iNKT cells use the same base methodology and incorporate a gene editing step.

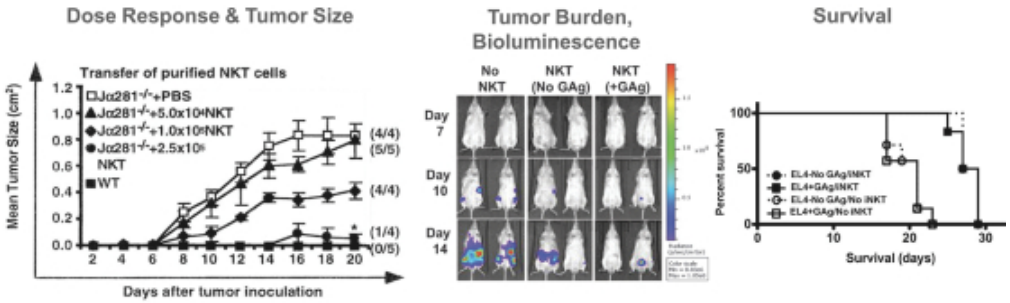
We estimate that manufacturing costs for iNKT cells will be significantly lower than the estimated manufacturing costs for autologous cell therapies.

Allogeneic cell product batch production also provides the opportunity for more rigorous quality control and release of consistent cell-product by producing large numbers of doses per manufacturing run for both non-engineered and engineered products. Using healthy donor cells as the starting material eliminates the risk that such cells will be exhausted, or damaged, from prior chemotherapy or HSCT. Advance manufacturing also reduces the risk of batch failure, as every manufacturing run of cells can be more rigorously validated prior to release. Homogeneity may also be able to mitigate risk of CRS as dosing can be more precisely tuned for an improved therapeutic index. The transfer to a CMO involves moving from a partially open to a fully closed and more automated process using industry-standard components. A closed process allows for new material to be introduced in the manufacturing system without opening the system to the outside air, which minimizes contamination risks. A more automated process reduces hands-on time, with the potential to optimize personnel usage and facility qualification and validation processes. These steps increase reproducibility, minimize run failures and greatly increase scalability.

Preclinical Efficacy Data for iNKT Cell Therapy

The efficacy of iNKT cells as a cancer treatment has been demonstrated by extensive public and proprietary preclinical *in-vivo* data. Such data has shown that iNKT cells can decrease tumor burden and improve survival in multiple animal models, including prophylactic and interventional administration of iNKT cells using xenograft, syngeneic and spontaneous tumor models of solid and hematologic tumors. Efficacy is achieved in part because iNKT cells remodel the TME by targeting suppressive myeloid cells and restricting the pro-angiogenic macrophages that are found in aggressive cancers.

In-vivo studies of adoptively transferred iNKT cells into iNKT-deficient animals have highlighted the key role iNKT cells play in anti-tumor immune responses to solid tumors. In murine sarcoma models, transferred iNKT cells control aggressive tumor growth in a dose-dependent manner, achieving complete control at higher doses. In a murine thymoma model, whole body bioluminescent imaging demonstrates systemic tumor control mediated by transferred iNKT cells, resulting in an increased survival of animals. In this model, tumor control is further improved by additional stimulation of iNKT cells by administration of the α-GalCer agonist.



Key Role For iNKT Cells In Tumor Surveillance – Solid Tumor

- Spontaneous sarcoma model in mice genetically engineered not to have iNKT cells
- Aggressive tumor development in absence of iNKT cells
- Complete tumor control by adoptively transferred iNKT cells

Adoptive Transfer Of iNKT Cells Controls T Cell Lymphoma

- Mouse model genetically engineered not to have iNKT cells
- Aggressive tumor development in absence of iNKT cells
- Tumor control by adoptively transferred iNKT cells
- Further improved survival by administration of α-GalCer

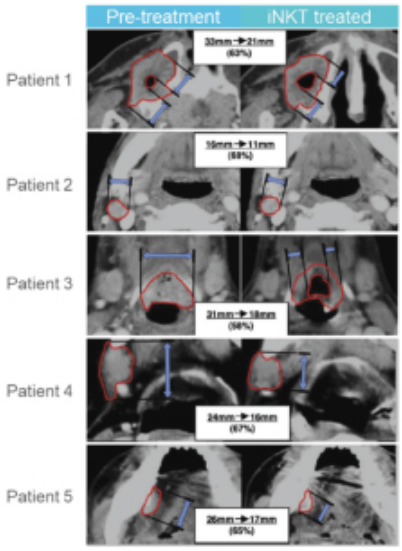
Although they display monotherapy activity, iNKT cells have shown improved efficacy in preclinical tests in combination with α-GalCer, with greater tumor infiltration and reduction of metastases. Activity of α-GalCer-activated iNKT cells can be further improved when used in combination with immuno-oncology antibodies, including anti-PD-1 and anti-CTLA-4 antibodies. These increase the ability of iNKT cells to control tumors by further increasing cell infiltration and reducing metastases, which resulted in robust tumor clearance in one model of metastatic lung cancer.

iNKT cells have shown minimal expression of PD-1, and anti-CTLA-4 combinations have to date demonstrated the best direct combinatorial effect *in-vivo*. The addition of anti-PD-1 antibodies further potentiates the endogenous immune response, which is considered critical for long-term tumor control. We intend to capitalize on our internal research findings and actively pursue preclinical and clinical development of iNKT cells in combination with immuno-oncology antibodies for treatment of solid tumors. Our close relationship with Agenus is a key enabler for this strategy.

Investigator-Initiated Clinical Data for iNKT Cell Therapy

Multiple investigator-initiated clinical trials using autologous iNKT cells have demonstrated safety and efficacy across multiple cancer indications, with clinical trials for three different cancers published to date: melanoma, non-small cell lung cancer (NSCLC), and HNSCC. Autologous iNKT cells were dosed at up to $2.2x10^8$ cells per dose, comparable to currently approved CAR-T cell therapies. All of the previously published trials showed an advantageous safety profile, with only one report of a Grade 3 adverse event among 33 patients treated across four trials. In the HNSCC trials, there was a 37.5% partial response in one trial and a 50% ORR in another trial of iNKT cells co-administered with α-GalCer pulsed antigen presenting cells (APCs), comparing favorably to currently available therapies in previously treated HNSCC, which have an ORR of 10% to 18%. Increased numbers of cells producing IFN-g, a key activator of the cytotoxic immune response, were observed in most patients in all trials. Tumor targeting by iNKT cells was also predictive of response in HNSCC, with responding patients having five-fold greater iNKT tumor infiltration relative to non-responders.

Cancer Type	Phase	Clinical Outcomes
HNSCC	2	**ORR: 50%** PR (5/10) SD (5/10)
HNSCC	1	**PR: 37.5%** PR (3/8) SD (4/8)
NSCLC	1	SD: 67% (4/6)



In addition to anti-cancer activity, iNKT cells can also regulate mechanisms combatting bacterial and viral infection, indicating potential as an infectious disease therapy. In preclinical models of bacterial or viral infections in the lung (including bacterial pneumonia, influenza, and respiratory syncytial virus), iNKT cells induced pro-inflammatory immunity, including increased cytotoxic T cell and NK activity, leading to clearance of infection. In influenza models, iNKT cells have additionally been shown to indirectly enhance immunity by reducing the immunosuppressive activity of myeloid-derived suppressor cells, similar to their immunomodulatory role in the TME. Moreover, in models of severe influenza with high-immune pathology, iNKT cells act to reduce lung injury by limiting infiltrating inflammatory monocytes.

Product Development Pipeline

AGENT-797

Our most advanced product candidate, AGENT-797, consists of allogeneic unmodified iNKT cells derived from healthy donors, which have been purified and expanded reproducibly to enable treatment of up to 100 patients per batch. AGENT-797 is currently in the clinic with two INDs, one for multiple myeloma and other B cell malignancies, and another for COVID-19-related pneumonia. The first patient was dosed in the Phase 1 clinical trial for AGENT-797 for COVID-19-related pneumonia in October 2020, and the initiation of the Phase 1 clinical trial for AGENT-797 for multiple myeloma and B cell malignancies is expected to take place in January 2021.

We selected multiple myeloma (which also expresses CD1d, a key TCR ligand for iNKT cells) and other B cell malignancies as the initial cancer indications for the Phase 1 clinical trial for AGENT-797. iNKT cells effectively home to the bone marrow and we believe marrow-invading hematologic malignancies represent promising tumors. We also believe that allogeneic iNKT cells have the potential to persist and function in the absence of lymphodepletion, which is the intentional destruction of a patient's existing T cells and lymphocytes prior to immunotherapy. An allogeneic cell therapy that does not require prior lymphodepletion would represent a major improvement over existing autologous and allogeneic cell therapies, as such a cell therapy would have the potential to significantly lower the treatment burden for patients and prevent further deterioration of their immune systems.

The first-in-human oncology clinical trial of AGENT-797 is enrolling patients with relapsed/refractory (3L+) multiple myeloma and selected B cell malignancies who have an Eastern Cooperative Oncology Group

performance status of 0 or 1. The trial design is a 3+3 dose escalation (first three patients at first dose level, second three patients at second dose level, and third three patients at third dose level) with a minimum sample size of 12 to 18 evaluable patients. Patients will be dosed with one intravenous (IV) infusion, ranging from 10^8 to 10^9 iNKT cells. The primary endpoint will be safety and maximum tolerated dose, including testing the need for lymphodepletion. Key secondary efficacy endpoints will include the best anti-tumor response and its duration, in addition to persistence of the dosed iNKT cells. We anticipate providing an update on interim data from the Phase 1 dose-escalation cohorts in the fourth quarter of 2021.

AGENT-797 is also in a Phase 1 clinical trial for COVID-19-related pneumonia. We chose to pursue this indication due to the potential benefits of allogeneic immune cell therapy in treating COVID-19-related pneumonia, the magnitude of the public health burden of the magnitude of the public health burden of COVID-19 and the lack of existing therapeutic options for patients with severe COVID-19 symptoms. Patients with COVID-19 admitted to the intensive care unit often have reduced and impaired innate and adaptive immune cells, with a majority of such patients developing ARDS. iNKT cells promote viral clearance and increase secondary anti-viral responses, offering the potential to control inflammation and limit lung tissue damage resulting from COVID-19-related pneumonia.

The first-in-human infectious disease clinical trial of AGENT-797 is enrolling patients with COVID-19 infection, requiring mechanical ventilation and with moderate-to-severe ARDS. The trial design is a 3+3 dose escalation with a minimum sample size of approximately 28 evaluable patients. Dose escalation progresses to the next level when no serious adverse event is seen. If an adverse event does happen, three additional patients need to be treated at the first dose level. Patients are being dosed with one IV infusion, ranging from 10^8 to 10^9 iNKT cells. The primary endpoints are safety and maximum tolerated dose. Key secondary efficacy endpoints include respiratory parameters, viral burden and persistence of allogeneic iNKT cells. One patient during the trial has experienced cardiac arrest, a serious adverse event that was deemed to be life threatening. The study investigator determined that the event was more likely related to Methicillin-resistant *Staphylococcus aureus* bacteremia, combined with the patient's clinical course of COVID-19-related pneumonia, and unrelated to AGENT-797. We anticipate providing an update on interim data from the Phase 1 dose-escalation cohorts in the fourth quarter of 2021.

Additional Product Development

Tumor Targeting with CARs and TCRs through CARDIS™ and T-Rx™

Unmodified iNKT cells display intrinsic tumor targeting and killing potential for a wide range of tumors. However, certain cancers may not express sufficient natural iNKT ligands to be effectively killed, or may have a suppressive TME that limits the effectiveness of infiltrating iNKT cells. Adding a CAR, TCR or bispecific antibody-based cell engager can target specific cancer cells and enhance the potency and efficacy of iNKT cell therapy in a broader range of indications.

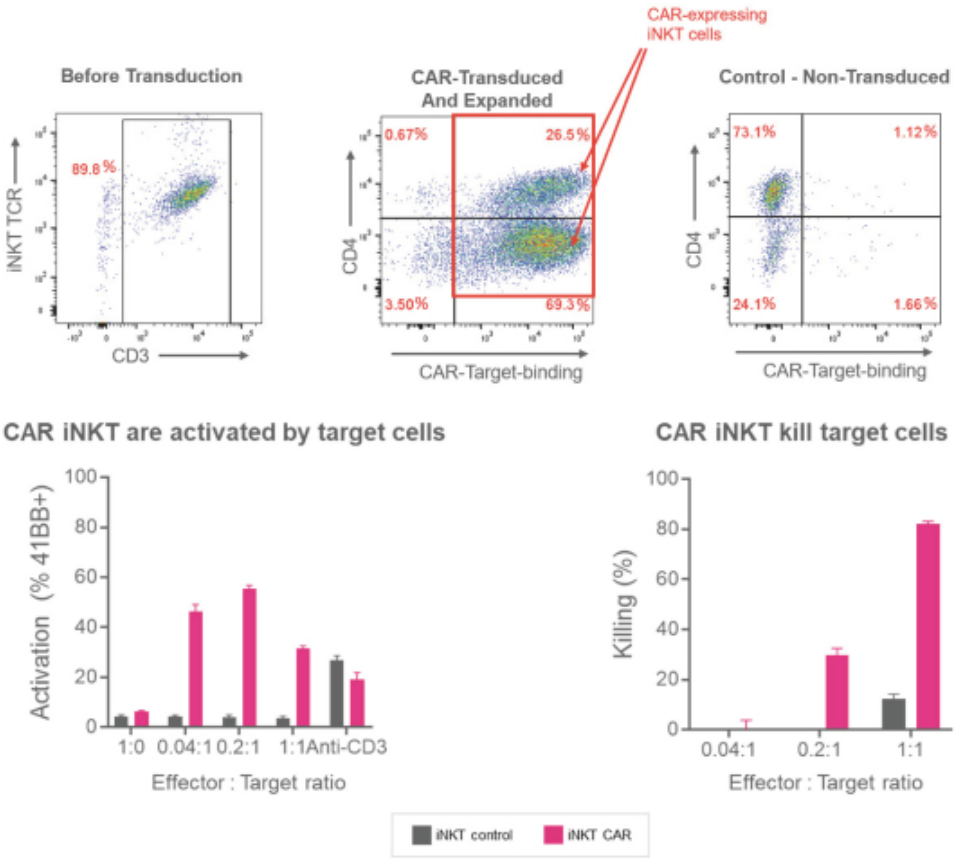
We are utilizing our extensive antibody knowledge and proprietary mammalian display screening platforms for identification of CAR candidates optimally tuned to further enhance the native iNKT cells' capabilities for tackling solid tumors, an area not well served by existing cell therapies. In addition, we are using our proprietary humanized iNKT-TCR binding antibodies to develop a portfolio of bispecific antibody-based iNKT cell engagers that can further increase the targeting and activation of iNKT cells for treatment of malignancies.

CARDIS

Our proprietary CAR generation platform, CARDIS (CAR-DISplay), is designed to be capable of discovering and engineering ScFv and ligand-based CARs to any surface-expressed tumor antigen. This is enabled by a hybrid of phage and proprietary mammalian display platforms. Direct functional selection from a pooled library results in a high number of functional leads, while fully human ScFv libraries impart a lower risk of

immunogenicity. We use iNKT-optimized intracellular signaling domains that are distinct from standard second-generation CARs used in current CAR-T cell therapies, which work in conjunction with the powerful array of endogenous receptors expressed naturally by iNKT cells. Our CAR-iNKT intracellular signaling domain and ScFv target affinity and epitope can be finely tuned to generate an optimal anti-tumor therapeutic window and minimize the chance of tumor escape and off-tumor toxicity.

Our manufacturing process is designed to enable us to introduce CARs into iNKT cells, and CAR-transduced iNKT cells can be manufactured to over 80% of CAR-expressing product. An example is shown in the middle graph below (26.5% + 69.3% equals 95.8% CAR-expressing iNKT cells).



T-Rx

Our platform to discover and optimize highly functional TCRs to intracellular antigens is called T-Rx (TCR-based prescription) and is designed to target any HLA and presented peptide or ligand. T-Rx is a proprietary *de-novo* mammalian TCR-display platform that uses direct functional selection from pooled library to obtain a high number of functional and specific leads. We are also able to leverage natural thymic selection by isolating TCRs from natural donors. Safety is ensured by using extensive proprietary off-target profiling. We have access to a large portfolio of proprietary phosphopeptide tumor targets (PTT) that can be utilized to generate neo-antigen-specific cell therapy products. PTT are phosphorylated peptides presented on tumor cells by MHC class I as a result of the inherent imbalance in kinase pathways in cancer cells. Normal cells do not have this imbalance and will not present the same PTTs as cancer cells. This allows the immune system (or an adoptive cell therapy) to recognize and eliminate PTT-presenting tumor cells.

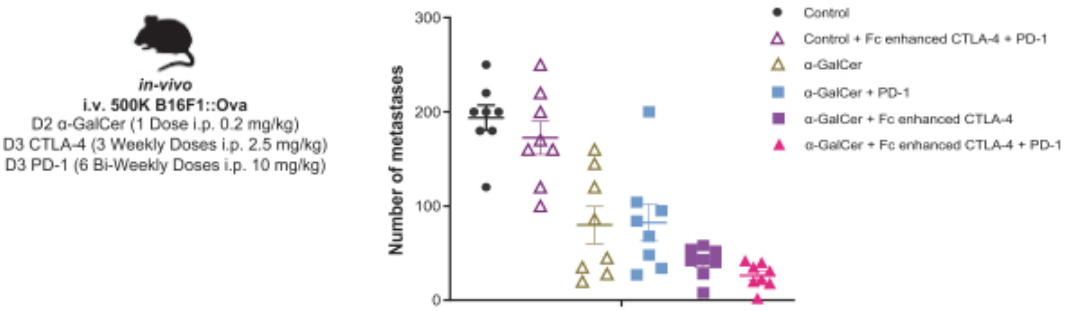
Immuno-Oncology Combination Therapy Collaboration with Agenus

We were formed in 2017 as a subsidiary of Agenus, a Nasdaq-listed immuno-oncology company with a library of immuno-oncology antibodies. We have an ongoing long-term collaboration with Agenus to access immuno-oncology antibodies, adjuvants and other potential synergistic combinations, and intend to pursue combination products between our allogeneic iNKT cell product candidates and products in Agenus' immuno-oncology portfolio.

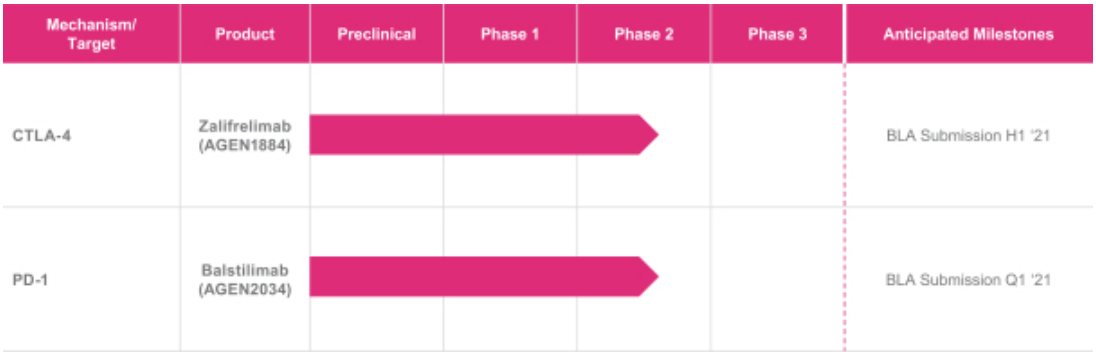
We believe current cancer therapy developments indicate that anti-PD-1 and anti-CTLA-4 immuno-oncology antibodies have the potential to become the standard of care for many tumor indications and will form the basis for most, if not all, future combination therapies in cancer. Access to Agenus' immuno-oncology products in this class provides us with flexibility in terms of clinical and commercial development strategy, and we believe there is a compelling scientific rationale for pursuing combination products for achieving better long-term remissions and cures.

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. Anti-PD-1 and anti-CTLA-4 immuno-oncology antibodies have been demonstrated to be effective in enhancing endogenous immune responses. Access to Agenus' immuno-oncology products allows us to combine our iNKT cells with immuno-oncology antibodies that are already in clinical development, creating more flexibility in our clinical strategy, a better window for optimization dosing and timing, and more control over commercial pricing of the combination.

We have conducted preclinical tests that validate the potential of activated iNKT cells with immuno-oncology antibodies. The study depicted below is a metastatic lung cancer model that is resistant to treatment with immuno-oncology antibodies alone (as depicted by the triangles in the second column from the left). However, when endogenous iNKT cells are activated by the synthetic glycolipid α-GalCer, the tumors are substantially cleared (as depicted by the triangles in the last column on the far right).



Agenus has a suite of key proprietary immune modulators that we believe will enable clinical iNKT cell combination therapy development. Agenus has a wide library of immuno-oncology antibodies that will be available to us through the collaboration, and we intend to initially focus on two of Agenus' assets, zalifrelimab and balstilimab.



We have significant operational expertise for preclinical and clinical research and development as a result of our shared history with Agenus. Since 2017, we and Agenus combined have had 12 INDs approved relating to immuno-oncology. Agenus expects to receive BLA approval from the FDA for its current lead product candidate, balstilimab, in 2021, slightly over four years after the IND for the product candidate.

Our relationship with Agenus also provides access to its manufacturing capabilities. We believe access to this manufacturing capability would enable us to eventually manufacture our iNKT products, if approved, in-house, and moreover, within the same facilities that will manufacture Agenus' immuno-oncology antibodies.

Lastly, we have access through our collaboration agreement with Agenus to its QS-21 Stimulon™ adjuvant, which we believe can be used as part of a combination therapy with iNKT cells to further augment a patient's own immune response. QS-21 Stimulon is a saponin-type adjuvant first identified in the bark of the Chilean soapbark tree. QS-21 Stimulon is a powerful immune stimulating adjuvant that Agenus commercializes and has licensed to GlaxoSmithKline plc for use in its Shingrix® vaccine.

Intellectual Property

We protect our intellectual property rights and proprietary technology with a combination of patent rights that we own or in-license in certain fields of use, 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 and enhance 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, 2020, we owned one issued patent and had 23 pending patent applications.

Our process to manufacture iNKT cells at scale from healthy donor PBMCs, using GMP-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 protected by trade secrets.

Agenus has pending patent applications intended to protect intellectual property relating to a TCR for cell therapy targeting NY-ESO-1 and a TCR for cell therapy targeting a PTT. We also have granted or pending patent rights intended to protect TCR display, including the T-Rx platform.

In addition to proprietary processes and patents on individual assets, we anticipate achieving a 12-year regulatory exclusivity period for AGENT-797 upon receiving BLA approval from the FDA, if approved.

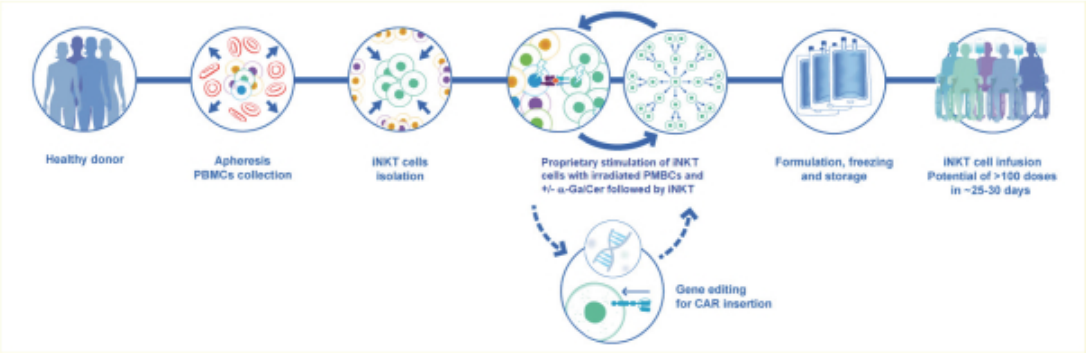
Our ongoing collaboration with Agenus provides access to Agenus' immuno-oncology antibodies, adjuvants, and other technology with the potential to be combined with our technology. Agenus has a suite of key proprietary immune modulators, including but not limited to balstilimab and zalifrelimab, to enable iNKT cell combination

therapies. We also have the option to obtain exclusive licenses from Agenus to use, develop and commercialize existing CARs, TCRs and other cell therapy technologies.

Manufacturing

We are in the late stages of transferring our manufacturing process to a commercial CMO to ensure stable, robust, and scalable production for advanced clinical trials and commercialization. We have begun transfer of our manufacturing process from Dana Farber Cancer Institute to a new CMO to manufacture clinical grade product. The transfer to a CMO involves moving from a partially open system to a fully closed and more automated process using industry-standard components. A closed process allows for new material to be introduced in the manufacturing system without opening the system to the outside air, which minimizes contamination risks. A more automated process reduces hands-on time, with the potential to optimize personnel usage and facility qualification and validation processes. These steps increase reproducibility, minimize run failures and greatly increase scalability.

Our ultimate goal is to migrate manufacturing in-house for eventual commercial grade product should one or more of our product candidates receive marketing approval. Our iNKT manufacturing involves a proprietary process that sources cells from healthy donors. These cells are isolated from PBMCs obtained by apheresis. The iNKT cells are stimulated with irradiated feeders loaded with α-GalCer. After expansion, the iNKT cells are formulated, frozen and stored to allow for off-the-shelf administration. This process takes between 25-30 days.



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), and 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 Investigational New Drug Application (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 (HCT/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 HCT/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 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. 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 Affordable Care Act (ACA) related to the biosimilar regulatory framework, if those efforts continue and if the ACA 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. We face substantial competition from many different sources, 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 derived from both autologous and allogeneic cell sources and are unmodified or genetically engineered with targeting ligands. Other modalities such as bispecific antibodies, antibody drug conjugates, as well as novel immuno-oncology antibodies, are constantly improving. Many bispecific approaches are using engagers to redirect a patients endogenous NK or T cells to the site of a tumor. Several companies are also using induced pluripotent stem cells (iPSCs) as a cell source, which could theoretically have enhanced scalability.

Key competitor companies developing autologous CAR-T cell therapies include but are not limited to: Autolus Therapeutics plc, Bristol-Myers Squibb Company (Celgene/Juno Therapeutics), bluebird bio, Inc., Gilead Sciences, Inc. (Kite Pharma), GlaxoSmithKline plc, Immatics N.V., Janssen Pharmaceutica N.V., Novartis AG and Tmunity Therapeutics Inc.

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

Key competitors in the NK cell therapy space include, but are not limited to, Astellas Pharma Inc., Fate Therapeutics, Inc., Glycostem Therapeutics B.V., Kiadis Pharma N.V., NantKwest, Inc., Nkarta, Inc.

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

Kuur Therapeutics Limited is a key competitor developing allogeneic cell therapies in the iNKT cell therapy space.

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.

Employees

As of January 2021, we had 27 full-time employees and consultants, 74% of whom have M.D. or 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, Regulatory Affairs, Finance, Clinical and R&D are provided by Agenus pursuant to our services agreement.

Facilities

We currently have no standalone facility and rent space in Agenus' facilities in Lexington, MA, and Cambridge, United Kingdom. There is current capacity to expand our operations within existing Agenus facilities.

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.

Management

Executive Officers and Directors

The following table sets forth the name, age (as of December 31, 2020) and position of each of our executive officers and directors.

Name	Age	Position
Executive Officers		
Jennifer S. Buell, Ph.D.	46	Interim Chief Executive Officer
Garo H. Armen, Ph.D.	67	President and Chairman of the Board of Directors
Patrick N. Jordan	43	Chief Operating Officer
Christine M. Klaskin	55	Treasurer
Non-Employee Directors		
Walter Flamenbaum, M.D.	77	Director
Brian Corvese	63	Director
Ulf Wiinberg	62	Director

Executive Team

Jennifer S. Buell, Ph.D. has served as our Interim Chief Executive Officer since January 2021. Dr. Buell also serves as the Chief Operating Officer and President of Agenus, the Company's parent, where she has served in such roles since 2018 and December 2019, respectively. Dr. Buell has more than 20 years of biopharmaceutical R&D experience. From November 2013 to July 2016, Dr. Buell was Agenus' Vice President, Research and Development Operations and Program Management. From July 2016 to November 2017, she was Agenus' Vice President, Research and External Affairs, and from November 2017 to November 2018, she served as the Chief Communications and External Affairs Officer. Dr. Buell obtained her Ph.D. in Cellular, Biochemical and Molecular Biochemistry with an MS in Biostatistics from Tufts University.

Garo H. Armen, Ph.D. has served as President and Chairman of our board of directors since July 2017. Dr. Armen also serves as Chairman and Chief Executive Officer of Agenus, which he co-founded in 1994. Dr. Armen serves as the sole director and Chief Executive Officer of AgenTus Therapeutics Limited, a wholly owned subsidiary of the Company. He previously served as President of Agenus from the company's founding until December 2019. From mid-2002 through 2004, Dr. Armen was Chairman of the board of directors for the biopharmaceutical company Elan Corporation, plc, which he helped restructure. Dr. Armen currently serves as non-executive Chairman of the board of directors of Protagenic Therapeutics, Inc., a publicly held biotechnology company. Dr. Armen is also the founder and Chairman of the Children of Armenia Fund, a philanthropic organization established in 2000 that is dedicated to the positive development of the children and youth of rural Armenia. He holds a Ph.D. degree in physical organic chemistry from the City University of New York. We believe Dr. Armen is qualified to serve as a member of our board of directors due to his extensive experience in the life sciences industry, including serving as an executive.

Patrick N. Jordan has served as our Chief Operating Officer since November 2020. Previously, from January 2018 until joining Agenus in June 2020, Mr. Jordan served as Vice President, Global Distributor Markets at Amryt Pharma plc. Before Amryt, from November 2016 until December 2017 he served as President of Agawam Enterprises LLC, a consulting firm focused on the pharmaceutical, biotechnology and medical devices industries. Before Agawam, Mr. Johnson served in various commercial leadership positions at Merck & Co., Inc., most recently as Assistant Vice President, Managing Director of Saudi Arabia, from November 2015 to November 2016, and, before that, Assistant Vice President, Managing Director EEI & NA Region from January 2015 until November 2015. Previously, Mr. Jordan served in various roles at Pfizer Inc. Mr. Jordan is also the owner of Vector Pharma, LLC and a Director of Equiseq Inc. He holds a BA in Biochemistry/Molecular Biology from Boston University and an MBA from Babson College.

Christine M. Klaskin has served as our Treasurer since July 2017. Since October 2016, Ms. Klaskin has also served as Vice President, Finance of Agenus. Since joining Agenus in 1996 as finance manager, Ms. Klaskin has held various positions within Agenus's finance department. From 2012 until 2017, Ms. Klaskin was a member of the board of directors of American DG Energy Inc. until its sale to Tecogen Inc. Prior to joining Agenus, Ms. Klaskin was employed by Arthur Andersen as an audit manager. Ms. Klaskin received her Bachelor of Accountancy from The George Washington University.

Walter Flamenbaum, M.D. has served as a member of our board of directors since November 2019. Dr. Flamenbaum also served as our Chief Executive Officer from November 2019 until January 2021. Dr. Flamenbaum has been a Managing Director of The Channel Group since 2014 and a member of the board of Smart Therapeutics since 2019. Dr. Flamendaum also served as a Director of Ose Pharma. From 1999 until November 2019, he was a Partner Emeritus at Paul Capital Partners, a private equity investment firm, and the Founding Partner of Paul Capital Healthcare Funds. Dr. Flamenbaum has been board certified in internal medicine, nephrology and clinical pharmacology and was a professor of medicine at the Mt. Sinai School of Medicine and Tufts University School of Medicine. Dr. Flamenbaum served in the U.S. Army at the Walter Reed Army Institute of Research and the Walter Reed Army Medical Center from 1970 until 1976. He completed his training in internal medicine at the Hospital of the University of Pennsylvania, and his fellowship in nephrology at the Peter Bent Brigham Hospital. He earned his M.D. from Columbia University's College of Physicians & Surgeons and his B.A. from Washington & Jefferson College. We believe Dr. Flamenbaum is qualified to serve as a member of our board of directors due to his broad-based medical knowledge and investment experience.

Brian Corvese has served as a member of our board of directors since July 2017. Since 1999, Mr. Corvese has been the President and Founder of Vencor Capital, a private equity firm with telecommunications and technology investments in the Middle East and Mediterranean regions. Prior to working at Vencor, Mr. Corvese worked on investments in the United States and global equity markets as a Managing Director and partner at Soros Fund Management, the largest hedge fund in the world at the time. From 1988 to 1996, Mr. Corvese was a partner at Chancellor Capital Management, a $25.0 billion money management firm. While at Chancellor, Mr. Corvese was a Portfolio Manager with responsibility for investments made in basic industries, restructurings, and special situations, corporate governance investments, as well as founded and managed his own hedge fund. From 1981 to 1988, Mr. Corvese was with Drexel Burnham Lambert as an equity analyst following the chemical and specialty chemical industries and participated in a significant number of merger and acquisition activities. While at Drexel, Mr. Corvese was a member of the top chemical and specialty chemical research team, as ranked by Institutional Investor. Mr. Corvese currently serves on the Board of Directors of the National Telecommunications Corporation, based in Cairo, Egypt, and Protagenic Therapeutics, Inc. based in Ontario, Canada. Mr. Corvese has served on the board of directors of Agenus since 2007. Mr. Corvese earned degrees in finance and political science from The University of Rhode Island and attended New York University Graduate School. We believe Mr. Corvese is qualified to serve as a member of our board of directors due to his over 30 years of experience in the financial industry.

Ulf Wiinberg has served as a member of our board of directors since July 2017. Mr. Wiinberg has also served as a Director of AgenTus Therapeutics SA since 2018. Mr. Wiinberg has almost 20 years of senior leadership experience and currently serves as the Chief Executive Officer of X-Vax Technology, Inc., a pre-clinical vaccine research company. Prior to X-Vax, Mr. Wiinberg served as Chief Executive Officer of H. Lundbeck A/S from June 2008 to December 2014. Lundbeck is a global pharmaceutical company developing and marketing treatments for psychiatric and neurological disorders. He previously served on the boards of several health care industry associations and held multiple executive roles at Wyeth, one of the world's largest research-driven pharmaceutical companies that was acquired by Pfizer in 2009. He served as President of Wyeth Europe, Africa and Middle East; President of Consumer Healthcare; Managing Director of Wyeth UK, and in various commercial positions. Mr. Wiinberg currently serves on the boards of UCB SA, a global biopharmaceutical company based in Belgium, Hansa Medical AB (Chairman), a Swedish biopharmaceutical company, and Alfa Laval AB, a Swedish industrial company. Mr. Wiinberg has served on the board of directors of Agenus since

2016. We believe Mr. Wiinberg is qualified to serve as a member of our board of directors due to his years of experience in the biotechnology, pharmaceutical and healthcare industries internationally.

There are no family relationships among any of our directors and executive officers.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, which will be in effect upon the closing of this offering, our board of directors will be divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms are then expiring, to serve from the time of election and qualification until the third annual meeting following their election or until their earlier death, resignation or removal. Upon the closing of this offering, our directors will be divided among the three classes as follows:

The Class I directors will be , and their terms will expire at our first annual meeting of stockholders following this offering.

The Class II directors will be , and their terms will expire at our second annual meeting of stockholders following this offering.

The Class III directors will be , and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation will provide that the authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control. See the section of this prospectus captioned “Description of Capital Stock—Anti-takeover Effects of Our Certificate of Incorporation and Our By-laws” for a discussion of these and other anti-takeover provisions found in our amended and restated certificate of incorporation and amended and restated by-laws, which will become effective immediately prior to the closing of this offering.

Director Independence

Under the rules of the Nasdaq Stock Market, we are a “controlled company” and are not required to have, and do not have, (i) a majority of independent directors on our board of directors, (ii) a nominating and corporate governance committee composed entirely of independent directors, or (iii) a compensation committee composed entirely of independent directors. We intend to rely on these exemptions for the foreseeable future. Accordingly, you will not have the same protections afforded to stockholders of companies that are not controlled companies.

Under the rules of the Nasdaq Stock Market, a director will only qualify as “independent” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that such person is “independent” as defined under Nasdaq Stock Market and the Exchange Act rules. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of

is an "independent director" as defined under applicable rules of the Nasdaq Stock Market, including, in the case of , the independence criteria set forth in Rule 10A-3 under the Exchange Act, and are "non-employee directors" as defined in Section 16b-3 of the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our Company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter adopted by our board of directors and which will be effective prior to the consummation of this offering. The board of directors may also establish other committees from time to time to assist us and the board of directors in their duties. Upon the effectiveness of the registration statement of which this prospectus forms a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, the Nasdaq Stock Market and the Exchange Act. Upon our listing on Nasdaq, each committee's charter will be available on the corporate governance section of our website at agentustherapeutics.com. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

Audit Committee

The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance and independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm, and pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- discussing our risk management policies with management;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and approving any related person transactions;
- overseeing our guidelines and policies governing risk assessment and risk management;
- overseeing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

The members of our audit committee are . chairs the audit committee. Our board of directors has determined that each member of our audit committee has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has also determined that is an "audit committee financial expert," as defined under Item 407 of Regulation S-K.

We expect to satisfy the member independence requirements for the audit committee prior to the end of the transition period provided under current Nasdaq Listing Rules and SEC rules and regulations for companies completing their initial public offering.

Compensation Committee

Our compensation committee's responsibilities upon completion of this offering will include:

- assisting our board of directors in developing and reviewing potential candidates for executive positions;
- reviewing our overall compensation strategy, including base salary, incentive compensation and equity-based grants;
- reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- overseeing and administering our cash and equity incentive plans;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and directors;
- reviewing and approving all employment contract and other compensation, severance and change-in-control arrangements for our executive officers;
- recommending to our board of directors any stock ownership guidelines for our executive officers and non-employee directors;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor, and determining the compensation and independence of such consultant or advisor;
- preparing, if required, the compensation committee report on executive compensation for inclusion in our annual proxy statement in accordance with the proxy rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- overseeing our compliance with applicable SEC rules regarding shareholder approval of certain executive compensation matters;
- reviewing the risks associated with our compensation policies and practices;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee are . chairs the compensation committee. Prior to establishing a compensation committee, our board of directors made decisions relating to the compensation of our executive officers.

Nominating and Governance Committee

Our nominating and corporate governance committee's responsibilities upon completion of this offering will include:

- identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing a policy under which our shareholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- reviewing and recommending committee slates on an annual basis;
- recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principals applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility;
- making recommendations to our board of directors processes for annual evaluations of the performance of our board of directors, our chief executive officer and committees of our board of directors;
- overseeing the process for annual evaluations of our board of directors, chief executive officer and committees of our board of directors and certifying that performance of our chief executive officer and other members of executive management is being properly evaluated;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions in the Company;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee are . chairs the nominating and corporate governance committee.

Our board of directors may establish other committees from time to time.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to

accounting matters and financial reporting. The nominating and governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

Code of Business Conduct and Ethics

Prior to the effectiveness of the registration statement of which this prospectus is a part, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the effectiveness of the registration statement of which this prospectus is a part, a current copy of the code will be posted on the investor section of our website. The information on our website is deemed not to be incorporated in this prospectus or to be a part of this prospectus. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq Stock Market rules concerning any substantive amendments to, or waivers from, any provision of the code.

Executive and Director Compensation

Overview

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from the programs summarized in this discussion.

The following tables and discussion describe the material elements of the compensation awarded to, earned by, or paid to Jennifer S. Buell, Ph.D., our Interim Chief Executive Officer, who also currently serves as the President and Chief Operating Officer of Agenus, Garo H. Armen, Ph.D., our President and Chairman of the Board, who also currently serves as the Chairman and Chief Executive Officer of Agenus, Walter Flamenbaum, M.D., our Vice Chairman and former Chief Executive Officer, and Patrick N. Jordan, our Chief Operating Officer, by us under our compensation and benefit plans and programs in respect of their service to us for the fiscal year ended December 31, 2020. These individuals are referred to collectively in this prospectus as our "named executive officers." Amounts in the tables below do not include any amounts awarded to, earned by, or paid to our named executive officers by Agenus in respect of their employment with or services provided to Agenus, if applicable.

Dr. Flamenbaum served as our Chief Executive Officer for all of fiscal year 2020. Effective as of January 1, 2021, Dr. Flamenbaum transitioned to a role on our board of directors as Vice Chairman and Dr. Buell was appointed to serve as our Interim Chief Executive Officer. During 2020, and prior to her appointment as our Interim Chief Executive Officer, Dr. Buell had not been formally appointed to any official title with AgenTus, but had a lead role in the management of our Company.

With respect to our named executive officers that are also officers of Agenus, and other than with respect to grants of Company awards, Agenus and the compensation committee of Agenus were responsible for determining the compensation of such executive officers for fiscal year 2020 and have continued to be responsible for doing so in fiscal year 2021. With respect to our named executive officers that are not officers of Agenus, and with respect to all grants of Company equity awards to any of our named executive officers, our board of directors was responsible for determining the compensation of such executive officers for fiscal year 2020 and has continued to be responsible for doing so in fiscal year 2021. Following this offering, the compensation committee of our board of directors will generally be responsible for making such determinations. Our former Chief Executive Officer also made recommendations with respect to the compensation of his direct reports for fiscal year 2020, and our current Interim Chief Executive Officer is expected to do so for fiscal year 2021.

Summary Compensation Table

The following table sets forth the compensation awarded to, earned by, or paid to our named executive officers in respect of their service to us for the fiscal year ended December 31, 2020:

Name and principal position	Year	Salary ($)	Bonus ($)(2)	Stock awards ($)(3)	Option awards ($)(4)	All other compensation ($)(5)	Total ($)
Jennifer S. Buell, Ph.D.							
Interim Chief Executive Officer	2020	—	—	—	917	—	917
Garo H. Armen, Ph.D.							
President and Chairman of the Board	2020	—	—	—	1,484	—	1,484
Walter Flamenbaum, M.D.							
Vice Chairman	2020	373,846		—	911	7,396	382,153
Patrick N. Jordan							
Chief Operating Officer	2020	150,000(1)		200	—	4,500	154,700

(1) Mr. Jordan originally commenced employment with Agenus on June 29, 2020 and formally transitioned to employment by us on November 12, 2020. The amounts in the table above reflect his compensation from

Agenus allocated to services he provided to the Company from August 2020 through November 2020 and from the Company for services provided to the Company since November 2020.

(2) We have not yet determined the annual cash bonuses, if any, that will be payable to Dr. Flamenbaum or Mr. Jordan for 2020. We expect that bonus amounts will be determined in the first quarter of 2021. Drs. Buell and Armen were not entitled to earn any annual cash bonus payment from AgenTus for 2020.

(3) The amount shown reflects the aggregate grant date fair value of performance-based restricted shares of our common stock granted to Mr. Jordan in fiscal year 2020, computed in accordance with FASB ASC Topic 718, disregarding the effect of estimated forfeitures. The assumptions used to value the restricted stock for this purpose are set forth in Note 8 to our consolidated financial statements included elsewhere in this prospectus.

(4) The amounts shown reflect the aggregate grant date fair value of options to purchase our common stock granted to Drs. Buell, Armen and Flamenbaum in fiscal year 2020, computed in accordance with FASB ASC Topic 718, disregarding the effects of estimated forfeitures. The assumptions used to value our options for this purpose are set forth in Note 8 to our consolidated financial statements included elsewhere in this prospectus.

(5) The amounts reported reflect matching contributions made to Dr. Flamenbaum and Mr. Jordan under the Agenus 401(k) Plan.

Named Executive Officer Compensation

Agreements with Our Named Executive Officers

Each of Dr. Flamenbaum and Mr. Jordan is party to a letter agreement with us that sets forth the terms and conditions of his employment. The material terms of the agreements are described below.

On November 14, 2019, we entered into a letter agreement with Dr. Flamenbaum that provides for a base salary of $360,000 per year, subject to periodic review. The letter agreement also provided for a sign-on bonus of $30,000, which was paid in 2019, and for the grant of an option to purchase 60,000 shares of our common stock, which was granted to him in 2019 as described under “Equity Compensation” below, and an option to purchase 15,000 shares of Agenus common stock, which was granted to him on November 14, 2019. Dr. Flamenbaum’s letter agreement also provides for a one-time performance bonus opportunity of up to $2,000,000, contingent upon the Company’s achievement of specified milestones related to clinical trials and equity financing, as determined by mutual agreement with the chairman of the Company’s board of directors.

Following his transition to Vice Chairman of our board of directors, and while he continues to provide services to the Company, it is expected that Dr. Flamenbaum will continue to be compensated pursuant to the terms of his employment agreement, described above, which will remain in effect.

Dr. Flamenbaum also entered into an Employee Nondisclosure Agreement under which he has agreed to a perpetual confidentiality covenant and an assignment of intellectual property covenant.

We entered into a letter agreement with Mr. Jordan on November 12, 2020 that provides for a base salary of $360,000 per year and a target annual bonus equal to 35% of his base salary. The letter agreement also provided for the grant of 20,000 restricted shares of our common stock. Mr. Jordan was granted restricted shares in satisfaction of this letter agreement provision in fiscal year 2020, as described below under “Equity Compensation.”

Mr. Jordan also entered into a Restrictive Covenant and Intellectual Property Agreement under which he has agreed not to solicit our employees, independent contractors, customers or suppliers during employment and for one year following his termination of employment and to a perpetual confidentiality covenant and an assignment of intellectual property covenant.

We granted stock options to each of Drs. Buell and Armen as compensation for their services to us, as described in "Equity Compensation" below, but we have not provided any other form of compensation to these named executive officers, who are also named executive officers of Agenus. No portion of Drs. Buell's and Armen's compensation from Agenus was allocated to us during 2020.

We expect that Dr. Buell's appointment to serve as our Interim Chief Executive Officer will be short-term and temporary, pending the anticipated success of our active search for a permanent replacement for Dr. Flamenbaum, and we have not entered into any agreements with respect to Dr. Buell's compensation as our Interim Chief Executive Officer.

We do not have any employment or services agreement with Dr. Armen.

Severance Upon Termination of Employment; Change in Control

Under his letter agreement, if Dr. Flamenbaum's employment is terminated by the Company, he will be entitled to receive continued payment of his initial base salary for a period of three months following termination, conditioned on Dr. Flamenbaum's execution of a separation agreement that includes a customary release of claims. Dr. Flamenbaum's letter agreement also provides that upon a termination of his employment for any reason other than cause (as defined in his letter agreement), his options to purchase 60,000 shares of our common stock and 15,000 shares of Agenus common stock will fully and immediately vest. In addition, pursuant to the letter agreement, these options will fully and immediately vest upon a change of control of either Agenus or the Company.

We have not provided any severance or change in control related benefits to any of our other named executive officers.

Equity Compensation

Drs. Buell, Armen and Flamenbaum each hold options to purchase shares of our common stock, and Mr. Jordan holds restricted shares of our common stock, in each case, granted under the 2018 Plan. Dr. Flamenbaum, in years prior to 2020, also received options to purchase shares of Agenus common stock granted under the Agenus 2019 Equity Incentive Plan (the Agenus 2019 Plan). The terms of the named executive officers' outstanding equity awards and the applicable plans are described below under "Equity Incentive Plans." Drs. Buell's and Armen's participation in the Agenus equity incentive plans is solely related to the services they provide to that entity and awards under those plans are not disclosed or otherwise discussed in this prospectus.

Each of our named executive officers received incentive equity grants during fiscal 2020, as follows:

On January 30, 2020, Dr. Buell was granted an option to purchase 125,000 shares of our common stock, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, in each case, generally subject to Dr. Buell's continued employment with us or our affiliates through the applicable vesting date.

On January 30, 2020, Dr. Armen was granted an option to purchase 250,000 shares of our common stock, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, in each case, generally subject to Dr. Armen's continued employment with us or our affiliates through the applicable vesting date.

On November 14, 2019, Dr. Flamenbaum was granted an option to purchase 60,000 shares of our common stock, which vests as to 25% of the underlying shares upon the achievement of a development milestone related to clinical trials, as to 25% upon the achievement of another development milestone related to clinical trials and as

to 50% upon the achievement of an equity financing, in each case, generally subject to Dr. Flamenbaum's continued employment or service with us through the applicable vesting date. On January 30, 2020, Dr. Flamenbaum was granted an option to purchase 50,000 shares of our common stock, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, in each case, generally subject to Dr. Flamenbaum's continued employment or service with us through the applicable vesting date.

On November 5, 2020, Mr. Jordan was granted 10,000 restricted shares of our common stock, which vest as to 2,500 shares on each of August 31, 2021, August 31, 2022, August 31, 2023 and August 31, 2024, in each case, generally subject to Mr. Jordan's continued employment through the applicable vesting date. On November 5, 2020, Mr. Jordan was also granted 10,000 restricted shares of our common stock, which vest upon the achievement of an equity financing on or before December 31, 2021 and prior to an initial public offering of our common stock (including this offering), generally subject to Mr. Jordan's continued employment through the vesting date.

Severance and Change of Control Payments and Benefits

Dr. Flamenbaum is entitled to severance benefits under his letter agreement upon a termination of employment in certain circumstances or upon the occurrence of a change in control, as described above under "Named Executive Officer Compensation."

None of the other named executive officers is party to an employment or letter agreement with us under which they are entitled to payments or benefits in connection with a termination of their employment with us or a change of control of the Company.

Employee and Retirement Benefits

During 2020, our named executive officers participated in broad-based health and welfare benefit plans offered by Agenus that are also available to all of our full-time employees, including health, life, disability, vision and dental insurance plans. Our named executive officers participate in these plans on the same basis as other eligible employees, and we do not maintain any supplemental health and welfare plans for our named executive officers. In addition, during fiscal year 2020, our named executive officers participated in the Agenus 401(k) retirement plan. The 401(k) plan is intended to be a tax-qualified defined contribution retirement plan under which eligible employees may defer their eligible compensation, subject to the limits imposed by the Internal Revenue Code. Other than the 401(k) plan, our employees, including our named executive officers, do not participate in any qualified or non-qualified retirement or deferred compensation benefits.

We may provide limited personal benefits or perquisites to our executive officers from time to time. During 2020, the Company reimbursed Dr. Flamenbaum for the cost of wireless internet for his home.

Outstanding Equity Awards at 2020 Fiscal Year-End

The following table shows outstanding Company (and, in the case of Dr. Flamenbaum, Agenus) equity awards held by the named executive officers as of December 31, 2020:

		Option awards					Stock awards			
Name	Grant Date	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)(1)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: market or payout value of unearned shares, units or other rights that have not vested ($)(1)
Jennifer S. Buell, Ph.D.	01/30/2020	—	125,000(2)	—	0.01	01/30/2030	—	—	—	—
Garo H. Armen, Ph.D.	11/19/2018	—	10,000(3)	—	0.04	11/19/2028	—	—	—	—
	11/19/2018	—	—	10,000(4)	0.04	11/19/2028	—	—	—	—
	01/30/2020	—	250,000(5)	—	0.01	01/30/2030	—	—	—	—
Walter Flamenbaum, M.D.	11/14/2019	—	15,000(6)	—	3.74	11/14/2029	—	—	—	—
	01/22/2020	—	—	60,000(7)	0.01	01/22/2030	—	—	—	—
	01/30/2020	—	50,000(8)	—	0.01	01/30/2030	—	—	—	—
Patrick N. Jordan	11/05/2020	—	—	—	—	—	10,000(9)	100	—	—
	11/05/2020	—	—	—	—	—	—	—	10,000(10)	100

(1) Stock awards were valued based on the fair market value of our common stock as of December 31, 2020, which was determined by our board of directors to be $0.01 per share.

(2) Represents an option to purchase 125,000 shares of our common stock, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, in each case, generally subject to continued employment.

(3) Represents an option to purchase 10,000 shares of our common stock, which vests as to 30% of the underlying shares on November 19, 2021 and as to the remaining 70% of the underlying shares on November 19, 2022, in each case, generally subject to continued employment.

(4) Represents an option to purchase 10,000 shares of our common stock, which vests on or about December 31, 2022, as to a portion of the underlying shares as determined by the achievement of certain milestones between January 1, 2019 and December, 31, 2022, with 20% vesting upon achievement of five milestones, and an additional 5% vesting for each additional milestone achieved. The option will also fully vest to the extent the Company undergoes a change of control prior to December 31, 2022.

(5) Represents an option to purchase 250,000 shares of our common stock, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, in each case, generally subject to continued employment.

(6) Represents an option to purchase 15,000 shares of Agenus common stock, which vests as to 25% of the underlying shares upon our achievement of a development milestone related to clinical trials, as to 25% upon our achievement of another development milestone related to clinical trials and as to 50% upon our achievement of an equity financing, in each case, generally subject to continued employment.

(7) Represents an option to purchase 60,000 shares of our common stock, which vests as to 25% of the underlying shares upon the achievement of a development milestone related to clinical trials, as to 25% upon the achievement of another development milestone related to clinical trials and as to 50% upon the achievement of an equity financing, in each case, generally subject to continued employment.

(8) Represents an option to purchase 50,000 shares of our common stock, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, in each case, generally subject to continued employment.

(9) Represents 10,000 restricted shares of our common stock, which vest as to 25% of the underlying shares on each of August 31, 2021, August 31, 2022, August 31, 2023 and August 31, 2023, in each case, generally subject to continued employment.

(10) Represents 10,000 performance shares granted by the Company that are eligible to vest upon the achievement of an equity financing on or before December 31, 2021 and prior to an initial public offering (including this offering), generally subject to continued employment. The number of shares reported in the table represent the number of performance shares that would be earned assuming the performance condition was satisfied in full.

Director Compensation

The following table sets forth the compensation awarded to, earned by or paid to our non-employee directors for services to us for the fiscal year ended December 31, 2020. Any compensation Drs. Armen and Flamenbaum received for 2020 is described in the "Summary Compensation Table" above. Drs. Armen and Flamenbaum did not receive any additional compensation for their services as members of our board of directors.

Name	Fees earned or paid in cash ($)(1)	Option awards ($)(2)	Total ($)
Brian Corvese	50,000	445	50,445
Ulf Wiinberg	50,000	237	50,237

(1) The amounts shown reflect cash fees earned in fiscal year 2020.

(2) The amounts shown reflect the grant date fair value of options to purchase our common stock computed in accordance with FASB ASC Topic 718. The assumptions used to value the options for this purpose are set forth in Note 8 to our consolidated financial statements included elsewhere in this prospectus. As of December 31, 2020, Mr. Corvese held an option to purchase 85,000 shares of our common stock and Mr. Wiinberg held an option to purchase 50,000 shares of our common stock.

In respect of their service on our board of directors in fiscal year 2020, Messrs. Corvese and Wiinberg were each entitled to receive a $50,000 cash retainer and stock options as determined by our board of directors.

In respect of his service as a member of our board of directors, Mr. Corvese received a grant of an option to purchase 75,000 shares of our common stock on January 30, 2020, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, generally subject to Mr. Corvese's continued service with us through the applicable vesting date.

In respect of his service as a member of our board of directors, Mr. Wiinberg received a grant of an option to purchase 40,000 shares of our common stock on January 30, 2020, which vests as to 25% of the underlying shares on each of January 30, 2022, January 30, 2023, January 30, 2024 and January 30, 2025, generally subject to Mr. Wiinberg's continued service with us through the applicable vesting date.

In connection with or following the completion of this offering, we plan to establish a formal policy governing the compensation of our non-employee directors.

Equity Incentive Plans

2018 Plan

In 2018, our board of directors approved the 2018 Plan. The 2018 Plan permits the grant of incentive stock options to our employees and the grant of nonqualified stock options, restricted stock awards, restricted stock units, unrestricted stock, stock appreciation rights and performance awards to our and our affiliates' employees, directors and consultants. Subject to adjustment, the maximum number of shares that may be granted under the 2018 Plan is 3,000,000. As of December 31, 2020, options to purchase 975,000 shares of our common stock were outstanding under the 2018 Plan and 337,500 options remained available for future issuance. Shares underlying awards that are settled in cash, expire or become unexercisable without having been exercised, or that are forfeited to or repurchased by us for cash and shares that are withheld in payment of an exercise price of an award or in satisfaction of tax withholding requirements will become available for subsequent awards under the 2018 Plan. It is anticipated that no further awards will be made under the 2018 Plan following the completion of this offering. In connection with this offering, we intend to adopt a new omnibus equity plan under which we will grant equity based awards in connection with and following this offering. This summary is not a complete

description of all provisions of the 2018 Plan and is qualified in its entirety by reference to the 2018 Plan, which is filed as an exhibit to the registration statement of which this prospectus is part.

Plan Administration.

Our board of directors, or one or more committees of our board of directors, administers the 2018 Plan. As used in this summary, the term "administrator" refers to our board of directors and its authorized delegates, as applicable. Subject to the provisions of the 2018 Plan, the administrator has the authority to, among other things, interpret the 2018 Plan, determine eligibility for and grant awards under the 2018 Plan, determine the form of settlement of awards under the 2018 Plan, prescribe forms, rules and procedures and otherwise do all things necessary or desirable to carry out the purposes of the 2018 Plan.

Non-Transferability of Awards.

The 2018 Plan generally does not allow for the transfer of awards and awards may generally be exercised only by the holder of an award, during his or her lifetime. However, the administrator may, in its discretion, permit the gratuitous transfer of an award other than an incentive stock option, subject to applicable securities and other laws and such other limitations as the administrator may impose.

Adjustments Upon Changes in Capitalization, Merger or Certain Other Transactions.

The 2018 Plan provides that in the event of any stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other similar change in the Company's capital structure, the administrator will make appropriate adjustments to the maximum number of shares reserved for issuance under the 2018 Plan, the number and kind of shares or securities subject to any then outstanding or subsequently granted awards under the 2018 Plan, any exercise prices or purchase prices (or base values) relating to awards under the 2018 Plan and any other provision of awards affected by such change.

In the case of a covered transaction (which does not include this offering), except as otherwise expressly provided in an award agreement or by the administrator, the administrator may, in its sole discretion, take the following actions: (i) if the covered transaction is one in which there is an acquiring or surviving entity, the administrator may provide for the assumption or continuation of some or all outstanding awards or any portion thereof or for the grant of substitute awards by the acquirer or survivor or an affiliate of the acquirer or survivor; (ii) the administrator may provide for the cash out of awards; and (iii) the administrator may provide for acceleration of awards. Except as the administrator may otherwise determine, each award will automatically terminate or be forfeited immediately upon the consummation of the covered transaction, other than awards that are assumed, continued or substituted for following the covered transaction.

Amendment and Termination.

The administrator may, at any time, amend the 2018 Plan or any outstanding award, and may, at any time, terminate the 2018 Plan as to any future grants of awards, provided, however, that no such action may adversely affect rights under any outstanding award without the consent of the holder of the award.

Agenus 2019 Plan

On April 10, 2019, the board of directors of Agenus adopted, and on June 19, 2019, the stockholders of Agenus approved, the Agenus 2019 Plan. The Agenus 2019 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Code, nonqualified stock options, restricted stock, unrestricted stock and other equity-based awards, such as stock appreciation rights, phantom stock awards and restricted stock units, for up to 35,917,776 shares of Agenus common stock (subject to adjustment in the event of stock splits and

other similar events). The board of directors of Agenus appointed the compensation committee of Agenus to administer the Agenus 2019 Plan. No awards will be granted under the Agenus 2019 Plan after June 19, 2029.

2021 Plans

We expect that we will adopt a new equity incentive plan, the 2021 Plan, and an employee stock purchase plan, the 2021 ESPP, in connection with this offering, the terms of which will be described in a subsequent filing.

Certain Relationships and Related Party Transactions

The following is a summary of the transactions since January 1, 2018 to which we have been a party in which the amount involved exceeded $120,000 and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus captioned “Executive and Director Compensation.”

Relationship with Agenus

We are dependent upon Agenus for all of our working capital requirements. Certain of our operations are currently fully integrated with Agenus, including, but not limited to, corporate functions such as finance, human resources, information technology and legal functions. Additionally, we are party to an Amended and Restated Intercompany License and Services Agreement effective September 14, 2018 (the Intercompany Agreement), which amended and restated the original Intercompany License and Services Agreement effective March 1, 2018, under which (i) for consideration of $600,000, we were granted a non-exclusive, field-limited, nontransferable license to certain licensed technology, (ii) Agenus is to perform research and business services (Agenus Services) to support our operations on a cost plus basis and (iii) we are to perform research services to Agenus, also on a cost plus basis.

Allocated Agenus Services primarily include payroll related expenses, facility costs and stock based compensation and. Allocation of Agenus Services, net of $1.4 million for the period ended December 31, 2019, is included in Operating expenses in our statement of operations and Due to related parties in our consolidated balance sheet.

On February 22, 2018, our Board of Directors awarded 1,520,000 of our common shares to directors and certain officers and employees of us and Agenus.

Convertible Promissory Note

On April 1, 2019, we issued a convertible promissory note to Agenus (the Note). The Note had a principal balance of $25.3 million at December 31, 2019. The Note is convertible upon a qualified financing, sale by us of our equity securities resulting in aggregate proceeds to us of at least $50.0 million, or upon a change of control, provided that a qualified financing does not constitute a change of control. In accordance with the terms of the Note, interest is computed on the basis of a 360-day year at 8% and shall accrue and not be payable until converted or paid. The Note was amended in July 2020 to increase the amount of borrowing to up to $35.0 million and extend the maturity to July 1, 2021.

Employment or Offer Letter Agreements

We have entered into employment or offer letter agreements with certain of our executive officers. See “Executive and Director Compensation—Named Executive Officer Compensation” for a further discussion of these arrangements.

We have granted stock options and/or restricted stock to our named executive officers, other executive officers and certain of our directors. See the section of this prospectus captioned “Executive and Director Compensation.”

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors’ and officers’ liability insurance. We also maintain a general liability insurance policy which covers certain liabilities of directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Related Person Transaction Policy

Our board of directors intends to adopt a written related person transaction policy, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act of 1933, as amended, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Principal Stockholders

The following table sets forth certain information with respect to the beneficial ownership of our common stock at December 31, 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person, or group of affiliated persons, who we know beneficially owns more than 5% of our outstanding common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a "beneficial" owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

Percentage ownership of our common stock before this offering is based on 8,687,500 shares of our common stock outstanding as of December 31, 2020. Percentage ownership of our common stock after this offering is based on shares of our common stock outstanding as of December 31, 2020, after giving effect to our issuance of shares of our common stock in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of December 31, 2020 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 3 Forbes Road, Lexington, MA 02421.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
5% or greater stockholders:			
Agenus Inc.	7,000,000	80.6%	%
Directors and Named Executive Officers:			
Jennifer S. Buell, Ph.D.	75,000	*	*
Garo H. Armen, Ph.D.	800,000	9.2%	
Patrick N. Jordan	—	—	—
Christine M. Klaskin	20,000	*	*
Brian Corvese(1)	106,666	1.2%	*
Ulf Wiinberg(2)	106,666	1.2%	*
Walter Flamenbaum	—	—	—
All executive officers and directors as a group (7 persons)	**1,108,332**	**12.7%**	**%**

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Consists of 100,000 shares of common stock and options to purchase 6,666 shares of common stock that are exercisable as of December 31, 2020, or will become exercisable within 60 days of such date.

(2) Consists of 100,000 shares of common stock and options to purchase 6,666 shares of common stock that are exercisable as of December 31, 2020, or will become exercisable within 60 days of such date.

Description of Capital Stock

Capital Structure

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated by-laws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated by-laws that will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

General

Upon completion of this offering, our authorized capital stock will consist of shares, all with a par value of $0.00001 per share, of which:

- shares are designated as common stock; and
- shares are designated as preferred stock.

Common Stock

As of December 31, 2020, we had outstanding 8,687,500 shares of common stock held of record by 34 stockholders.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

As of December 31, 2020, we had no shares of preferred stock outstanding.

Under the terms of our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Options

As of December 31, 2020, options to purchase 975,000 shares of our common stock were outstanding under our 2018 Equity Incentive Plan, of which 84,332 options were vested as of that date.

Anti-Takeover Effects of Our Certificate of Incorporation and Our By-Laws

Our certificate of incorporation and by-laws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Classified board. Our certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have four members.

Action by written consent; special meetings of stockholders. Our certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the by-laws will also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of our board of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require our board of directors to call a special meeting.

Removal of directors. Our certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance notice procedures. Our by-laws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the by-laws will not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the by-laws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Supermajority approval requirements. The DGCL generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless either a corporation's certificate of incorporation or by-laws requires a greater percentage. Our certificate of incorporation and by-laws will provide that the affirmative vote of holders of at least 75% of the

total votes eligible to be cast in the election of directors will be required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our certificate of incorporation and by-laws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but unissued shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum. Our certificate of incorporation will require, to the fullest extent permitted by law, that derivative actions brought in the name of the Company, actions against directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the State of Delaware. Under our 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 does not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Furthermore, our amended and restated by-laws will 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 compliant asserting a cause of action arising under the Securities Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, these provisions may have the effect of discouraging lawsuits against our directors and officers. See “Risk Factors—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.”

Section 203 of the DGCL

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation’s voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by our board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

Listing

We intend to apply to have our common stock approved for listing on the Nasdaq Global Market under the symbol “AGTS.”

Shares Eligible for Future Sale

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See "Risk Factors—Risks related to this offering and ownership of our common stock—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." Furthermore, although we have applied to have our common stock approved for listing on the Nasdaq Stock Market, we cannot assure you that there will be an active public trading market for our common stock.

Upon the closing of this offering, based on the number of shares of our common stock outstanding as of December 31, 2020, we will have an aggregate of shares of our common stock outstanding (or shares of our common stock if the underwriters exercise in full their option to purchase additional shares). Of these shares of our common stock, all of the shares sold in this offering (or shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of our common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

Lock-Up Agreements

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, who will collectively own shares of our common stock upon the closing of this offering (based on our shares outstanding as of December 31, 2020), have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of Mizuho Securities USA LLC.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see "Underwriting."

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares (or shares if the underwriters exercise their option to purchase additional shares in full) of our common stock immediately after this offering; or

- the average weekly trading volume in shares of our common stock on the Nasdaq Stock Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and the Nasdaq Stock Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options and shares of our common stock issued or issuable under our incentive plans. We expect to file the registration statement covering shares offered pursuant to our incentive plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

Material U.S. Federal Income Tax Consequences to Non-U.S. Holders of Our Common Stock

The following discussion is a summary of the material U.S. federal income tax consequences of the purchase, ownership and disposition of our common stock to Non-U.S. Holders (as defined below) that acquire such common stock pursuant to this offering. It does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case, in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

This discussion does not address the tax treatment of partnerships or other pass-through entities or arrangements, or persons who hold our common stock through partnerships or other pass-through entities or arrangements, for U.S. federal income tax purposes. If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND

DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE AND GIFT TAX LAWS, UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION AND UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes (or a partner thereof). A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a domestic corporation;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying any distributions to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any remaining portion of a distribution will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition of Our Common Stock."

Subject to the discussion below on effectively connected income, FATCA and backup withholding, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI (or successor form), certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussion below on backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a "U.S. real property holding corporation," or USRPHC, at any time within the shorter of the five-year period preceding the disposition and the Non-U.S. Holder's holding period for our shares (the relevant period) and the Non-U.S. Holder (i) disposes of our shares during a calendar year when our shares are no longer regularly traded on an established securities market or (ii) owned (directly, indirectly, and constructively) more than 5% of our shares at any time during the relevant period, in which case such a Non-U.S. Holder will be subject to tax on the gain on the disposition of shares generally as if the gain were effectively connected with the conduct of a trade or business in the United States, except that the "branch profits tax" will not apply.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

We believe we currently are not, and we do not anticipate becoming, a USRPHC. Generally, a corporation is a USRPHC only if the fair market value of its United States real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we are not currently a USRPHC or will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" (as defined by applicable Treasury Regulations) on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI (or

successor forms) or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether any distributions constitute dividends or whether any tax was actually withheld.

Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting. However, a sale of our shares by a Non-U.S. Holder that is effected at a foreign office of a broker will be subject to information reporting and backup withholding if: (1) the proceeds are transferred to an account maintained by the Non-U.S. Holder in the United States; (2) the payment of proceeds or the confirmation of the sale is mailed to the Non-U.S. Holder at a United States address; or (3) the sale has some other specified connection with the United States as provided in the Treasury regulations, unless the broker does not have actual knowledge or reason to know that the holder is a United States person and the documentation requirements described above are met or the Non-U.S. Holder otherwise establishes an exemption.

In addition, a sale of shares will be subject to information reporting if it is effected at a foreign office of a broker that is: (1) a United States person; (2) a "controlled foreign corporation" for United States federal income tax purposes; (3) a foreign person 50% or more of whose gross income is effectively connected with the conduct of a United States trade or business for a specified three-year period; or (4) a foreign partnership, if at any time during its tax year (a) one or more of its partners are "U.S. persons", as defined in U.S. Treasury regulations, who in the aggregate hold more than 50% of the income or capital interest in the partnership, or (b) such foreign partnership is engaged in the conduct of a trade or business in the United States, unless the broker does not have actual knowledge or reason to know that the holder is a United States person and the documentation requirements described above are met or an exemption is otherwise established. Backup withholding will apply if the sale is subject to information reporting and the broker has actual knowledge that the holder is a United States person.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code and related Treasury Regulations and guidance, or FATCA, on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on our common stock paid to a foreign entity if the foreign entity is:

- A "foreign financial institution" (as defined under FATCA) that does not furnish proper documentation, typically on IRS Form W-8BEN-E, evidencing either (i) an exemption from FATCA withholding or (ii) its compliance (or deemed compliance) with specified due diligence, reporting, withholding and certification obligations under FATCA or (iii) residence in a jurisdiction that has entered into an intergovernmental agreement with the United States relating to FATCA and compliance with the diligence and reporting requirements of the intergovernmental agreement and local implementing rules; or
- A "non-financial foreign entity" (as defined under FATCA) that does not provide sufficient documentation, typically on IRS Form W-8BEN-E, evidencing either (i) an exemption from FATCA or (ii) adequate information regarding substantial United States beneficial owners of such entity (if any).

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. Under proposed Treasury Regulations, FATCA

withholding would not apply to payments of gross proceeds. Parties obligated to withhold under FATCA generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Under certain circumstances, a Non-U.S. Holder will be eligible for refunds or credits of withholding taxes imposed under FATCA by filing a United States federal income tax return.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Underwriting

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2021, between us and Mizuho Securities USA LLC, as the representative of the underwriters named below and the sole book-running manager of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

Underwriter	Number of Shares
Mizuho Securities USA LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We also have agreed to reimburse the underwriters for up to $ for their FINRA counsel fee. In accordance with FINRA Rule 5110, these reimbursed fees and expenses are deemed underwriting compensation for this offering.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representative. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We intend to apply to have our common stock listed on the Nasdaq Global Market under the trading symbol "AGTS".

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding common stock or of securities convertible into or exchangeable or exercisable for shares of our common stock have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of the representative.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

The representative may, in its sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our

common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

Canada

Resale Restrictions

The distribution of the securities in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the securities in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing the securities in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the securities without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106—Prospectus Exemptions,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of the securities should consult their own legal and tax advisors with respect to the tax consequences of an investment in the securities in their particular circumstances and about the eligibility of the securities for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the company under section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance. You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each Member State of the European Economic Area (each, a Relevant State), no offer of securities that are the subject of the offering has been, or will be made to the public in that Relevant State, except that an offer of shares to the public in that Relevant State may be made at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of securities shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Regulation or to supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or SFO, and any rules made under that Ordinance; or in other circumstances which do not result in

the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or CO, or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) (the FIEL), and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined in Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities under Section 275 of the SFA except:
    - to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
    - where no consideration is or will be given for the transfer;

- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX), or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the Israeli Securities Law), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum (the Addendum), to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals”, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the U.K. that are qualified investors (as defined in the U.K. Prospectus Regulation) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated or caused to be communicated. Each such person is referred to herein as a “Relevant Person.”

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the U.K. Any person in the U.K. that is not a Relevant Person should not act or rely on this document or any of its contents. Any invitation or inducement to engage in investment activity within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the FSMA) may only be communicated or caused to be communicated in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply. All applicable provisions of the FSMA must be complied with in respect of anything done by any person in relation to the securities in, from or otherwise involving the U.K.

No offer of securities that are the subject of the offering has been, or will be made to the public in the U.K., except that an offer of shares to the public in the U.K. may be made at any time:

- to any legal entity which is a qualified investor as defined in the U.K. Prospectus Regulation;
- to fewer than 150 natural or legal persons in the U.K. (other than qualified investors as defined in the U.K. Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of securities shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Section 85 of the FSMA or to supplement a prospectus pursuant to Article 23 of the U.K. Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities, and the expression "U.K. Prospectus Regulation" means Regulation (EU) 2017/1129, as it applies in the U.K. pursuant to the European Union (Withdrawal) Act 2018, as amended.

Cayman Islands

The company is prohibited from making any invitation to the public of the Cayman Islands to subscribe for shares of its common stock and this prospectus does not constitute an invitation or offer to the public in the Cayman Islands with respect to the common stock, whether by way of sale or subscription. "Public" for these purposes shall have the same meaning as 'public in the Islands' as defined in the Cayman Islands Mutual Funds Law. However, shares of our common stock may be beneficially owned by persons resident, domiciled, established, incorporated or registered pursuant to the laws of the Cayman Islands. The company will not undertake business with any person in the Cayman Islands except in furtherance of the business of the company carried on outside of the Cayman Islands.

Legal Matters

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Ropes & Gray, LLP, Boston, Massachusetts. Covington & Burling LLP, New York, New York is counsel to the underwriters in connection with this offering.

Experts

The consolidated financial statements of AgenTus Therapeutics, Inc. as of December 31, 2019 and for the year ended December 31, 2019, have been included herein and in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the December 31, 2019 consolidated financial statements contains an explanatory paragraph that states that the Company's recurring losses from operations and net capital deficiency raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

Where You Can Find Additional Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is *www.sec.gov*.

Upon the effectiveness of the registration statement, we will be subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, will file reports, proxy and information statements and other information with the SEC. Such annual, quarterly and special reports, proxy and information statements and other information can be inspected and copied at the locations set forth above. We intend to make this information available on the investor relations section of our website, which is located at *www.agentustherapeutics.com*. Information on, or accessible through, our website is not part of this prospectus.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
AgenTus Therapeutics, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of AgenTus Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2019, the related consolidated statement of operations and comprehensive loss, stockholders' deficit and cash flows for the year ended December 31, 2019, 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, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, 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 audit. 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 audit in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. 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. Our audit 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 audit 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 audit provide a reasonable basis for our opinion.

/s/ KPMG LLP

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

Boston, Massachusetts
January 22, 2021

AGENTUS THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET
DECEMBER 31, 2019

ASSETS	
Cash	$ 299,036
Prepaid expenses	87,700
Other current assets	531,664
Total current assets	918,400
Equipment, net of accumulated depreciation of $36,816	390,519
Total assets	$ 1,308,919
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Deferred revenue	$ 191,012
Accounts payable	2,456,186
Accrued liabilities	2,600,543
Due to related parties	2,171,160
Total current liabilities	7,418,901
Convertible affiliated note	26,790,402
Other long-term liabilities	3,433,376
Commitments and contingencies	
Stockholders' deficit	
Common stock, par value $0.00001 per share, 10,000,000 shares authorized, 8,645,000 shares issued	86
Additional paid-in capital	294,938
Accumulated other comprehensive loss	(132,590)
Accumulated deficit	(36,496,194)
Total stockholders' deficit	(36,333,760)
Total liabilities and stockholders' deficit	$ 1,308,919

See accompanying notes to consolidated financial statements.

AGENTUS THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEAR ENDED DECEMBER 31, 2019

Revenue	$ 689,626
Operating expenses:	
Research and development	19,654,135
General and administrative	3,828,040
Change in fair value of convertible note	(508,071)
Operating loss	(22,284,478)
Other expense, net:	
Interest expense	(1,560,868)
Other income, net	43,164
Net loss	$ (23,802,182)
Per common share data:	
Basic and diluted net loss per common share	$ (2.75)
Weighted average number of common shares outstanding	8,645,000
Other comprehensive loss	
Foreign currency translation loss	$ (269,174)
Comprehensive loss	$ (24,071,356)

See accompanying notes to consolidated financial statements.

AGENTUS THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT
FOR THE YEAR ENDED DECEMBER 31, 2019

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Number of shares	Par Value				
Balance at December 31, 2018	8,645,000	$ 86	$ 75,367	$ 136,584	$ (12,694,012)	$ (12,481,975)
Net Loss	—	—	—	—	(23,802,182)	(23,802,182)
Other comprehensive loss	—	—	—	(269,174)	—	(269,174)
Grant and recognition of stock options	—	—	734	—	—	734
Recognition of parent stock options	—	—	218,837	—	—	218,837
Balance at December 31, 2019	8,645,000	$ 86	$ 294,938	$ (132,590)	$ (36,496,194)	$ (36,333,760)

See accompanying notes to consolidated financial statements.

AGENTUS THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED DECEMBER 31, 2019

Cash flows from operating activities:	
Net loss	$ (23,802,182)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	36,816
Share-based compensation	219,571
Interest accrued on convertible affiliated note	1,560,868
Change in fair value of convertible affiliated note	(508,071)
Changes in operating assets and liabilities:	
Prepaid expenses	507,544
Accounts payable	886,667
Deferred revenue	190,655
Accrued liabilities	1,419,811
Repayable advance received	3,433,376
Other operating assets and liabilities	1,110,629
Net cash used in operating activities	(14,944,316)
Cash flows from investing activities:	
Purchases of equipment	(426,469)
Net cash used in investing activities	(426,469)
Cash flows from financing activities:	
Proceeds from issuance of convertible affiliated notes	11,436,006
Net cash provided by financing activities	11,436,006
Effect of exchange rate changes on cash	(122,076)
Net decrease in cash	(4,056,855)
Cash, beginning of period	4,355,891
Cash, end of period	$ 299,036

See accompanying notes to consolidated financial statements.

AGENTUS THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Description of Business

AgenTus Therapeutics, Inc. ("AgenTus," "the Company," "we" or "our") is a clinical stage biopharmaceutical company focused on developing allogeneic invariant natural killer T (iNKT) cell therapies to treat cancer and other life-threatening illnesses. We are a majority-owned subsidiary of Agenus Inc. ("Agenus").

We have incurred losses since inception and, as of December 31, 2019, had an accumulated deficit of $36.5 million. Since inception, we have financed our operations primarily through funding from Agenus. We expect to continue to incur operating losses and negative cash flows for the foreseeable future. Until we are successful in our efforts for capital infusion, and because the completion of such is not entirely within our control, a substantial doubt exists about our ability to continue as a going concern for a period of one year after the date these financial statements were issued.

Management continually addresses our liquidity position and adjusts spending as needed in order to preserve liquidity. Our future liquidity needs will be determined primarily by the success of our operations with respect to the progression of our product candidates and key development and regulatory events in the future. Potential sources of additional funding include: (1) pursuing collaboration, out-licensing and/or partnering opportunities for our portfolio programs and product candidates with one or more third parties, (2) securing additional debt financing and/or (3) selling equity securities.

Our product candidates are in various stages of development and significant additional expenditures will be required if we start new 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 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 our programs are early stage, 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.

(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 and include the accounts of us and our subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation.

(b) Segment Information

We are managed and operated as one business segment. The entire business is managed by a single executive operating committee that reports to the chief executive officer. We do not operate separate lines of business with respect to any of our product candidates or geographic locations. Accordingly, we do not prepare discrete financial information with respect to separate product areas or by location and do 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 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 consolidated 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.

(d) Equipment

Equipment is carried at cost, $391,000 at December 31, 2019. 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 of equipment was $37,000, for the year ended December 31, 2019.

(e) Fair Value Option

Under the Fair Value Option subsection of ASC 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 elected to report the convertible promissory note, as amended, it issued to Agenus on April 1, 2019, (the "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 $25.3 million at December 31, 2019.

(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 convertible affiliate note are carried at fair value (a Level 1 measurement and Level 2 measurement, respectively), determined according to the fair value hierarchy described above (see Note 11). 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) Foreign Currency Transactions

Gains and losses from our foreign currency-based accounts and transactions, such as those resulting from the translation and settlement of receivables and payables denominated in foreign currencies, are included in the consolidated statements of operations within other income (expense). We do not currently use derivative financial instruments to manage the risks associated with foreign currency fluctuations. We recorded a foreign currency gain of $43,000 for the year ended December 31, 2019.

(h) Revenue Recognition

Revenue includes grant income recognized in accordance with ASC 958-605, *Not-for-Profit Entities, Revenue Recognition.*

(i) Research and Development

Research and development expenses include the costs associated with our 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 us by outside advisors. Research and development expenses also include the cost of clinical trial materials shipped to our research partners. Research and development costs are expensed as incurred.

(j) Share-Based Compensation

We account 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 a further discussion on share-based compensation.

(k) Income Taxes

Our operations were historically included in the consolidated U.S. Federal and state income tax returns of Agenus. The provision for income taxes has been determined based on the separate return method for the period presented. 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 and 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 we 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, 2019, as they would be anti-dilutive:

	2019
Stock options	402,000
Nonvested shares	125,000

(l) Recent Accounting Pronouncements

Recently Issued and Adopted

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). The amendments in ASU

2018-07 simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. We adopted the new standard on January 1, 2019. The adoption did not have a material impact on our consolidated financial statements.

Recently Issued, Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements of fair value measurements. The standard will be effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with early adoption permitted. Certain disclosures are required to be applied on a retrospective basis and others on a prospective basis. We are currently evaluating the impact of adoption of ASU 2018-13 on our financial statement disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 enhances and simplifies multiple aspects of the income tax accounting guidance in ASC 740. The standard will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of adoption of ASU 2019-12 on our consolidated financial statements.

No other new accounting pronouncement issued or effective during the year ended December 31, 2019 had or is expected to have a material impact on our consolidated financial statements or disclosures.

(3) Other Current Assets

Other current assets consist of the following as of December 31, 2019 (in thousands):

	December 31, 2019
VAT receivable	$ 317
Insurance recovery	209
Other	6
Total	$ 532

(4) Equipment

Property, plant and equipment, net, consist of the following as of December 31, 2019 (in thousands):

	December 31, 2019
Equipment	$ 428
Less accumulated depreciation	(37)
Equipment, net	$ 391

(5) Income Taxes

We are subject to taxation in the United States and in various state, local and foreign jurisdictions. We remain subject to examination by U.S. Federal, state, local and foreign tax authorities for tax years 2017 through 2019. Our policy is to recognize income tax related penalties and interest, if any, in our 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, 2019, we had available net operating loss carryforwards of $16.0 million and $16.0 million for Federal and state income tax purposes, respectively, which are available to offset future Federal and state taxable income, if any. $15.9 million of these Federal net operating loss carryforwards do not expire, while the remaining net operating loss carryforwards expire in 2037. Our ability to use these net operating losses is limited by change of control provisions under Internal Revenue Code Section 382 and may expire unused. We also have foreign net operating loss carryforwards, which do not expire, available to offset future foreign taxable income of $8.0 million in the United Kingdom, $8.4 million in Belgium, and $359,000 in Hong Kong. The potential impacts of such provisions are among the items considered and reflected in management's assessment of our valuation allowance requirements.

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, 2019 are presented below (in thousands).

	2019
Deferred tax assets:	
U.S. Federal and state net operating loss carryforwards	$ 4,281
Foreign net operating loss carryforwards	3,878
Share-based compensation	101
Other	260
Total deferred tax assets	8,520
Less: valuation allowance	(8,520)
Net deferred tax assets	$ —

In assessing the realizability of deferred tax assets, we consider 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. We consider projected future taxable income and tax planning strategies in making this assessment. To fully realize the deferred tax asset, we will need to generate future taxable income sufficient to utilize net operating losses prior to their expiration. Based upon our history of not generating taxable income, we believe 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 $5.6 million during the year ended December 31, 2019.

Income tax benefit was nil for the year ended December 31, 2019. Income taxes recorded differed from the amounts computed by applying the U.S. Federal income tax rate of 21% in 2019 to loss before income taxes as a result of the following (in thousands).

	2019
Computed "expected" Federal tax benefit	$(4,998)
(Increase) reduction in income taxes benefit resulting from:	
Change in valuation allowance	5,614
Decrease due to uncertain tax positions	14
State and local income benefit, net of Federal income tax benefit	(593)
Foreign rate differential	(540)
Permanent differences	425
Other, net	78
Income tax benefit	$ —

(6) Accrued Liabilities

Accrued liabilities consist of the following as of December 31, 2019 (in thousands):

	December 31, 2019
Payroll	$ 1,690
Professional fees	300
Research services	597
Other	14
Total	$ 2,601

(7) Equity

Our authorized capital stock consists of 10,000,000 shares of common stock, $0.00001 par value per share. At inception Agenus Inc. owned 100 percent of our outstanding shares of our common stock. Under our 2018 Equity Incentive Plan (the “2018 Plan”), in February 2018, our Board of Directors issued 1,520,000 shares of our common stock with value of $0.04 per share, see Note 10.

(8) Share-based Compensation Plan

The 2018 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, 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 3,000,000 shares of our common stock (subject to adjustment in the event of stock splits and other similar events).

We primarily use the Black-Scholes option pricing model to value options granted to employees and non-employees, as well as options granted to members of our Board of Directors. All stock option grants have 10-year terms 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:

	2019
Expected volatility	66%
Expected term in years	6
Risk-free interest rate	2.6%
Dividend yield	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 2019 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	509,000	$ 0.04		
Granted	15,000	0.04		
Forfeited	(122,000)			
Outstanding at December 31, 2019	402,000	0.04	8.9	—
Vested or expected to vest at December 31, 2019	82,917	0.04		—
Exercisable at December 31, 2019	82,917	$ 0.04	8.9	—

The weighted average grant-date fair values of options granted during the year ended December 31, 2019, was $0.02. During 2019, all options were granted with exercise prices equal to the market value of the underlying shares of common stock on the grant date.

As of December 31, 2019, there was $6,858 of unrecognized share-based compensation expense related to stock options granted to employees, consultants and directors which, if all milestones are achieved, will be recognized over a weighted average period of 2.7 years.

A summary of non-vested stock activity for 2019 is presented below:

	Nonvested Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	375,000	$ 0.04
Forfeited	(375,000)	0.04
Outstanding at December 31, 2019	—	

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

	2019
Research and development	$ 165,785
General and administrative	53,786
Total share-based compensation expense	$ 219,571

(9) Research and Development Agreement

In December 2018, we entered into an agreement with the Belgium Walloon Region Government 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 our research programs. We recognized $690,000 of grant revenue during the year ended December 31, 2019. Included in our balance sheet at December 31, 2019 is deferred revenue of $191,000 related to the grant funds received and a long-term liability of $3.4 million related to the repayable advance received. During 2020 we discontinued research efforts related to this program and are evaluating our options in accordance with the terms of the agreement.

(10) Related Party Transactions

We are dependent upon Agenus for all of our working capital requirements. For the periods presented, certain of our operations were fully integrated with Agenus, including, but not limited to, corporate functions such as finance, human resources, information technology and legal functions. We are party to an Amended and Restated Intercompany License and Services Agreement effective September 14, 2018 (the "Intercompany Agreement"), which amended and restated the original Intercompany License and Services Agreement effective March 1, 2018, under which (i) for consideration of $600,000, we were granted a non-exclusive, field-limited, nontransferable license to Licensed Technology (as defined in the Intercompany Agreement), (ii) Agenus is to perform research and business services ("Agenus Services") to support our operations on a cost plus basis and (iii) we are to perform research services to Agenus, also on a cost plus basis.

Allocated Agenus Services primarily include payroll related expenses, facility costs and stock based compensation and are included in the accompanying financial statements based on certain estimates and allocations. The allocation methods primarily include time devoted to activities and headcount-based allocations. As such, these allocations may not be indicative of the actual amounts that would have been recorded had we operated as an independent, publicly traded company for the periods presented.

Allocation of Agenus Services, net of $1.4 million for the period ended December 31, 2019, is included in Operating expenses in our statement of operations and Due to related parties in our consolidated balance sheet.

The Note had a principal balance of $25.3 million at December 31, 2019. The Note is convertible upon a qualified financing, sale by us of our equity securities resulting in aggregate proceeds to us of at least $50.0 million, or upon a change of control, provided that a qualified financing does not constitute a change of control. Upon a qualified financing, 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, we 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 accordance with the terms of the Note, interest is computed on the basis of a 360-day year at 8% and shall accrue and not be payable until converted or paid. The Note was amended in July 2020. See Note 15 Subsequent Events.

On February 22, 2018, our Board of Directors awarded 1,520,000 of our common shares to directors and certain officers and employees of us and Agenus.

(11) Fair Value Measurement

We measure the Note at fair value. The fair value of our Note at December 31, 2019 was $26.8 million, based on the Level 2 valuation hierarchy of the fair value measurements standard using a scenario based present value methodology that was derived by evaluating the nature and terms of each note and considering the prevailing economic and market conditions at the balance sheet date. The principal amount of the Note at December 31, 2019 was $25.3 million.

(12) Contingencies

We may currently be, or may become, a party to legal proceedings. While we currently believe that the ultimate outcome of any of these proceedings will not have a material adverse effect on our financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

(13) Benefit Plans

Our 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 year ended December 31, 2019, we expensed $101,000, related to the discretionary contribution to the Plans.

(14) Geographic Information

Our revenue for the year ended December 31, 2019 was earned in Europe based on the domicile of the related business operation.

(15) Subsequent Events

In March 2020, in response to the COVID-19 pandemic, we streamlined our organization, which included a headcount reduction. The full extent to which the COVID-19 pandemic will impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19. We have considered potential impacts arising from the COVID-19 pandemic and are not presently aware of any events or circumstances that would require updates to estimates or judgments, or revise the carrying value of any assets or liabilities.

In May 2020, we entered into a promissory note with Bank of America, NA for aggregate loan proceeds of $356,000 (the “Loan”) under the Small Business Administration (the “SBA”) Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”). We intend to use at least 60% of the Loan proceeds for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act, as amended by the Paycheck Protection Program Flexibility Act. The Loan has a two-year term and bears interest at a rate of 1% per annum. The Loan may be forgiven partially or fully if the Loan proceeds are used for covered costs provided that such amounts are incurred during the covered period commencing on receipt of the Loan proceeds and at least 60% of any forgiven amount has been used for covered payroll costs. Any forgiveness of the Loan will be subject to approval by the SBA and will require us to apply for such treatment in the future.

In July 2020, we entered into a third Convertible Promissory Note with Agenus with terms identical to the Note but increasing the amount of borrowing to up to $35.0 million and extending the maturity to July 1, 2021.

The Company has evaluated subsequent events from the balance sheet date through January 22, 2021, the date at which the consolidated financial statements were available to be issued.

AgenTus Therapeutics, Inc.

shares of common stock

Mizuho Securities

, 2021

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Part II

Information Not Required in Prospectus

Item 13. Other expenses of issuance and distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the Nasdaq listing fee:

Item	Amount to be paid
SEC registration fee	$
FINRA filing fee	
Nasdaq listing fee	
Printing and engraving expenses	
Legal fees and expenses	
Accounting fees and expenses	
Transfer agent fees and expenses	
Miscellaneous expenses	
Total	$

Item 14. Indemnification of directors and officers.

As permitted by Section 102(b)(7) of the DGCL, we plan to include in our amended and restated certificate of incorporation a provision to eliminate the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors, subject to certain exceptions. In addition, our amended and restated certificate of incorporation and by-laws will provide that we are required to indemnify our officers and directors under certain circumstances, including those circumstances in which indemnification would otherwise be discretionary, and we are required to advance expenses to our officers and directors as incurred in connection with proceedings against them for which they may be indemnified, in each case except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145(a) of the DGCL provides that a corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

Section 145(b) of the DGCL provides that a corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a

director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

We have entered into indemnification agreements with our directors and, prior to the completion of this offering, intend to enter into indemnification agreements with each of our officers. These indemnification agreements will provide broader indemnity rights than those provided under the DGCL and our amended and restated certificate of incorporation. These indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

The underwriting agreement will provide that the underwriters are obligated, under certain circumstances, to indemnify our directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act.

We maintain directors' and officers' liability insurance for the benefit of our directors and officers.

Item 15. Recent sales of unregistered securities.

Since January 1, 2021, we have granted shares of restricted stock and stock options to purchase an aggregate of shares of our common stock at a weighted-average exercise price of $ per share to employees and directors.

In 2020, we granted 20,000 shares of restricted stock and stock options to purchase an aggregate of 809,750 shares of our common stock at a weighted-average exercise price of $0.01 per share to employees and directors.

In 2019, we granted stock options to purchase an aggregate of 75,000 shares of our common stock at a weighted-average exercise price of $0.0141 to employees and directors.

In 2018, we granted 1,520,000 shares of common stock, 500,000 shares of restricted stock and stock options to purchase an aggregate of 509,000 shares of our common stock at a weighted-average exercise price of $0.04 to employees and directors.

The issuances of the above securities were exempt either pursuant to Rule 701, as transactions pursuant to a compensatory benefit plan, or pursuant to Section 4(a)(2), as transactions by an issuer not involving a public offering.

Item 16. Exhibits and consolidated financial statement schedules.

(a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Consolidated Financial Statement Schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

2. For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Exhibit Index

Exhibit number	Description of document
1.1*	Form of Underwriting Agreement
3.1*	Certificate of Incorporation of AgenTus Therapeutics, Inc.
3.2*	Amended and Restated Certificate of Incorporation of AgenTus Therapeutics, Inc. (to be effective upon the closing of this offering)
3.3*	Form of Amended and Restated By-laws of AgenTus Therapeutics, Inc.
4.1*	Specimen stock certificate evidencing shares of common stock
5.1*	Opinion of Ropes & Gray LLP
10.1*	Amended and Restated Agenus-AgenTus Intercompany License and Services Agreement, by and among Agenus Inc., Agenus Switzerland Inc., Agenus UK LTD, AgenTus Therapeutics, Inc., AgenTus Therapeutics SA, and AgenTus Therapeutics LTD., dated September 14, 2018.
10.2*	Convertible Promissory Note, by and between AgenTus Therapeutics, Inc. and Agenus Inc., dated July 1, 2020.
10.3+*	AgenTus Therapeutics, Inc. 2021 Equity Incentive Plan
10.4+*	AgenTus Therapeutics, Inc. 2021 Employee Stock Purchase Plan
10.5+*	Form of Restricted Stock Award Agreement under the AgenTus Therapeutics, Inc. 2021 Equity Incentive Plan.
10.6+*	Form of Non-Qualified Stock Option Award Agreement under the AgenTus Therapeutics, Inc. 2021 Equity Incentive Plan.
10.7+*	Form of Incentive Stock Option Award Agreement under the AgenTus Therapeutics, Inc. 2021 Equity Incentive Plan.
10.8+*	AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan.
10.9+*	Form of Restricted Stock Award Agreement under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan.
10.10+*	Form of Non-Qualified Stock Option Award Agreement under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan.
10.11+*	Form of Incentive Stock Option Award Agreement under the AgenTus Therapeutics, Inc. 2018 Equity Incentive Plan.
10.12+*	Letter Agreement between AgenTus Therapeutics, Inc. and Walter Flamenbaum, M.D., dated November 14, 2019.
10.13+*	Letter Agreement between AgenTus Therapeutics, Inc. and Patrick Jordan, dated November 12, 2020.
21.1*	List of Subsidiaries of AgenTus Therapeutics, Inc.
23.1*	Consent of KPMG LLP
23.2*	Consent of Ropes & Gray LLP (included in Exhibit 5.1)
24.1*	Powers of Attorney (included on signature page)

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.

Table of Contents

Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lexington, Commonwealth of Massachusetts, on , 2021.

AgenTus Therapeutics, Inc.

By: _____
Jennifer S. Buell
Interim Chief Executive Officer

Each individual whose signature appears below hereby constitutes and appoints each of Jennifer S. Buell and Garo H. Armen and as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
Jennifer S. Buell, Ph.D.	Interim Chief Executive Officer (Principal Executive Officer)	, 2021
Christine M. Klaskin	Treasurer (Principal Financial Officer and Principal Accounting Officer)	, 2021
Garo H. Armen, Ph.D.	Chairman of the Board of Directors	, 2021
Walter Flamenbaum, M.D.	Director	, 2021
Brian Corvese	Director	, 2021
Ulf Wiinberg	Director	, 2021