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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 24, 2020

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

Delaware	**001-37507**	**43-1979754**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

3530 John Hopkins Court
San Diego, California 92121
(Address of principal executive offices, including zip code)

(858) 633-0300
(Registrant's telephone number, including area code)
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**NK**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☒

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

Item 8.01 Other Events.

On June 24, 2020, NantKwest, Inc. (the "Company") issued a press release announcing the Company's proposed offer and sale of shares of its common stock in an underwritten public offering.

In connection with the proposed offering, the Company has updated its disclosures regarding its business and risk factors. The revised disclosure is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Business and Risk Factor disclosure.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NantKwest, Inc.

By: /s/ Sonja Nelson
Sonja Nelson
Chief Financial Officer

Date: June 24, 2020

BUSINESS

The following summary highlights selected information about us. This summary is not complete and does not contain all the information that you should consider before investing in our common stock. Before making an investment decision, you should carefully read the section titled "Risk Factors" and the financial statements and related notes and the other information that we file with the Securities and Exchange Commission. Our actual results could differ materially from those anticipated in the forward-looking statements made in our filings with the Securities and Exchange Commission as a result of different factors, including the risks we face described below and those described in other documents we file with the Securities and Exchange Commission.

Overview

We are a pioneering clinical-stage immunotherapy company focused on harnessing the power of the innate immune system by using our natural killer cell, or NK cells, to treat cancer and viral infectious diseases. NK cells are the body's first line of defense due to their innate ability to rapidly seek and destroy abnormal cells, such as cancer or virally infected cells, without prior exposure or co-activation by other support molecules that are typically required to train and activate adaptive immune cells such as T-cells.

A critical aspect of our strategy is to invest significantly in innovating new therapeutic candidates, based upon our proprietary activated NK, or aNK, cell platform, and conducting clinical testing and scale manufacturing of our most promising biologic product candidates. We believe our aNK cell is capable of being manufactured as a cell-based "off-the-shelf" therapy that can be molecularly engineered in a variety of ways to boost its killing capabilities against cancers and virally infected cells.

We retain worldwide commercial rights to clinical and research data, intellectual property and know-how developed with our aNK cells, as well as what we believe is the only clinical grade master cell bank of aNK cells in existence.

Our Off-the-Shelf Approach

Our NK platforms have demonstrated the ability to induce cell death in cancers and virally infected cells through a variety of concurrent mechanisms including innate killing, antibody-mediated killing, CAR-directed killing and a combination of both antibody-mediated and CAR-directed killing.

Innate Killing—the aNK Platform. We have developed a unique NK cell platform, which we believe is capable of being manufactured as a cell-based "off-the-shelf" therapy that can be molecularly engineered in a variety of ways to boost its killing capabilities against cancers and virally infected cells. Unlike normal natural killer cells, our NK cells do not express the key inhibitory receptors that diseased cells often exploit to turn off the killing function of natural killer cells and escape elimination. We have developed a unique aNK cell, which omits key inhibitory receptors, while preserving critical activation receptors that enable selective innate targeting and killing of distressed and diseased cells. They do so through the recognition and binding of stress-proteins that are overexpressed on the surfaces of

i. rapidly growing cancer cells due to oxidative and metabolic stress, nutrient deprivation and waste accumulation that typically occurs when cell growth outpaces the capacity of local circulation; and

ii. virally infected cells where the cellular machinery is hijacked to produce an abundance of viral proteins and virons.

Our aNK cells are also designed to deliver a more lethal blow to their target by delivering a larger payload of lytic enzymes and cytokines responsible for both direct and indirect killing when compared to other natural killer cells isolated from healthy donors. This is due to the higher density of lytic granules and larger cell volume possessed by aNK cells when compared to that of donor derived natural killer cells. We believe that our aNK cells can be produced at commercial scale as a 'living drug' using our proprietary manufacturing and distribution processes to adequately address select global cancer markets.

Several phase I safety studies with aNK cells have been conducted in a variety of bulky hematological cancers and solid tumors, enrolling 46 patients in a range of dose levels and schedules with encouraging evidence of single-agent activity and a durable remission, including some complete responses in liquid tumors. Based on these earlier clinical trials, we have further modified our aNK platform through virus- free molecular engineering designed to leverage additional modes of killing available to aNKs, including antibody-mediated killing, the haNK platform, and both antibody-mediated and CAR-directed antigen targeted killing, the t-haNK platform.

Antibody-Mediated Killing—the haNK Platform. We have genetically engineered our aNK cell platform to overexpress high-affinity CD16 receptors, which bind to antibodies. These antibody-targeted haNK cells are designed to directly bind to IgG1-type antibodies, such as avelumab, trastuzumab, cetuximab and rituximab, with the intention of enhancing the cancer killing efficacy of these antibodies by boosting the population of competent natural killer cells that can kill cancer cells through Antibody Dependent Cellular Cytotoxicity. Antibody products are abundantly utilized to treat cancer and it is estimated that they generate over $100 billion in reported annual sales. A growing number of studies suggest that clinically meaningful responses to these antibody therapies correlate directly with the overall health of a patient's natural killer cell population and whether they express the high-affinity variant of the CD16 receptor. Currently available literature estimates that only approximately 10% to 15% of the addressable patient population eligible for antibody therapies carry high-affinity CD16 receptors. This implies that our haNK product candidate may have significant market potential as a combination therapy to potentially address a large number of patients who do not carry high-affinity CD16 receptors and, as a result, exhibit a poorer response to antibody therapies. We therefore intend to develop our haNK product candidate as a combination therapy with widely-used U.S. Food and Drug Administration, or FDA, approved antibody products such as avelumab, trastuzumab, cetuximab and rituximab. Current Good Manufacturing Practice, or cGMP, master and working cell banks of our haNK product candidate have been successfully established and will serve as our source for product for our clinical trials and, if approved, commercialization going forward. We have optimized our manufacturing process partly by designing our haNK product candidate to not require IL-2 cytokine supplementation to the growth media every few days, thereby enabling us to overcome a technically challenging and costly limitation that many other natural killer cell-based therapies face. We have also successfully established processes for large-scale production, cryopreservation and long-term storage of final dose forms, thereby optimizing production efficiencies and allowing for on-demand availability with minimal handling at the infusion sites. Our cryopreserved haNK product candidate has been cleared for clinical testing in several phase Ib/II clinical trials, including our phase II Merkel cell cancer study.

CAR-Directed Killing—the taNK Platform. We have genetically engineered our aNK platform to express CARs that target tumor-specific antigens found on the surfaces of cancers and virally infected cells. Our taNK cells are designed to bind directly to these surface antigens and induce cell death through the release of toxic granules directly into the tumor cells and release cytokines and chemokines to recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells. These tumor antigens encompass four categories of proteins, all of which can be targeted individually by our engineered taNK products:

i. Checkpoint ligands, such as PD-L1;

ii. Well-established tumor proteins such as CD19, HER2 and EGFR;

iii. Novel surface antigens associated with cancer stem cells, such as CD123 and IGF-R1; and

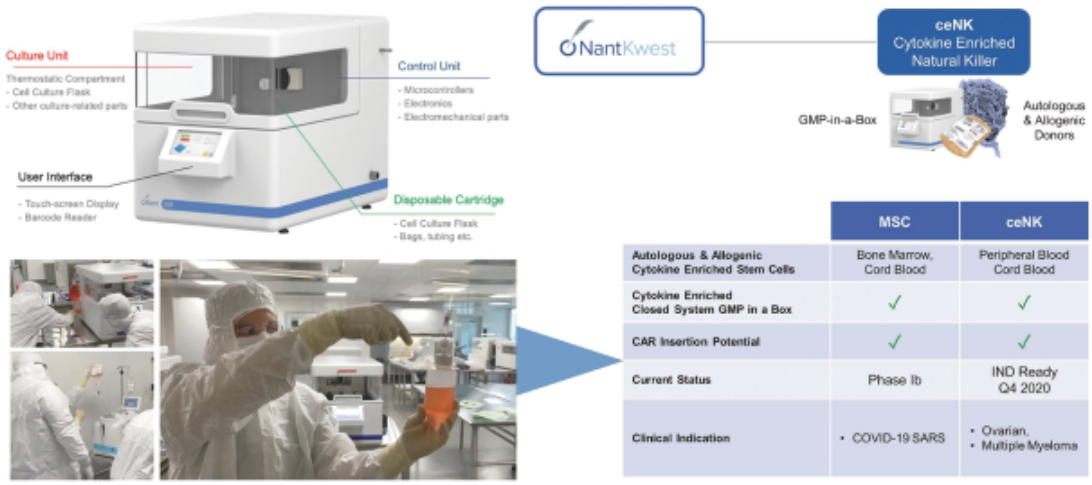
iv. Newly discovered proteins, or neoepitopes, from individual patient tumor samples.

Preclinical evidence has been mounting which indicates that taNK cell activation through the binding of its CAR receptors to these cancer specific proteins may be potent enough to override many of the pre- existing inhibitory signals and immunosuppressive factors present in the tumor microenvironment that may be responsible for tumor resistance.

CAR-Directed and Antibody-Mediated Killing—the t-haNK Platform. Our newest and most promising platform for the development of therapeutic product candidates is an innovative, bioengineered combination of our haNK and taNK platforms that incorporates all the features of our haNK platform together with a CAR. The resulting line of product candidates under this platform avails itself to all three modes of killing: innate, antibody-mediated and CAR-directed killing. These product candidates also include one or more additional expression elements such as functional cytokines, chemokines and trafficking factors, making them amongst the most versatile in our portfolio. These product candidates are intended to be combined with commercially available therapeutic antibodies to effectively target either two different epitopes of the same cancer specific protein or two entirely different cancer specific proteins. In addition to our two t-haNK product candidates, PD-L1.t-haNK, recently cleared to commence phase II testing, and CD19.t-haNK, cleared to commence phase I testing, we believe a pipeline of prominent CARs for t-haNK, including HER2, which is nearing IND submission, and EGFR, which is advancing through clinical enabling studies, among others, will enable us to potentially address an even broader range of cancers as part of a chemotherapy-free combination regimen.

Our GMP-in-a-Box Approach

Nantkwest is a leading company in the efforts to generate allogeneic and autologous sourced NK and mesenchymal stem cell, or MSC, therapeutics. We utilize a scalable GMP production process that combines the use of ImmunityBio's, a related party, semi-automated manufacturing equipment, cytokine expansion and activation reagents such as ImmunityBio's N-803, and unique and simple processing methods, all of which are proprietary. We have optimized processes for generating both fresh and cryopreserved clinical dose forms of memory-like NK cells with 100% purity (in the allogeneic setting) from a variety of sources, including cord blood and allogeneic and autologous peripheral blood. We have also optimized processes for generating fresh and cryopreserved clinical dose forms of MSCs from cord tissue and allogeneic bone marrow sources. We avoid the use of both feeder-layers for activation as well as other commonly applied additives that frequently create downstream issues in achieving a high-quality releasable final dose form and have been able to generate multiple dose forms from each donor product, both of which are critical features in achieving scalability.



Cytokine Enriched Natural Killer (ceNK) Cell Platform. Cytokine-induced memory-like NK cells are a unique set of lymphocytes that differentiate after a brief pre-activation with interleukin-12 (IL-12), IL-15, and IL-18 and exhibit enhanced responses to cytokine re-stimulation that include enhanced interferon-g production and cytotoxicity against leukemic cell lines. These cells have been isolated and characterized by their unique cell-surface marker profile and their highly desirable feature of immune-memory, marked by their pronounced anti-cancer activity for weeks to months in duration, which has made these cells a research focus for more than a decade.

Based on published literature, to date we believe the ability to generate these memory-like cells at scale has been limited to the work performed at Washington University by T.A. Fehniger, et al. Published data so far has been limited to the acute myeloid leukemia patient population in the post-allogeneic, haploidentical stem cell transplantation setting. Based on published literature, to date the Fehniger group has generated enough cells to provide a one-time dose of these cytokine-activated, memory-like NK cells.

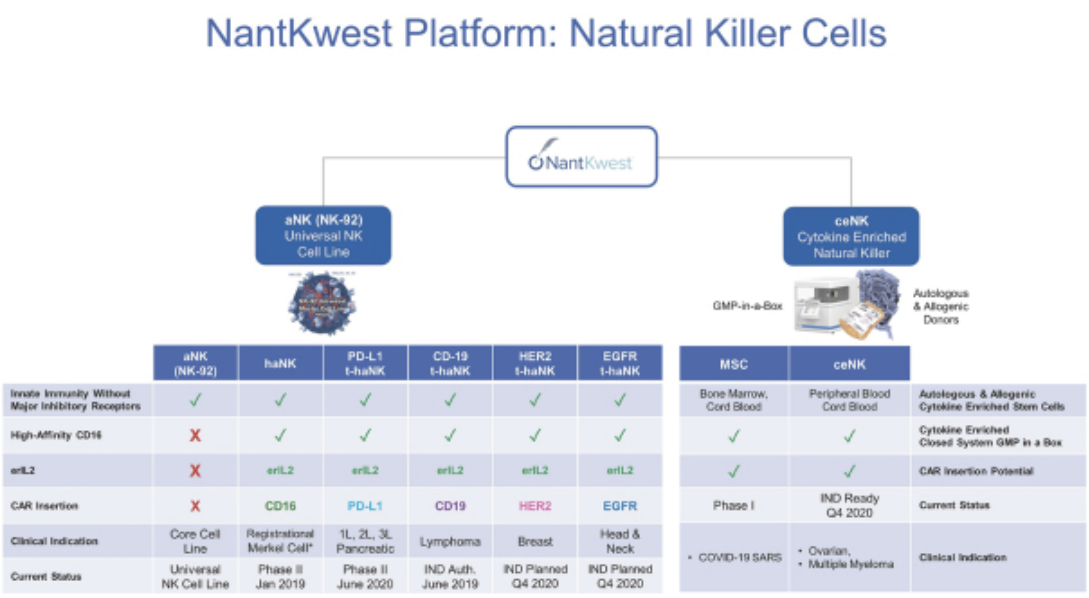
Our cytokine enriched natural killer cell program is based on the ability to enrich and expand donor sourced NK cells in a GMP facility to a clinically relevant scale which allows for the production of a pure cytokine activated and expanded NK cell population that possesses the unique phenotype we call ceNK cells.

NantKwest has developed a unique ability to generate a portfolio of distinct ceNK cell products through the application of ImmunityBio’s proprietary bioreactors and cytokines and our proprietary methods.

Mesenchymal Stem Cell (MSC) Platform. Bone marrow-derived allogeneic mesenchymal stem cells are considered to be a prominent cell type to treat degenerative diseases and autoimmune disorders. MSCs are reported to be immunoprivileged, allowing for transplantation of allogeneic MSCs without the risk of being rejected by host immune system. MSCs have been found to be capable of modulating immune responses, thereby reducing inflammation as well as immunopathology and protecting alveolar epithelial

cells during acute respiratory distress syndrome (ARDS), including that triggered by cytokine storm. More importantly, MSCs demonstrated promising activity in reducing the non-productive inflammation and in promoting lung generation in a phase II clinical trial, as well as in patients with ARDS in clinic practice. As a result, we believe MSCs have the potential to alleviate the SARS-CoV-2-derived cytokine storm and ARDS, and thereby have an effect on the treatment of subsequent chronic respiratory dysfunction and lung fibrosis.

We have developed and optimized procedures and proprietary protocols to generate multiple dose forms of MSC products from a single bone marrow or cord sample, in a scalable format using ImmunityBio's GMP-in-a-Box system.



Research Update on our Product Candidates

Our haNK cell therapeutic candidate is a molecularly engineered variant of our aNK cell platform, which incorporates both the expression of

i. A natural, high-affinity antibody engager, FcgRIIIa/CD16 receptor, which is designed to bind to therapeutically administered cancer-targeting antibodies and result in destruction of the cancer targets through a mechanism widely referred to as ADCC, and

ii. The IL-2 support cytokine, whose expression is retained within the cell where it can exert its maximum effects of supporting growth and killing function while sparing leakage into the extracellular surroundings, where it could result in cytokine-related symptoms.

Recently published preclinical research by our collaborators at the National Cancer Institute under a NantKwest funded clinical research and development agreement confirms and expands upon earlier research which demonstrated that irradiated and cryopreserved haNK cells showed increased resistance to hypoxic conditions as seen in suppressive tumor microenvironments, a marked distinction from healthy donor-derived natural killer cells, which exhibit significant impairment in both innate killing and antibody-mediated killing as well as in serial killing capabilities. We believe NK performance under

hypoxemic conditions is indicative of how natural killer cell therapies will fare within the tumor micro-environment. Key points include:

i. Of the healthy donor natural killer cells tested, 92% exhibited a significant loss of innate lytic capability against cancer cell lines after exposure to 0% oxygen. In contrast, haNK cells maintained killing ability under the same hypoxic conditions.

ii. Hypoxia led to decreases in antibody-mediated, or ADCC, killing by as much as 90% in healthy donor natural killer cells, whereas our haNK cells did not show diminished ADCC capacity under hypoxic conditions.

iii. When combined with a human monoclonal antibody to mediate ADCC, killing by haNK cells was superior to that of healthy donor natural killer cells in all examined donors.

iv. Healthy donor natural killer cells serial killing was significantly decreased under 0% oxygen. The addition of cetuximab increased serial killing by six-fold at 20% oxygen and 0% oxygen brought serial killing down to levels similar to those without cetuximab. Our haNK cells displayed a 24.6-fold increase in serial killing compared with healthy donor natural killer cells under 20% oxygen and this was not significantly decreased under 0% oxygen. The addition of cetuximab increased haNK cell serial killing 99-fold over healthy donor natural killer cells at 20% oxygen and likewise, was not significantly decreased under 0% oxygen.

v. All findings were corroborated by corresponding RNAseq and proteomic analysis.

Our haNK platform is itself being evaluated as a product candidate in a phase II clinical trial in patients with Merkel cell carcinoma who have progressed on or after checkpoint inhibitor therapy.

Additionally, the haNK platform forms the basis of all our t-haNK product candidates, including PD-L1.t-haNK, CD19.t-haNK and Her2.t-haNK, adding an additional mode of cancer targeting via CARs. A second recent publication of preclinical results by our collaborators at the National Cancer Institute on our PD-L1 t-haNK cells, haNK cells engineered to express PD-L1 checkpoint-directed chimeric antigen receptors, demonstrated:

i. In-vivo tumor trafficking,

ii. Significant elimination of both monocytic and granulocytic Myeloid Derived Suppressor Cells, immune-suppressive cells often present in the tumor microenvironment,

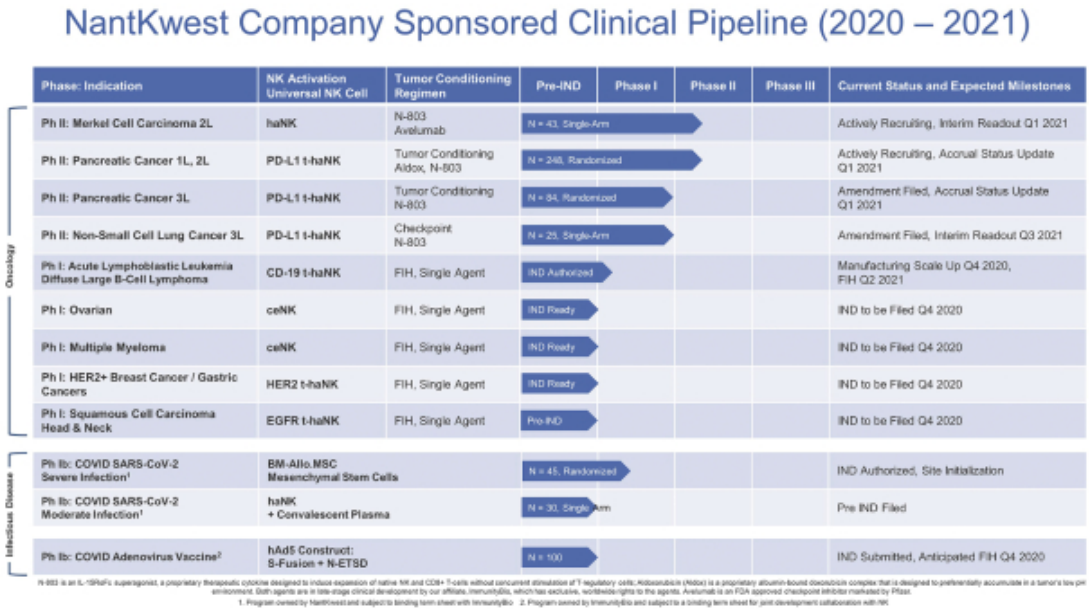
iii. Robust anti-tumor activity in cancer cell lines and in mouse models, and

iv. The ability to kill 20 out of 20 human cancer cell lines tested, including triple negative breast cancer (TNBC) and lung, urogenital, and gastric cancer cells.

Our PD-L1.t-haNK product candidate is being evaluated in a phase II clinical trial in patients with pancreatic cancers as first-line maintenance or as a second-line therapy. Additional studies in other cancers are at various stages of advanced planning.

Our primary target therapeutic area is cancer, with a heavy emphasis on solid tumors. According to the National Cancer Institute, there will be an estimated 1.8 million newly diagnosed cases of cancer in the U.S. in 2020. In 2019 there were an estimated 16.9 million people already living with cancer in the United States. In addition, we plan to advance therapies for hematologic malignancies and virally induced infectious diseases.

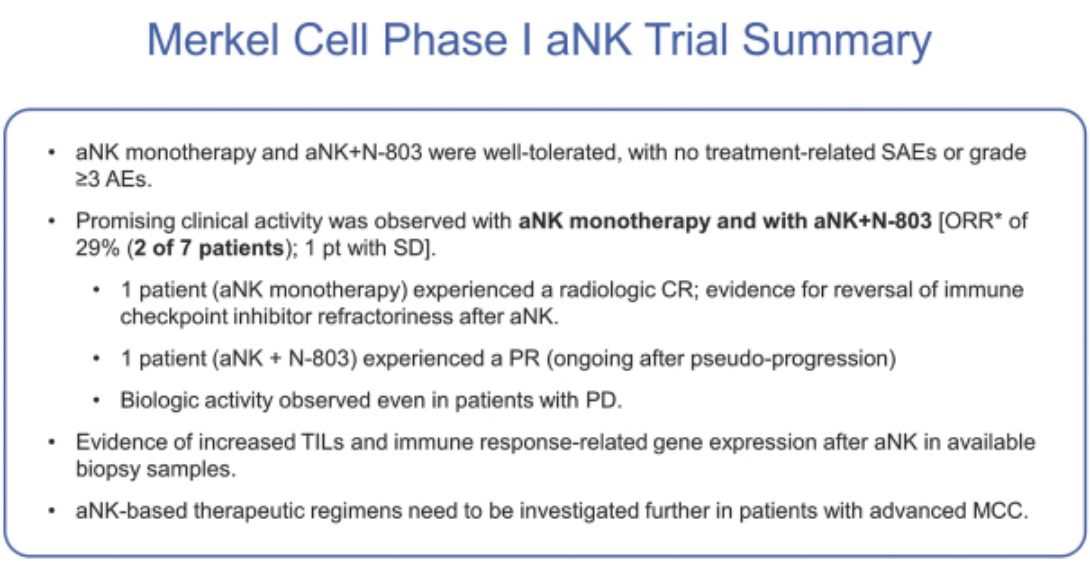
The following table summarizes our current development programs:



Our leading programs reside in two core disease areas: Oncology, which includes haNK and PD-L1.t-haNK programs, and COVID-19, which includes our BM-Allo-MSC and haNK programs. We also have a pipeline of earlier stage t-haNK projects in both Oncology and COVID-19.

haNK Program

Initial clinical experience with aNK and haNK in Merkel cell carcinoma



Based on these encouraging data, we have proceeded with a phase II MCC trial.

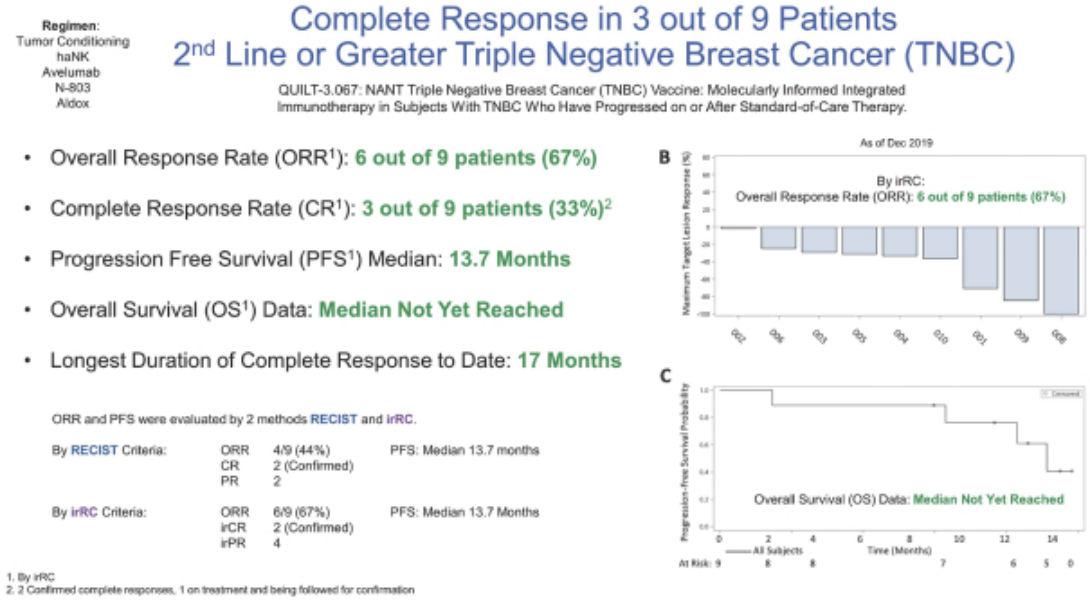
Phase II Trial of haNK in Second Line or Greater Merkel Cell Carcinoma

QUILT 3.063 is a phase II, open label, single-arm trial evaluating the novel triple combination of "off-the-shelf" haNK cell therapy with N-803 and avelumab, without chemotherapy in subjects that have progressed after treatment with a checkpoint inhibitor for Merkel cell carcinoma. Avelumab was the first approved checkpoint inhibitor therapy for front-line treatment of patients with Merkel cell carcinomas. This trial, which is currently enrolling patients, will be evaluating the objective response rate using Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 based on blinded independent central review. Additional measures of efficacy by progression-free survival, overall survival, disease-specific survival, duration of response, disease control rate, and quality of life by patient-reported outcomes and measures of safety will also be assessed. Exploratory objectives include the assessment of the pharmacokinetic and immunogenicity profiles, assessment of tumor molecular profiles and therapy-induced changes in immune responses, and molecular changes in cell-free circulating DNA and RNA, and their correlations with subject outcomes.

This triple combination of immunotherapies has been safely studied in our prior trials for other solid cancer indications. The goal of combining these therapies is to synergistically maximize the killing of cancer cells while attempting to spare patients from chemotherapy and its associated adverse side effects. In both *in vitro* and *in vivo* studies we conducted, the combination of haNK cells with a number of different therapeutic antibodies, including avelumab, led to enhanced tumor cell killing when compared to the use of the antibody alone. Avelumab is a checkpoint inhibitor which targets the programmed death-ligand 1 protein, or PD-L1, commonly expressed on a wide range of cancers. N-803 has been shown to synergistically activate natural killer and T-cells and enhance cancer cell killing in both single agent and combination therapy. When N-803 is combined with haNK cells, a synergistic response was likewise observed in both *in vivo* and *in vitro* models.

Merkel Cell Carcinoma. Merkel cell carcinoma, is a rare and aggressive skin cancer that arises from uncontrolled growth of cells in the skin. Increasing in incidence, approximately 2,500 new cases are reported in the U.S. each year. Patients with metastatic or locally advanced MCC have an extremely poor prognosis, with less than 20% of patients surviving longer than five years. Typically, these patients are treated with a range of drugs, including chemotherapy, which can result in significant side effects. Although new immune therapies have the potential to improve survival, MCC is still fatal for a majority of patients who have progressed on or after treatment with a checkpoint inhibitor and represents an unmet medical need.

Initial clinical experience with haNK in Triple Negative Breast Cancer (TNBC)



Based on these encouraging phase Ib data, we plan to request an end of phase I meeting with FDA to discuss the potential for a registration path in TNBC with our PD-L1.t-haNK product candidate.

PD-L1.t-haNK Program

Our novel GMP-grade, cryopreserved, “off-the-shelf” bi-specific PD-L1.t-haNK NK cell therapy candidate received authorization from the FDA in June 2019 to proceed with a first-in-human, dose escalation-single agent safety study. To date, we completed treatment for the first nine patients and one patient whose treatment is ongoing, across the first three dose cohorts of this phase I study in patients with locally advanced or metastatic solid cancers. In this study, five of the patients had a significant adverse event, or SAE, only one of which was suspected to have been drug related. This patient experienced shortness of breath and after recovery continued in the study at the same dosage as before with no subsequent adverse events. The remainder of the SAEs were judged to be possibly related to drug in patients with very advanced disease. One patient at the highest dose level experienced a dose-limiting toxicity involving neutropenia and we subsequently determined to reduce the dosing frequency from twice per week to once per week. We expect to enroll an additional four to six patients at this dosing schedule and to be ready for full study readout in the fourth quarter of 2020.

While efficacy assessment was not part of this monotherapy trial, we did observe that several patients achieved a stable disease response early on but note that all patients went on to develop progressive disease. Since PD-L1.t-haNK is not intended for use as a monotherapy, it will be applied as the backbone of a combination regimen that includes a therapeutic monoclonal antibody in addition to the IL-15 superagonist, N-803, through our exclusive co-development agreement with Altor, a related party. We believe that the addition of this selective IL-15 cytokine therapy will complement the activity of our bispecific NK cell therapy through its stimulation of the patient’s own resident population of natural killer and cytotoxic CD8 T-cells. A similar approach will be used for our CD19.t-haNK NK cell therapy in CD19 positive B-cell malignancies.

After evaluation of safety and initial activity, we plan to conduct a wide range of additional immunotherapy studies with this agent in simple combinations to address the PD-L1 molecular marker across select tumor types beyond pancreatic cancer, including non-small cell lung cancers, and do not intend to pursue development of PD-L1.t-haNK as a monotherapy. By the conclusion of the study, we believe we will have characterized the pharmacologic profile for PD-L1.t-haNK, obtained preliminary estimates of efficacy as a monotherapy in terms of objective response rate, progression-free survival and overall survival, assessed tumor molecular profiles, as well as therapy-induced changes in immune responses and their correlations with subject outcomes.

On a related note, a patient with late stage pancreatic cancer was enrolled to a special IND (spIND) to receive PD-L1.t-haNK cells in combination with N-803 and aldoxorubicin. This protocol design was a streamlined version of the design that evolved across three phase Ib haNK combination protocols for patients with pancreatic cancers who have progressed on or after standard-of-care therapy. All patients tolerated the combination therapy with haNK cells and while survival was not formally assessed, it was noted that ten of the 13 patients on study experienced a stable disease at their first scheduled assessment and five continued to experience stable disease on subsequent scheduled assessments, which ranged from four to seven months. These observations were encouraging, given that at the time of enrollment, all patients were experiencing progressive disease.

The patient enrolled into the spIND protocol was confirmed to have a complete response by Positron Emission Tomography CT at six months. While this single data point is not statistically significant or indicative of the likelihood to secure approval, it serves as a proof of concept for us that PD-L1.t-haNK in combination with N-803 and a tumor conditioning regimen that includes aldoxorubicin may have encouraging clinical activity that warrants further study. QUILT 88, a phase II/III protocol that was recently filed with the FDA, will investigate this combination of agents further. The results of this spIND were very positive; however, it has no statistical significance and will not be included in any application we may make to the FDA regarding the use of PD-L1.t-haNK.

Phase II/III Front-Line Maintenance, Second Line and Third Line Treatment of Locally Advanced or Metastatic Pancreatic Cancer

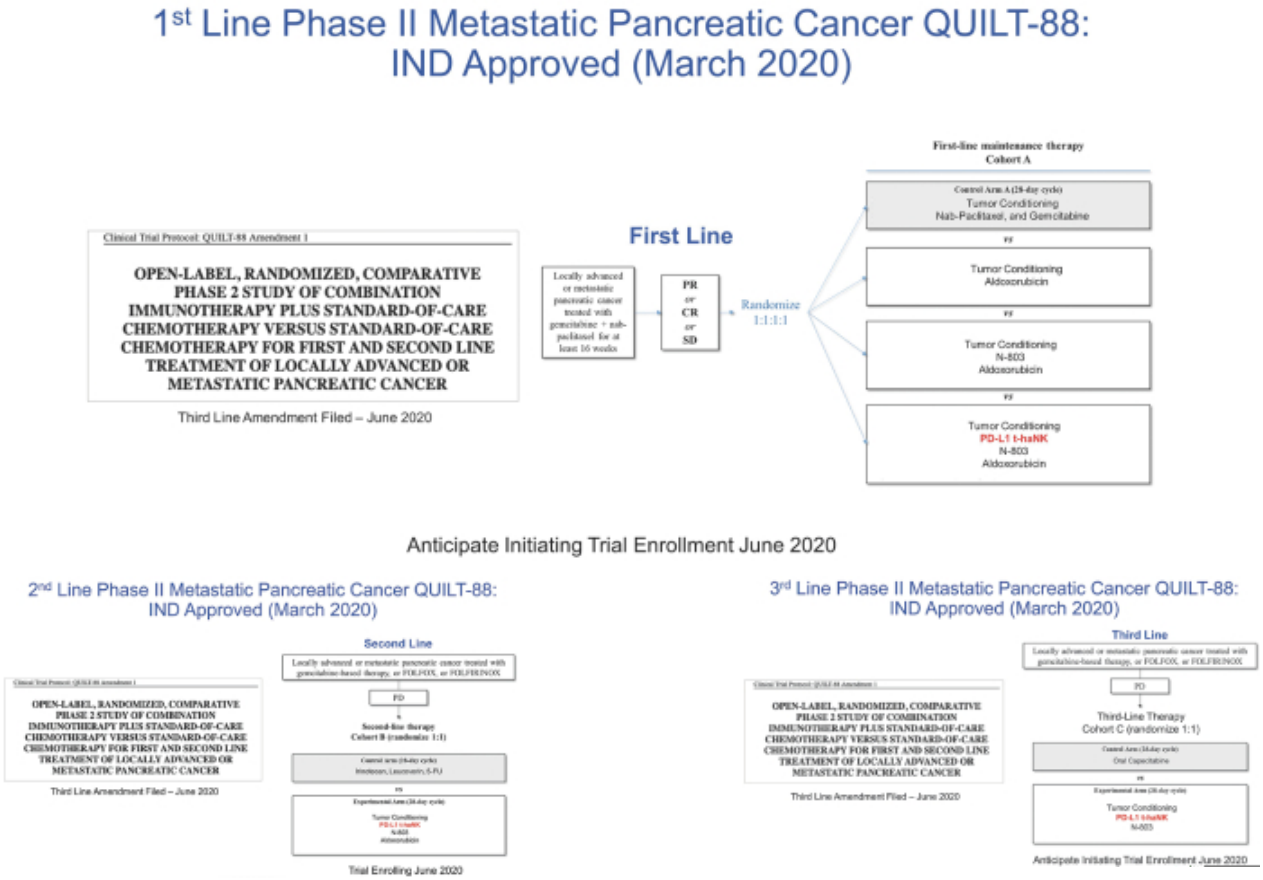
QUILT 88 is a phase II/III open-label, randomized, three-cohort comparative study of PD-L1.t-haNK, N-803 and aldoxorubicin in combination with standard-of-care therapy versus standard-of-care therapy alone for front-line maintenance and second line treatment of subjects with locally advanced or metastatic pancreatic cancer. The three cohorts include:

A. Front-line maintenance therapy in patients that have achieved either a partial response, complete response, or stable disease after first-line standard-of-care therapy;

B. Second line therapy; and

C. Third line therapy or greater.

Within each cohort, enrolled subjects will be randomly assigned to receive a combination of PD-L1.t-haNK, N-803 and aldoxorubicin with standard-of-care in an experimental arm or standard-of-care only in the control arm.



Safety and progression-free survival will be compared between the groups using RECIST version 1.1 based on blinded independent central review. The IND application for QUILT 88 has recently been cleared by the FDA, the IND amendment for the addition of cohort C for third-line or greater has been filed with the FDA and multiple clinical sites are being engaged. We anticipate initiating study enrollment in June 2020.

Pancreatic Cancer. Pancreatic cancer is one of the deadliest cancers for patients in the U.S. Pancreatic cancer is the third leading cause of cancer-related death in the U.S., behind only lung cancer and colorectal cancer, and is expected to become the second-leading cause after lung cancer around 2020. The overall five-year survival rate is just 9%. In 2019, an estimated 56,770 people were diagnosed with pancreatic cancer in the U.S., and it is estimated that approximately 45,750 of those newly diagnosed will die from the disease. Pancreatic cancer is the ninth-most commonly diagnosed cancer in women and the tenth-most commonly diagnosed in men. Only about 20% to 30% of cases are found early enough to treat surgically, before the cancer has spread, and surgery gives the only chance that this cancer can be eradicated. Treatment options for pancreatic cancer patients include surgery, chemotherapy, radiation

therapy, targeted therapy, immunotherapy, and clinical trials. Pancreatic cancer is uniformly accepted as an area of serious unmet medical need, with five-year relative survival rates by SEER (The Surveillance, Epidemiology, and End Results program of the NCI) stage at diagnosis of 37% for localized, 12% for regional, 3% for distant, and 9% for all SEER stages combined.

COVID-19 Programs Update

QUILT-COVID-19-MSC. COVID-19 infection causes progressive severe lung infection that can lead to death in a significant number of infected patients. Prior work using allogeneic MSCs in severely infected individuals has shown promise in reversing the severe consequences of infection in critically ill patients such as the consequences of cytokine release syndrome. Thus, the potential exists for allogeneic MSCs to slow or halt disease progression and reduce time on ventilators in critically ill patients infected with COVID-19, and thus improve disease outcomes.

We plan to conduct a randomized, double-blind placebo-controlled phase Ib study to assess the safety of therapeutic treatment with immunomodulatory bone marrow-derived mesenchymal stem cells, or BM-Allo-MSC, in adults with severe COVID-19 infection. This clinical trial will evaluate the safety and efficacy of BM-Allo-MSC versus best supporting care in treating patients with severe disease requiring ventilator support during COVID-19 infection. A total of 45 subjects receiving care in the critical care or ICU setting for COVID-19 will be enrolled in this study. Subjects will be randomized in a 2:1 fashion to the experimental and control arms, respectively.

Primary endpoints include incidence of adverse events, mortality and number of ventilator-free days within 60 days of randomization. All subjects will also be assessed using the standard National Early Warning Score (NEWS) score (Royal College of Physicians 2012). The NEWS score has demonstrated an ability to identify patients at risk of poor outcomes and will be used as a measure of efficacy. This score is based on 7 clinical parameters (respiration rate, oxygen saturation, any supplemental oxygen, temperature, systolic blood pressure, heart rate, level of consciousness). We will be evaluating any changes in NEWS scores from baseline assessments.

We recently announced FDA clearance of our IND for BM-Allo-MSC and are moving rapidly to initiate the Phase Ib trial. To expedite trial initiation, we engaged a national marrow donor service to provide us with cryopreserved donor stem cell material. We believe the accelerated access to material, combined with our scalable manufacturing processes, will allow for rapid enrollment in the trial. Enrollment is anticipated to begin in July 2020 and is currently planned at several area hospitals in Southern California.

QUILT-haNK-COVID-19. We plan to conduct an open-label, phase Ib study of the safety of haNK in combination with convalescent plasma, or CP, for treatment of high-risk, hospitalized adults with COVID-19. This clinical trial is designed to assess the safety and the immune enhancement activity of haNK alone and in combination with CP in hospitalized subjects with COVID-19. A total of 30 subjects who have tested positive for SARS-CoV-2 and have confirmed COVID-19 lung disease that require supplemental oxygen, but not ventilator assistance, will be enrolled. Subjects may be receiving other supportive care in the hospitalized setting. A pre-IND for this project was filed with the FDA in April 2020, and we anticipate completing the regulatory authorization process, filing an IND and preparing clinical sites for study enrollment in the third quarter of 2020.

Additional Programs Update

We anticipate pursuing an additional indication for our PD-L1.t-haNK product candidate, specifically in non-small cell lung cancer and we anticipate filing an IND for each in the second half of 2020. Following clearance of the IND, we plan to conduct a phase II clinical trial in this indication. Earlier stage t-haNK

programs, including CD19.t-haNK, which has IND clearance for a phase I B-cell lymphoma trial, and Her2.t-haNK, which is IND ready for a phase I Her2+ breast cancer trial, are both anticipated to progress in the first half of 2021.

Additionally, we anticipate filing IND applications for first-in-human phase I safety testing of ceNK cells in advanced, metastatic ovarian cancer and multiple myeloma in the fourth quarter of 2020.

Ovarian cancer. Pre-clinical data demonstrate encouraging cytotoxic activity of ceNK cells against ovarian cancer cell lines in both in vitro and in vivo models. Given the large unmet medical need with few available treatment options for patients who fail second-line therapy, such an approach potentially holds great promise. Separately, N-803 has likewise demonstrated promising activity in the same setting, holding promise for a potential combination regimen after establishing safety in phase I testing.

Multiple Myeloma. The importance of natural killer cells in multiple myeloma and its potential utility in patients who failed stem cell transplantation is well supported in the literature. Likewise, memory like natural killer cells have demonstrated the potential for clinical utility in this setting. In vitro testing of our own ceNK cells against highly resistant myeloma cell lines have consistently demonstrated potent killing in laboratory assays. Given the industry's focus on the use of BCMA directed CAR-T therapies despite the risk often associated with CAR-T products of life-threatening cytokine release syndrome in addition to expensive in-patient hospital stays, we believe that ceNK cells, either in their native form or modified with a BCMA CAR being developed in-house, could be an attractive product candidate to evaluate in phase I and II clinical studies.

Joint Development Agreement with ImmunityBio for COVID-19

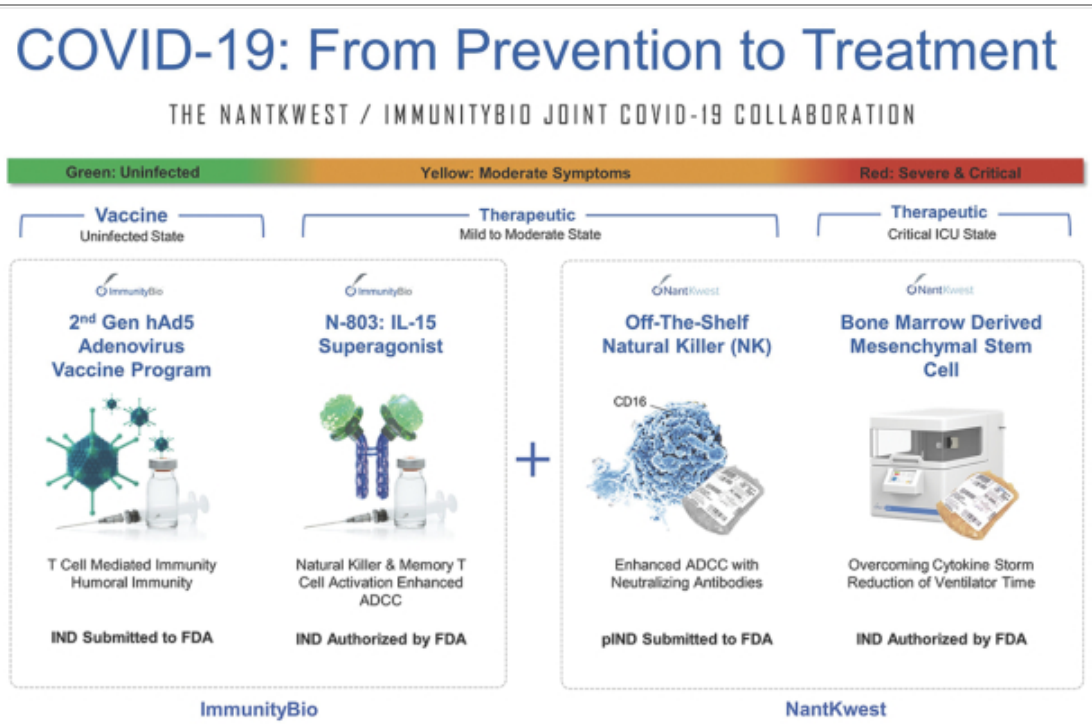
We recently entered into a binding term sheet with one of our affiliate companies, ImmunityBio, Inc., regarding the joint development, manufacturing and marketing of a vaccine and multiple therapeutics for COVID-19 (the "Joint COVID-19 Collaboration"). We are negotiating and finalizing a definitive agreement related to this term sheet and expect to complete this definitive agreement by late August 2020, and our current plans and operations assume that this definitive agreement will be executed to continue the Joint COVID-19 Collaboration. Until the definitive agreement is finalized, any investments made by each entity are the responsibility of the contributing party. As of May 31, 2020, we have incurred expenditures of approximately $0.6 million relating to this joint development program and have committed expenditures of $5.2 million that we will incur in future periods.

In this Joint COVID-19 Collaboration, we contributed the following programs:

- ***QUILT-COVID-19-MSC*** (as described above) as a therapeutic candidate for patients with severe symptoms of COVID-19, or what we refer to as a "red" status, to modulate the immune system's excessive response to COVID-19 infection, thereby potentially reducing the debilitating and sometimes fatal effects of the disease; and
- ***QUILT-haNK-COVID-19*** (as described above) as a therapeutic candidate for moderate-risk, hospitalized adults with moderate to severe symptoms of COVID-19, or "yellow" status.

ImmunityBio contributed the following programs:

- ***IL-15***—as a therapeutic candidate for patients with mild symptoms of COVID-19, or "yellow" status, prior to the onset of severe disease by potentially activating natural killer cells to mitigate viral replication; and
- ***Human adenovirus (hAd5***)—as a vaccine candidate for those individuals in an uninfected state, or "green" status, to prevent the onset of COVID-19.



In addition to the above programs contributed by each party, we will contribute our manufacturing capabilities in the form of facilities, equipment, personnel and related know-how, including our GMP manufacturing facility in El Segundo, California, and ImmunityBio will contribute certain manufacturing equipment and related technology and know-how. To date, Nantkwest and ImmunityBio have each prepared a GMP-ready manufacturing plant for COVID-19 vaccine production, which we and ImmunityBio expect will have a combined estimated capacity to produce 100 million doses by year-end 2020. We have prepared one of our GMP manufacturing facilities previously used to manufacture product for our oncology trials to manufacture and produce the vaccine candidate and are in the process of identifying, and subsequently readying, one or more new locations to manufacture and produce clinical products for our oncology trials which will result in additional facilities and related facility operating costs in future periods. We have established a clinical product inventory to continue to supply clinical product for our ongoing oncology trials. In addition, we have repurposed some of our manufacturing facility in Culver City, California, and personnel to support our QUILT-COVID-19-MSC program and have repurposed some of our personnel overseeing quality of our oncology programs to support the Joint COVID-19 Collaboration. We also expect to hire additional staff to support the Joint COVID-19 Collaboration. We believe the Joint COVID-19 Collaboration will have no material impact on our current oncology efforts and trials and we expect that we will be able to continue to manufacture adequate product to continue our ongoing oncology trials.

Additionally, with the sole exception of IL-15 manufacturing, we will have primary responsibility for manufacturing and supplying the COIVD-19 collaboration products for clinical and commercial purposes. We will also have the primary responsibly in the U.S. for sales and marketing of the COVID-19 collaboration products and the parties will share responsibility in the rest of the world for sales and marketing for the COVID-19 collaboration products.

The COVID-19 Joint Collaboration term sheet outlines how development costs will be shared, how profits will be apportioned for any successfully marketed products, and the structure of shared governance of the joint efforts. Under the terms of the collaboration, we and ImmunityBio will share equally in all costs relating to developing, manufacturing, and marketing of the product candidates globally, starting from and after the effective date of the definitive agreement, and the global net profits from the collaboration products will be shared 60%/40% in favor of the party contributing the product on which the sales are based. All net profits from sales of any combined collaboration products will be shared equally. The Joint COVID-19 Collaboration will be supervised by joint committees, comprised of an equal number of representatives from both companies. The term of the agreement will be five years and it is renewable for an additional five year period upon mutual agreement. Each party will also have a right to terminate in the event of material breach, bankruptcy, or insolvency. If the definitive agreement is not entered into by both parties on or prior to August 21, 2020, then either party may thereafter terminate the term sheet upon five business days' notice.

Anticipated Clinical Milestones

** Although there can be no assurance that we will meet these anticipated milestones due to unforeseen circumstances and risks we may face as discussed in the Section "Risk Factors" below.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the novel coronavirus (SARS-CoV-2) a pandemic. In the same month, the President of the United States declared a State of National Emergency due to the COVID-19 outbreak. Many jurisdictions, particularly in North America (including the United

States), Europe and Asia, as well as U.S. states in which we operate, including California, have adopted or continue to consider laws, rules, regulations or decrees intended to address the COVID-19 outbreak, including travel restrictions, closing or, more recently, re-opening of non-essential businesses and/or restricting daily activities. In addition, many communities have limited, and may consider continuing to limit, social mobility and gathering, in particular also in response to the recent rise in COVID-19 cases and fatalities in certain U.S. states including California. Such restrictions and other impacts from COVID-19 may have an impact on our business.

Given the unprecedented and evolving nature of the pandemic, the future impact of these changes and potential changes on our company are unknown at this time. To date, we have seen no material adverse impact to our business from the COVID-19 pandemic. We anticipate, however, that enrollment of patients in our studies will likely take longer than forecasted in prior SEC filings and that our clinical trials may require additional time to complete which would in turn impact the timeline in which we were previously forecasting BLA submissions of our product candidates and subsequent revenue generation. These factors have been accounted for in the anticipated upcoming milestones table, above. During any such delays in our clinical trials, we will continue to incur fixed costs such as selling, general and administrative expenses and operating expenses related to our laboratory, GMP manufacturing, and office facilities.

Our office-based employees have been working from home since mid-March 2020, while ensuring essential staffing levels for our research and development operations remain in place, including maintaining key personnel in our laboratory and GMP manufacturing facilities. While we have not previously experienced or been notified of any anticipated impact amongst our third party vendors, it is likely that the COVID-19 pandemic and resulting mitigation efforts could have an impact in the future on our third-party suppliers who manufacture laboratory supplies required for our in-house manufacturing process, which in turn could have an impact on having sufficient clinical product supply available for our clinical trials. We have addressed this in part by ensuring that we have ample supplies on hand to weather interruptions in our supply chain.

There is significant uncertainly about the progression and ultimate impact of the pandemic on our business and operations. While COVID-19 did not materially impact our year-to-date 2020 results, we anticipate that COVID-19 could impact our business in the short-term due to factors such as fewer patients accessing treatment for cancer.

RISK FACTORS

Investors should carefully consider the risks described below before deciding whether to invest in our securities. The risks described below are not the only ones we face. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made in our filings with the Securities and Exchange Commission as a result of different factors, including the risks we face described below and those described in other documents we file with the Securities and Exchange Commission.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company with a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which our business can be evaluated. To date, we have generated minimal revenue related to the non-clinical use of our cell lines and intellectual property, and we have no products approved for commercial sale and have not generated any revenue from product sales. We have incurred operating losses on an annual basis since our formation and we may never become profitable. As of March 31, 2020, we had an accumulated deficit of $680.6 million. We incurred net losses of $18.4 million and $17.9 million for the three months ended March 31, 2020 and 2019, respectively. Our losses have resulted principally from costs incurred in ongoing preclinical studies, clinical trials and operations, as well as research and development expenses, and general and administrative expenses.

A critical aspect of our strategy is to invest significantly in expanding our haNK, taNK, t-, haNK, CeNK and MSC platforms and the development of our product candidates. We expect to incur significant expenses as we continue to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals and, upon successful receipt of U.S. Food and Drug Administration, or FDA, approval, commercializing our products. We will also incur costs as we hire additional personnel and increase our manufacturing capabilities, including the lease or purchase of a facility for the manufacturing of our product candidates for our ongoing and any future clinical trials and, upon receipt of any FDA approval, for our initial commercialization activities. Moreover, we do not expect to have any significant product sales or revenue for at least the next several years. These losses have had and, as our operating losses continue to increase significantly in the future due to these expenditures, will continue to have an adverse effect on our stockholders' deficit and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all. Additionally, our net losses may fluctuate significantly from quarter to quarter, and as a result, a period-to-period comparison of our results of operations may not be meaningful. For example, we expect our operating expenses to increase in the second quarter of 2020 compared to the first quarter due to increased general and administrative expenses and capital and operating expenditures in preparation for our Joint COVID-19 Collaboration with ImmunityBio. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. In addition, we expect increased expenses in future quarters as a result of the Joint COVID-19 Collaboration.

We do not have any therapeutic products that are approved for commercial sale. Our ability to generate revenue from product sales and achieve and maintain profitability depends significantly on our success in a number of factors.

We currently do not have any therapeutic products that are approved for commercial sale. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the

commercialization of our product candidates if approved. To obtain revenue from sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing therapies with commercial potential. Our ability to generate revenue and achieve and maintain profitability depends significantly on our success in many areas, including:

- our research and development efforts, including preclinical studies and clinical trials of our haNK, taNK, t-, haNK, CeNK and MSC platforms and our product candidates;
- continuing to develop sustainable, scalable, reliable and cost-effective manufacturing and distribution processes for our product candidates, if approved, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own current Good Manufacturing Practices, or cGMP, manufacturing facilities and processes to support clinical development and meet the market demand for product candidates that we develop, if approved;
- addressing any competing therapies and technological and industry developments;
- identifying, assessing, acquiring and developing new technology platforms and product candidates across numerous therapeutic areas;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the U.S. and internationally, of our product candidates;
- successful and timely completion of preclinical and clinical development of our product candidates and any other future product candidates;
- obtaining regulatory approvals and marketing authorizations for our current and future product candidates, including a continued acceptable safety profile both prior to and following any marketing approval of our product candidates;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- launching and commercializing any approved products, either directly or with a collaborator or distributor, including the development of a commercial infrastructure;
- obtaining market acceptance of and acceptable reimbursement for any approved products;
- completing collaborations, licenses and other strategic transactions on favorable terms, if at all;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates is eventually approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and we may not generate significant revenue from sales of such products, resulting in limited or no profitability in the future. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital for the foreseeable future. Any failure to become and remain profitable may adversely affect the market price of our common stock, our ability to raise additional capital and our future viability.

We will need to obtain substantial additional financing to complete the development and any commercialization of our product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our commercialization efforts, product development or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially in the foreseeable future. Developing our product candidates and conducting clinical trials for the treatment of cancer, virally infectious diseases, and other diseases requires substantial amounts of capital. We will also require a significant additional amount of capital to commercialize any approved products.

As of March 31, 2020, we had cash and cash equivalents of $17.0 million and marketable debt securities of $23.3 million. We are using and expect to continue to use our existing cash and cash equivalents and marketable debt securities to fund expenses in connection with our ongoing and any future clinical trials, our manufacturing facilities and processes and the hiring of additional personnel, and for other research and development activities, working capital and general corporate purposes, including our previously announced share repurchase program. We believe that our existing cash, cash equivalents, and investments in marketable debt securities, and our ability to borrow from affiliated entities, will be sufficient to fund our operations for at least the next 12 months following the issuance date of the financial statements based upon our Chairman and CEO's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required. Our estimate as to how long we expect our existing cash and cash equivalents to be available to fund our operations is based on assumptions that may be proved inaccurate, and we could deplete our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and any commercialization of our product candidates and may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly.

Our future capital requirements may depend on, and could increase significantly as a result of, many factors, including:

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our oncology product candidates;
- the timing of, and the costs involved with, the joint development, manufacturing and marketing of a vaccine and multiple therapeutics for COVID-19 with ImmunityBio;
- the costs of manufacturing, distributing and processing our product candidates and any products for which we receive regulatory approval, if any;
- the number and characteristics of any other product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements, including our arrangements with ImmunityBio and its subsidiaries and Viracta;
- the degree and rate of market acceptance of any approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property claims, including litigation costs and the outcome of such litigation;

- the costs related to commercializing product candidates independently;
- the timing, receipt and amount of sales of, or royalties on, any approved products; and
- any product liability or other lawsuits related to our product candidates or the company.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. 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 or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Additional capital may not be available when we need it, on terms that are acceptable to us or at all. 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 any approved products that we would otherwise prefer to develop and market ourselves, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of our common stock to decline.

If we are not be able to finalize a definitive agreement with ImmunityBio, Inc. regarding a joint collaboration, our recent expenditures in contemplation of executing a definitive agreement may not be recoverable.

As described above, we have executed a binding term sheet with ImmunityBio regarding the joint development, manufacturing and marketing of a vaccine and multiple therapeutics for COVID-19. This binding term sheet provides that if we and ImmunityBio are unable to execute a definitive agreement regarding the Joint COVID Collaboration by August 21, 2020, then either party may terminate the binding term sheet upon five business days written notice to the other party. Until the definitive agreement is finalized, any investments made by each entity are the responsibility of the contributing party and at each contributing party's risk. We have started to incur expenses in connection with pursuing the Joint COVID-19 Collaboration and have made significant expense commitments for scaling up the manufacturing of ImmunityBio's COVID-19 vaccine candidate. We expect that we will share equally in all costs relating to developing, manufacturing, and marketing of the product candidates globally, starting from and after the effective date of the definitive agreement, if any. However, if after August 21, 2020 we have not executed a definitive agreement and either party decides to no longer pursue the Joint COVID-19 Collaboration, such party could terminate the arrangement, and our expenses incurred at termination will not be reimbursable at the agreed upon 50% cost sharing basis. In addition, expenditures incurred before the execution of the definitive agreement are also not subject to the agreed upon 50% cost sharing basis. Furthermore, depending on the extent of each party's expense incurred in connection with the Joint COVID-19 Collaboration, we could be responsible for additional unknown costs of ImmunityBio. In addition, if we are unable to execute a definitive collaboration agreement, we will not have rights to share in net profits from any future sales of ImmunityBio's COVID-19 product candidates.

We expect our business to be adversely affected by outbreaks of epidemic, pandemic or contagious diseases, including the recent coronavirus disease (COVID-19) outbreak.

Outbreaks of epidemic, pandemic or contagious diseases, such as COVID-19, may significantly disrupt our operations and adversely affect our business, financial condition and results of operations. In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic as the novel coronavirus continues to spread throughout the world. The spread of this pandemic has caused

significant volatility and uncertainty in the U.S. and international markets and has resulted in increased risks to our operations. We are monitoring a number of risks related to this pandemic, including the following:

- Financial: While to date, the financial impact to our business has not been material, we anticipate that the pandemic could have an adverse financial impact in the short-term and potentially beyond. As a result of slower patient enrollment, we may not be able to complete our clinical trials as planned or in a timely manner. We expect to continue spending on research and development in the second quarter of 2020 and beyond, and we could also have unexpected expenses related to the pandemic. The short-term continued expenses, as well as the overall uncertainty and disruption caused by the pandemic, will likely cause a delay in our ability to commercialize a product and adversely impact our financial results.
- Supply Chain: While to date we have not experienced significant disruptions in our supply chain and distribution, an extended duration of this pandemic could result in disruptions in the future. For example, quarantines, shelter-in-place and similar government orders, travel restrictions and health impacts of the COVID-19 pandemic, could impact the availability or productivity of personnel at third-party laboratory supply manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in disruptions in our supply chain and adversely affect our ability to manufacture and distribute certain product candidates for clinical supply.
- Clinical Trials: This pandemic has not significantly impacted our business or financial results during the first quarter of 2020, however, it is likely to adversely affect certain of our clinical trials, including our ability to initiate and complete our clinical trials within the anticipated timelines. Due to site and participant availability during the pandemic, new subject enrollment is expected to slow in the short-term for most of our clinical trials. For ongoing trials, we have seen an increasing number of clinical trial sites imposing restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. The current pressures on medical systems and the prioritization of healthcare resources toward the COVID-19 pandemic have also resulted in interruptions in data collection and submissions for certain clinical trials and delayed starts for certain planned studies. As a result, our anticipated filing and marketing timelines may be adversely impacted.
- Overall economic and capital markets decline: The impact of the COVID-19 pandemic could result in a prolonged recession or depression in the U.S. or globally that could harm the banking system, limit demand for all products and services and cause other seen and unforeseen events and circumstances, all of which could negatively impact us. The continued spread of COVID-19 has led to and could continue to lead to severe disruption and volatility in the U.S. and global capital markets, which could result in a decline in stock price, increase our cost of capital and adversely affect our ability to access the capital markets in the future. In addition, trading prices on the public stock market, including our common stock, have been highly volatile as a result of the COVID-19 pandemic.
- Regulatory Reviews: The operations of the FDA or other regulatory agencies may be adversely affected. In response to COVID-19, federal, state and local governments are issuing new rules, regulations, orders and advisories on a regular basis. These government actions can impact us, our members and our suppliers. There is also the possibility that we may experience delays with obtaining approvals for our Investigational New Drug, or IND, applications.

The foregoing and other risks may have an adverse effect on our overall business, financial condition and results of operations. Additionally, the ongoing COVID-19 pandemic may also affect our operating and financial results in a manner that is not presently known to us or that we currently have not considered as significant risks to our operations. This pandemic may also amplify many of the other risks described throughout the "Risk Factors" section. Any resulting financial impact cannot be reasonably estimated at this time. The extent to which the COVID-19 pandemic impacts our business and results will depend on future developments, which are uncertain and cannot be predicted with confidence, including the duration and scope of the outbreak, any potential future waves of the pandemic, new information which may emerge concerning the severity of COVID-19 and the ongoing and future actions to contain it or treat its impact, among others.

We may use our financial and human resources to pursue a particular type of treatment, or treatment for a particular type of cancer, and fail to capitalize on programs or treatment of other types of cancer that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of cancer, and may forego or delay pursuit of opportunities with other programs, investigational medicines, or treatment for other types of cancer, which could later prove to have greater commercial potential. Moreover, given the rapidly evolving competitive landscape and the time it takes to advance a product through clinical development, an incorrect decision to pursue a particular type of treatment or cancer may have a material adverse effect on our results of operation and negatively impact our future clinical strategies. 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 for investigational medicines or clinical trials may not yield any commercially viable products. If we do not accurately evaluate and anticipate the commercial potential or target market for a particular type of treatment or cancer, we may choose to spend our limited resources on a particular treatment, or treatment for a particular type of cancer, and then later learn that another type of treatment or cancer that we previously decided not to pursue would have been more advantageous.

We invest our cash on hand in various financial instruments which are subject to risks that could adversely affect our business, results of operations, liquidity and financial condition.

We invest our cash in a variety of financial instruments, principally commercial paper, corporate debt securities and foreign government bonds. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities.

Risks Relating to Our Business and Industry

The foundation of our business is based upon the success of our aNK cells as a technology platform. Our aNK platform and product candidates derived thereof, including genetically modified haNK, taNK, t-, haNK, CeNK and MSC product candidates, will require significant additional clinical testing before we can potentially seek regulatory approval and launch commercial sales.

Our business and future success depend on our ability to utilize our aNK cells as a technology platform, and to obtain regulatory approval for one or more product candidates derived from it, and then successfully commercialize our product candidates addressing numerous therapeutic areas. Our aNK platform and our haNK, taNK, t-, haNK, CeNK and MSC product candidates are in varying stages of development and

may never become commercialized. All of our product candidates developed from our technology platform will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Because all of our product candidates are based on the same core aNK technology, if any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, these could impact the development plans for our other product candidates.

Utilizing haNK, taNK, t-, haNK, CeNK and MSC cells represents a novel approach to immunotherapy, including cancer treatment, and we must overcome significant challenges in order to successfully develop, commercialize and manufacture our product candidates.

We have concentrated our research and development efforts on utilizing aNK cells as an immunotherapy platform and genetically modified aNK cells as product candidates based on this platform. We believe that our product candidates represent a novel approach to immunotherapy, including cancer treatment. Advancing this novel immunotherapy creates significant challenges for us, including:

- educating medical personnel regarding the potential side effect profile of our cells;
- training a sufficient number of medical personnel how to properly administer our cells;
- enrolling sufficient numbers of patients in clinical trials;
- developing a reliable, safe and effective means of genetically modifying our cells;
- manufacturing our cells on a large scale and in a cost-effective manner;
- submitting applications for and obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of immunotherapies for cancer and viral associated infectious diseases; and
- establishing sales and marketing capabilities, 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 successfully develop, commercialize and manufacture our product candidates utilizing haNK, taNK, t-, haNK, CeNK and MSC cells.

Even if we successfully develop and commercialize our haNK product candidate for Merkel cell carcinoma, we may not be successful in developing and commercializing our other product candidates, and our commercial opportunities may be limited.

We believe that our ability to realize the full value of our aNK platform will depend on our ability to successfully develop and commercialize haNK and our other product candidates in a wider range of indications. We are simultaneously pursuing preclinical and clinical development of a number of product candidates spanning several types of cancers. For example, we are devoting substantial resources toward the development of haNK and t-haNK product candidates as combination therapies with commercially approved monoclonal antibodies and late-stage product candidates for solid tumors such as breast, pancreatic, lung, head and neck and hematologic malignancies such as diffuse large B-cell lymphoma, or DLBCL, and serious viral diseases such as COVID-19.

Even if we are successful in continuing to build our pipeline of product candidates based on our technology platform, obtaining regulatory approvals and commercializing any approved product candidates will require substantial additional funding beyond our existing cash and cash equivalents and marketable debt securities, and are prone to numerous risks of failure. Investment in biopharmaceutical product development involves significant risks that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile to the satisfaction of regulatory authorities, gain

regulatory approval or become commercially viable. We cannot assure you that we will be able to successfully advance any product candidates through the development process. Our research programs may initially show promise in identifying product candidates, but ultimately fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our product candidates may not succeed in preclinical or clinical testing due to failing to generate enough data to support the initiation or continuation of clinical trials or due to lack of patient enrollment in clinical trials;
- a product candidate may be shown to have harmful side effects or other characteristics in larger scale clinical studies that indicate it is unlikely to meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates from our technology platform;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being manufactured in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or the entire platform, or we may not be able to identify, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.

Prior to commencing clinical trials in the U.S. for any of our product candidates, we may be required to have an allowed IND for each product candidate. As of the date of this filing, we have numerous INDs for clinical trials that have been authorized in the U.S. We are required to file additional INDs prior to initiating our planned clinical trials. Submission of an IND may not result in the FDA allowing further clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, these regulatory authorities may change their requirements in the future. The fact that we are pursuing novel technologies may also exacerbate these risks with respect to our product candidates, and as a result, we may not meet our anticipated clinical development timelines.

Our plans to support the Joint COVID-19 Collaboration by moving some of our current manufacturing facilities or repurposing personnel may cause delays in our oncology trials.

We have prepared one of our GMP manufacturing facilities previously used to manufacture product for our oncology trials to manufacture and develop a COVID-19 vaccine, and are in the process of identifying, and subsequently readying, a new location to manufacture and produce clinical product for our oncology product candidate trials. We cannot assure you that we will be able to achieve GMP qualifications for these new manufacturing facilities, or the extent of costs or delays in timing to do so.

Failure to achieve GMP status could adversely impact our ability to successfully develop our oncology product candidates. In addition, we have repurposed some of our manufacturing facility in Culver City, California, and personnel to support the Joint COVD-19 Collaboration. While we believe we have sufficient product in our inventory to not incur any interruptions in our current or planned oncology trials, we cannot be sure that the moving of these facilities or repurposing of personnel will not experience any unforeseen circumstances that causes a delay in our ability to manufacture sufficient product for our current or planned trials. If this occurs, such trials could be significantly delayed which would have an adverse effect on our business, financial condition, results of operations and prospects.

Our efforts regarding the Joint COVID-19 Collaboration may be difficult to integrate into our current operations and will require additional personnel who will require training which may cause some of our employees to reallocate their time from our current operations or manufacturing duties which could in turn cause delays in clinical supply of our products or trials.

Since we signed the binding term sheet regarding the Joint COVID-19 Collaboration, we have started to plan for the development of the COVID-19 products. We have repurposed some of our personnel to support our QUILT-COVID-19-MSC program and have repurposed some of our personnel overseeing quality of our oncology products to support the Joint COVID-19 Collaboration. We also plan to hire additional staff to support the Joint COVID-19 Collaboration, which will increase our expenses. Although we believe it will have an immaterial impact on our current oncology trials in the near term, if our current personnel fail to remain focused on our oncology drug candidates, or new personnel that we plan to hire to support the Joint COVID-19 Collaboration require extensive training, our current oncology operations may be adversely impacted.

We face significant competition in the biopharmaceutical industry, and many of our competitors have substantially greater experience and resources than we have.

Even if our aNK platform products prove successful, we might not be able to remain competitive because of the rapid pace of technological development in the biopharmaceutical field. Our haNK, taNK, t-, haNK, CeNK and MSC product candidates compete with other cell and molecule-based immunotherapy approaches using or targeting natural killer cells, T-cells and dendritic cells.

Competitors focused on CAR-T related treatment approaches include AbbVie Inc., Atara Biotherapeutics, Inc., Precigen Corporation, Inc., Allogene Therapeutics, Inc., Bristol-Myers Squibb Company, Beijing Immunochina Pharmaceuticals Co., Ltd., Cellular Biomedicine Group, Inc., iCell Gene Therapeutics LLC, JW Therapeutics Co., Ltd., Amgen, Inc., Leucid Bio Ltd., Bellicum Pharmaceuticals, Inc., Medisix Therapeutics Pte Ltd., Bluebird Bio, Inc., Mesoblast Ltd., Calibr/Scripps Research, Mustang Bio, Inc., Carina Biotech, Inc., CARsgen Therapeutics, CRISPR Therapeutics, Inc., GEMoaB Monoclonals GmbH, Nanjing Legend Biotechnology Co., Ltd, Cartherics Pty Ltd, Novartis AG, Pfizer, Inc., Cellectis SA, Poseida Therapeutics, Inc., Prepromene Bio, Inc., Celularity, Inc., Servier Laboratories, Sorrento Therapeutics, Inc., Celyad SA, Takeda Pharmaceutical Company Limited, Fortress Biotech, Inc., TC BioPharm Ltd., Tessa Therapeutics Pte Ltd, Gilead Sciences, Inc., Tmunity Therapeutics, Inc., Transposagen Biopharmaceuticals, Inc., Humanigen, Inc., Unum Therapeutics, Inc., Immune Therapeutics, Inc. and Xyphos, Inc.

Competitor companies focused on other T-cell based approaches include Adaptimmune Ltd., Adicet Bio, Inc., Autolus Therapeutics, plc, Cell Medica Limited, Eureka Therapeutics, Inc., Formula Pharmaceuticals, Inc., GlaxoSmithKline plc., Green Cross LabCell Corp., Immatics Biotechnologies GmbH, Immunocore Limited, Iovance Biotherapeutics, Inc., Kiadis Pharma Netherlands B.V., Lion TCR Pte Ltd., MolMed, S.p.A., Precision Biosciences, Inc., Janssen Pharmaceuticals, Inc., Noile-Immune Biotech, Inc., Anixa Biosciences, Inc., Beam Therapeutics Inc., BioNTech SE, Cartesian Therapeutics, Inc., Marker Therapeutics, Inc., Refuge Biotechnologies, Inc., Repertoire Immune Medicines, Inc., Sensei Biotherapeutics, Inc., Senti Biosciences, Inc., TCR² Therapeutics Inc., TScan Therapeutics, Inc., and Takara Bio, Inc.

Competitor companies focused on dendritic cell based approaches include Argos Therapeutics, Inc., Biovest International, Inc., ImmunoCellular Therapeutics, Ltd., Merck & Co, Inc./Immune Design, Inc., Inovio Pharmaceuticals, Inc., Precigen Corporation, Inc., Medigene AG, and Northwest Biotherapeutics, Inc.

Competitor companies focused on natural killer cell based approaches include Celularity, Inc., Kiadis Pharma Netherlands B.V./CytoSen Therapeutics, Inc., Dragonfly Therapeutics, Inc., Fate Therapeutics, Inc., Gamida Cell, Ltd., Nkarta Therapeutics, Inc., Onkimmune Ltd., NKMax America, Artiva Biotherapeutics, HebeCell Corp., Vycellix, Inc., oNKo-innate Pty Ltd., Takeda Pharmaceutical Company Limited, and Ziopharm Oncology, Inc.

Competitor companies focused on large molecule immunotherapy approaches include Cytomx Therapeutics, Inc., Innate Pharma SA, and Sorrento Therapeutics, Inc. Other potential immunotherapy competitors include Affimed GmbH, Agios Pharmaceuticals, Inc., Codiak Biosciences, Glycostem Therapeutics BV, Triumvira Immunologics, Century Therapeutics, Incysus Therapeutics, Inc., GammaDelta Therapeutics Ltd., Lyell Immunopharma, Inc., and GT Biopharma, Inc.

Competitor companies/efforts focused on COVID-19 cell therapy currently include Athersys/Healios, Capricor, CAR-T (Shanghai) Biotechnology, Cellavita, Cellenkos, Cellular Biomedicine Group, Celularity, Sorrento Therapeutics, Chinese Academy of Sciences, Chongqing Sidemu Biotechnology Technology/ImmunCyte, Enlivex Therapeutics, Green Cross LabCell (Green Cross), Hope Biosciences, Mesoblast, Orbsen, Pluristem, Rigshospitalet, Tianhe Stem Cell Biotechnologies Inc., University of Minnesota/Fate Therapeutics, and Xinjiang Medical University.

There are currently two approved T-cell based treatments which are marketed by Novartis AG and Gilead Sciences/Kite Pharma. There is currently one approved dendritic cell-based cancer vaccine which is marketed by Dendron Pharmaceuticals, LLC for the treatment of metastatic castration resistant prostate cancer.

In addition, a very large number of companies, government agencies and academic centers around the world are developing COVID-19 vaccines, and many of these entities are in more advanced stages of development than ImmunityBio, including some that have started Phase II and/or III clinical trials. Even if ImmunityBio’s COVID-19 vaccine candidate is ultimately approved for marketing, the value of our profit-sharing opportunity would be adversely impacted if other COVID-19 vaccines are approved earlier or show better efficacy or safety than ImmunityBio’s COVID vaccine candidate.

Many of our current or potential competitors have greater financial and other resources, larger research and development staffs, and more experienced capabilities in researching, developing and testing products than we do. Many of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals, and manufacturing, marketing and distributing therapeutic products. Smaller or clinical-stage companies like us may successfully compete by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of cancer and other diseases, which could give such products significant regulatory and market timing advantages over any of our product candidates. In addition, large

pharmaceutical companies or other companies with greater resources or experience than us may choose to forgo therapy opportunities that would have otherwise been complementary to our product development and collaboration plans. Our competitors may succeed in developing, obtaining patent protection for, or commercializing their products more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market. A competing company developing or acquiring rights to a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment could render our products noncompetitive or obsolete. We may not be successful in marketing against competitors any product candidates we may develop.

Our business plan involves the creation of a complex integrated ecosystem capable of addressing a wide range of indications. As a result, our future success depends on our ability to prioritize among many different opportunities.

We do not have sufficient resources to pursue development of all or even a substantial portion of the potential opportunities that we believe will be afforded to us by our planned integrated ecosystem. Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions as to which product candidates to pursue and how much of our resources to allocate to each. Our management has broad discretion to suspend, scale down, or discontinue any or all of these development efforts, or to initiate new programs to treat other diseases. If we select and commit resources to opportunities that we are unable to successfully develop, or we forego more promising opportunities, our business, financial condition and results of operations will be adversely affected.

We plan to develop our product candidates and potentially other programs in combination with other commercially available therapies or therapies we, or an affiliate of ours, have in development, which exposes us to additional risks. We do not know whether our attempts to use our product candidates in combination will be safe or effective.

We intend to develop cryopreserved PD-L1.t-haNK, haNK, and potentially other programs in combination with one or more currently approved cancer therapies or therapies in development. For Merkel cell carcinoma, we plan to evaluate haNK in combination with N-803 and avelumab. For pancreatic cancer, TNBC, and breast cancer indications, we plan to evaluate PD-L1.t-haNK in combination with N-803 and aldoxorubicin. For NSCLC indications, we plan to evaluate PD-L1.t-haNK in combination with N-803 and a checkpoint inhibitor.

Patients may not be able to tolerate any of our other product candidates in combination with any other therapies or dosing of our product candidates in combination with other therapies may have serious or unexpected adverse events. Furthermore, we will be required to show with substantial evidence that the combination of drugs when used together are more effective than each of the individual drugs used separately. We can provide no assurance that we can establish that any of our product candidates, when used in combination with other drugs, will be more effective than each individual drug when used alone.

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, the European Medicines Agency, or EMA, or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, purity, potency, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. If clinical trial collaboration and supply agreement terminates or if we cannot negotiate favorable terms for combination therapies, our combination therapy development plans could be delayed or terminated, and the cost to us to conduct such trials may significantly increase.

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

It is impossible to predict when or if any of our product candidates and therapies will prove safe, effective, or potent in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete extensive preclinical studies and clinical trials to demonstrate the safety, efficacy or potency of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of 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, and 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. Our pre-clinical studies and future clinical trials may not be successful.

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

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

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our tissue-agnostic anti-tumor development strategy;
- delays in obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each clinical trial site;

- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers.

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials, including additional procedures and contingency measures in response to the COVID-19 pandemic or as required by clinical sites, IRB, or FDA;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our research efforts for our other future product candidates;
- clinical trials of our product candidates may not produce differentiated or clinically significant results across tumor types or indications;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, for example, if we experience delays or challenges in identifying patients with the mutations required for our clinical trials, we may have to reimburse sites for genetic sequencing costs in order to encourage sequencing of additional patients;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

We have commenced studies that may provide the basis for regulatory approval, but we have not sought or obtained FDA input on the trial design, number of patients that will be enrolled in the studies, or statistical analysis plan. FDA may not accept the data generated from these studies and my reject any regulatory applications we submit with this data. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our preclinical studies or clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline and platform would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and clinical trials may not be predictive of future clinical trial results, we may not be able to rely on the aNK and haNK phase I and II clinical trials data for our other product candidates, and our clinical trials may fail to adequately demonstrate substantial evidence of safety and efficacy of our product candidates. The results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is a high failure rate for product candidates proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to support obtaining regulatory approval for our product candidates. In addition, our strategy and anticipated timelines are predicated upon our ability to utilize the phase I and II clinical trial data for aNK, haNK, and t-haNK observed to

date to support our planned clinical trials for all of our product candidates, including our haNK and t-haNK product candidates. To date, we have several INDs for our haNK and t-haNK product candidates, and we cannot offer assurances that the FDA will allow us to utilize the phase I and II aNK and haNK data to support other planned clinical trials or allow our anticipated INDs for (i) planned phase I or phase Ib/IIa clinical trials for our other product candidates, (ii) planned phase IIb/III clinical trials for our haNK and t-haNK product candidates as potential combination therapies, or (iii) any other planned clinical trials, including registration studies.

We have in the past experienced delays in our ongoing clinical trials and we may experience additional delays in the future. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated by us, regulatory authorities, clinical trial investigators, and ethics committees for a variety of reasons, including failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory authorization, or feedback on clinical trial design, to commence a clinical trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective Contract Research Organizations, or CROs, and clinical trial sites;
- obtain and maintain IRB approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a clinical trial;
- have a sufficient number of patients complete a clinical trial or return for post-treatment follow-up;
- ensure that our third-party contractors and clinical investigators comply with clinical trial protocols, comply with regulatory requirements, or meet their obligations to us in a timely manner;
- address any patient safety concerns that arise during the course of a clinical trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- timely manufacture sufficient quantities of product candidate for use in clinical trials; or
    - raise sufficient capital to fund a clinical trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such clinical trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with

regulatory requirements, including Good Clinical Practices, or GCPs, or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We have used one clinical trial site, Immuno-Oncology Clinic, Inc., a related party, in some of our Phase I trials which may expose us to significant regulatory risks. If our data is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or required to contract with other clinical trial sites, and our clinical development plans will be significantly delayed, and we will incur additional costs.

To date, our Phase I clinical trials for our haNK, PDL1 t-haNK and other t-haNK products have been conducted by a single clinical trial site, Immuno-Oncology Clinic, Inc., which is a related party. Relying on a single, or a related party, clinical site to develop data that is used as the basis to support regulatory approval can expose us to significant regulatory risks. For example, a study used to support regulatory approval that is conducted at a single, or a related party, site can be rejected by the FDA if there are data integrity issues, or if there are significant good clinical practice violations at the site. If any data integrity, or regulatory non-compliance issues occur during the study, we may not be able to use the data for our regulatory approval. Furthermore, if the operations of the clinical site is disrupted or if the site experiences disruptions in its clinical supplies or resources, such as potential disruptions due to COVID-19, then we may be required to suspend or terminate the study at this site, and we may need to contract with other clinical sites for the study, which will delay our clinical development and regulatory approval for the product candidate. Failure of this single site to comply with the regulations or to recruit a sufficient number of patients may require us to delay submission for regulatory approval or repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if the site violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Results for any patient who receives compassionate use access to our product candidates should not be viewed as representative of how the product candidate will perform in a well-controlled clinical trial, and cannot be used to establish safety or efficacy for regulatory approval.

We often receive requests for compassionate use access to our investigational drugs by patients that do not meet the entry criteria for enrollment into our clinical studies. Generally, patients requesting

compassionate use have no other treatment alternatives for life threatening conditions. We evaluate each compassionate use request on an individual basis, and in some cases grant access to our investigational products outside of our sponsored clinical studies, and where a physician certifies the patient they are treating is critically ill and does not meet the entry criteria for one of our open clinical trials. Individual patient results from compassionate use access may not be used to support submission of a regulatory application, nor support approval of a product candidate. Although one patient with pancreatic cancer who was provided compassionate use access to our product candidates has experienced a six month complete remission after being treated, such results should not be considered to be indicative of results from any on-going or future well-controlled clinical trial. Before we can seek regulatory approval for any of our product candidates, we must demonstrate in well-controlled clinical trials statistically significant evidence that the product candidate is both safe and effective for the indication we are seeking approval. The results of our compassionate use program may not be used to establish safety or efficacy or regulatory approval.

We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import of biopharmaceutical products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide regulatory authorities with substantial evidence of safety, purity and potency of the product for each indication we seek to commercialize. We have not yet obtained regulatory approval to market any of our product candidates in the U.S. or any other country. Our business depends upon obtaining these regulatory approvals.

The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate with substantial clinical evidence that the product candidates are safe, pure and potent for the requested indication;
- the FDA's disagreement with our clinical trial protocol or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial not being sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional preclinical or clinical trials are required;
- the FDA's non-approval of the labeling or the specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we may contract;
- for clinical trials conducted by the Immuno-Oncology Clinic, Inc., or the Clinic, a related party, the FDA or other regulatory authorities could view our study results as potentially biased even if we achieve such clinical trial endpoints; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually successfully complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may only grant approval contingent on the performance of costly

additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or our inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations, financial condition and prospects.

Use of our product candidates could be associated with side effects or adverse events.

As with most biopharmaceutical products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which will harm our business. We may be required by regulatory agencies to conduct additional preclinical or clinical trials regarding the safety and efficacy of our product candidates, which we have not planned or anticipated. We cannot provide any assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

If we are successful in commercializing our product candidates, the FDA and other foreign regulatory agency regulations will require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event, as well as the nature of the event. We may inadvertently fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

The clinical and commercial utility of our aNK, haNK, t-haNK and CeNK platforms are uncertain and may never be realized.

Our NK platforms are in the early stages of development. The company currently has multiple ongoing clinical trials to evaluate cryopreserved haNK and t-haNK cells in company sponsored clinical trials. Success in early clinical trials does not ensure that large-scale clinical trials will be successful nor does it predict final results. In addition, we will not be able to treat patients if we cannot manufacture a sufficient quantity of NK cells that meet our minimum specifications. In addition, our haNK product candidate has only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of our products as we expand into larger clinical trials.

We may not ultimately be able to provide the FDA with substantial clinical evidence to support a claim of safety, purity and potency sufficient to enable the FDA to approve aNK platform product candidates for any indication. This may be because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the FDA disagrees with how we interpret the data from these clinical trials, or because the FDA does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. We will also need to demonstrate that aNK platform product candidates

are safe. We do not have data on possible harmful long-term effects of aNK platform product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our aNK platform therapy is uncertain and is subject to significant risk.

We have limited experience as a company conducting clinical trials and have relied and will rely on third parties and related parties to conduct many of our preclinical studies and clinical trials. Any failure by a third party, related party, or by us to conduct the clinical trials according to Good Clinical Practices and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

To date, the only company sponsored studies to engage in patient enrollment have been for the following indications: Merkel cell, pancreatic, squamous head and neck, non-small cell lung, triple negative breast, AML, colorectal and advanced solid tumor. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. In addition, we have entered into an agreement with the Clinic, a related party, to continue to conduct and oversee certain of our clinical trials. Large-scale clinical trials will require significant additional resources and reliance on Contract Research Organizations, or CROs, clinical investigators, or consultants. Consequently, our reliance on outside parties may introduce delays beyond our control. Our CROs, the Clinic, and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs, the Clinic, and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs, the Clinic, or other third parties conducting our clinical trials do not perform their contractual duties or regulatory obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCPs, or other regulatory requirements or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

We, the Clinic, and the third parties upon which we rely are required to comply with GCPs. GCPs are regulations and guidelines enforced by regulatory authorities around the world, through periodic inspections, for products in clinical development. If we or these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and have to be repeated, and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We are subject to the risk that, upon inspection, a regulatory authority will determine that any of our clinical trials fail to comply or failed to comply with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under GMP and Good Tissue Practice, or GTP, regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be significantly impacted if our CROs, the Clinic, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

We also anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by our aNK, haNK, taNK, t-, haNK, CeNK and MSC platforms will involve further investigator-initiated clinical trials. While these trials generally provide us with valuable clinical data that can inform our future development strategy in a cost-efficient manner, we generally have less control over not only the conduct but also the design of these clinical trials. Third-party investigators may design clinical trials involving our product candidates with clinical endpoints that are more difficult to achieve or in other ways that increase the risk of negative clinical trial results compared to clinical trials we may design on

our own. Negative results in investigator-initiated clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our prospects and the perception of our product candidates.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. In addition, some of our trials are being run by the Clinic, which is controlled by one of our employees. Under certain circumstances, the company may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between the company, the Clinic and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We and ImmunityBio may not be successful in jointly developing and obtaining regulatory approval for any collaborative COVID-19 product candidates.

The risks described in this section regarding the development and regulatory approval of our product candidates in oncology are also applicable to the product candidates that we and ImmunityBio intend to jointly develop under the Joint COVID Collaboration, including ImmunityBio's COVID-19 vaccine candidate. In particular, while the second generation adenovirus used in ImmunityBio's COVID-19 vaccine candidate has been tested in Phase I trials for oncology indications and has been generally well-tolerated in those studies, the COVID-19 vaccine candidate uses a different construct directed towards the SARS-COV-2 virus. This vaccine candidate has never been tested in humans and very limited preclinical data has been generated to date. In addition, the biology of the SARS-COV-2 virus and pathology of COVID-19 disease are not fully understood and new information is constantly emerging. Thus, there remains substantial uncertainty about how ImmunityBio's COVID-19 vaccine candidate will perform in clinical trials, the timelines to complete development of the vaccine candidate and whether the FDA or other regulatory agencies will approve the vaccine candidate for marketing. If we and ImmunityBio are unable to successfully develop, obtain regulatory approval for, manufacture at scale and commercialize product candidates for COVID-19, or if the Joint COVID Collaboration is terminated, we may not be able to realize any share of net sales of resulting products or recoup the substantial investments we expect to make in our joint development efforts.

We are heavily dependent on our senior management, particularly Drs. Patrick Soon-Shiong and Barry Simon, and a loss of a member of our senior management team in the future, even if only temporary, could harm our business.

If we lose members of our senior management for a short or an extended time, we may not be able to find appropriate replacements on a timely basis, and our business could be adversely affected. Our existing operations and continued future development depend to a significant extent upon the performance and active participation of certain key individuals, including Drs. Patrick Soon-Shiong, our Chairman and CEO and our principal stockholder, and Barry Simon, our President and Chief Administrative Officer. Although Dr. Soon-Shiong focuses heavily on NantKwest matters and is highly active in our management, he does devote a certain amount of his time to a number of different endeavors and companies, including ImmunityBio and NantWorks, which is a collection of multiple companies in the healthcare and technology space. The risks related to our dependence upon Dr. Soon-Shiong are particularly acute given his ownership percentage, the commercial and other relationships that we have with entities affiliated with him, role in our company and reputation. We may also be dependent on additional funding from Dr. Soon-Shiong and his affiliates, which may not be available when needed. If we were to lose Drs. Soon-Shiong or Simon for a short or an extended time, for any reason, including the contraction of COVID-19, we may not be able to find appropriate replacements on a timely basis and our financial condition and results of operations could be materially adversely affected.

Competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options, warrants, and restricted stock units that vest over time. Additionally, we provided warrants that vested upon the achievement of certain performance milestones to Dr. Soon-Shiong. These performance warrants provided to Dr. Soon-Shiong were exercised in full in March 2019. The value to employees of stock options, warrants, and restricted stock units that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We face significant competition for employees, particularly scientific personnel, from other biopharmaceutical companies, which include both publicly traded and privately held companies, and we may not be able to hire new employees quickly enough to meet our needs. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Except with respect to Dr. Simon, we do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

Dr. Soon-Shiong, our Chairman and CEO and our principal stockholder, has significant interests in other companies which may conflict with our interests.

Our Chairman and CEO, Dr. Soon-Shiong, is the founder of NantWorks. The various NantWorks companies are currently exploring opportunities in the immunotherapy, infectious disease and inflammatory disease fields. In particular, we have agreements with a number of related parties that provide services, technology and equipment for use in our efforts to develop our product pipeline. Dr. Soon-Shiong holds a controlling interest, either directly or indirectly, in these entities. Consequently, Dr. Soon-Shiong's interests may not be aligned with our other stockholders and he may from time to time be incentivized to take certain actions that benefit his other interests and that our other stockholders do not view as being in their interest as investors in our company. In addition, other companies affiliated with Dr. Soon-Shiong may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in other therapeutic fields which we may target in the future). Moreover, even if they do not directly relate to us, actions taken by Dr. Soon-Shiong and the companies with which he is involved could impact us.

We are also pursuing supply arrangements for various investigational agents controlled by affiliates to be used in our clinical trials. If Dr. Soon-Shiong was to cease his affiliation with us, ImmunityBio, or with NantWorks, these entities may be unwilling to continue these relationships with us on commercially reasonable terms, or at all, and as a result may impede our ability to control the supply chain for our combination therapies. These collaboration agreements do not typically specify how sales will be apportioned between the parties upon successful commercialization of the product. As a result, we cannot guarantee that we will receive a percentage of the revenue that is at least proportional to the costs that we will incur in commercializing the product candidate.

Furthermore, in November 2015, we entered into a Shared Services Agreement with NantWorks, pursuant to which NantWorks and/or any of its affiliates provides corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy, and other support services to us and our subsidiaries. If Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, we may be unable to establish or maintain this relationship with NantWorks on a commercially reasonable basis, if at all. As a result, we could experience a lack of business continuity due to loss of historical and institutional knowledge and a lack of familiarity of new employees and/or new

service providers with business processes, operating requirements, policies and procedures, and we may incur additional costs as new employees and/or service providers gain necessary experience, particularly in connection with issues or concerns we may have as a public company. In addition, the loss of the services of NantWorks might significantly delay or prevent the development of our products or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business and results of operations.

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

To effect our business plan, we will need to add other management, accounting, regulatory, manufacturing and scientific staff. As of March 31, 2020, we had 153 employees. We will need to attract, retain and motivate a significant number of new additional managerial, operational, sales, marketing, financial, and other personnel, as well as highly skilled scientific and medical personnel, and to expand our capabilities to successfully pursue our research, development, manufacturing and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We also intend to add personnel in our research and development and manufacturing departments as we expand our clinical trial and research capabilities. Moreover, we may need to hire additional accounting and other personnel and augment our infrastructure as a result of operating as a public company. Any inability to attract and retain qualified employees to enable our planned growth and establish additional capabilities or our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business.

We have limited manufacturing experience and may not be able to manufacture haNK, taNK, t-haNK or CeNK cells on a large scale or in a cost-effective manner.

haNK, taNK, t-haNK and CeNK cells have been grown in various quantities in closed cell culture systems and intermediate to larger-scale bioreactors. With all manufacturing efforts being conducted in-house, we will need to develop the ability to grow haNK, taNK, t-haNK and CeNK cells on a large-scale basis in a cost efficient manner. While we have made great strides with our haNK production, including a validated cryopreserved form of the product, we have not demonstrated the ability to manufacture these cells beyond quantities sufficient for our clinical programs. We have not demonstrated the ability to manufacture our taNK, t-haNK and CeNK cells beyond quantities sufficient for research and development and limited clinical activities. We have also experienced increases in manufacturing costs and sporadic decreases in manufacturing yield of haNK, taNK, t-haNK and CeNK cells. In addition, we have no experience manufacturing our NK cells specifically at the capacity that will be necessary to support commercial sales. The novel nature of our technology also increases the complexity and risk in the manufacturing process. In 2017, we opened our Culver City, California, site for the manufacture of cryopreserved haNK cells for our planned clinical trials and finished the build-out of our larger El Segundo, California, site in 2018 for the manufacture of our haNK, taNK, t-haNK and CeNK cells for our clinical trials and, if we receive FDA approval, initial commercialization. However, we may encounter difficulties in obtaining the approvals for, and designing, constructing, validating and operating, any new manufacturing facility. We may also be unable to hire the qualified personnel that we will require to accommodate the expansion of our operations and manufacturing capabilities. If we relocate our manufacturing activities to a new facility during or after a pivotal clinical trial, we may be unable to obtain regulatory approval unless and until we demonstrate to the FDA's satisfaction the similarity of our haNK, taNK, t-haNK and CeNK cells manufactured in the new facility to our cells manufactured in prior facilities. If we cannot adequately demonstrate similarity to the FDA, we could be required to repeat clinical trials, which would be expensive, and would substantially delay regulatory approval.

Because our product candidates are cell-based, their manufacture is complicated. In addition, we rely on certain third party suppliers for manufacturing supplies such as X-VIVO 10 media to grow and produce

our cells. Reliance on such third-party suppliers exposes us to supply interruptions and shortages that could have an adverse effect on our ability to produce product. Moreover, our present production process may not meet our initial expectations as to reproducibility, yield, purity or other measurements of performance. Any supply interruption from third parties and entities that are affiliated with Dr. Soon-Shiong and/or NantWorks could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. In addition, we may have to customize a bioreactor system to our manufacturing process. Because our manufacturing process is unproven, we may never successfully commercialize our products. In addition, because the clinical trials were conducted using a system that will not be sufficient for commercial quantities, we may have to show comparability of the different versions of systems we have used. For these and other reasons, we may not be able to manufacture haNK, taNK, t-,haNK , CeNK and MSC cells on a large scale or in a cost-effective manner.

aNK platform cells have been produced at academic institutions associated with our other clinical trial sites. In the past, the lack of production of aNK platform cells has caused delays in the commencement of our clinical trials. We have been establishing NK cell production capacity to meet anticipated demand for our planned clinical trials but may not be able to successfully build out our capacity to meet our current and anticipated future needs. Any damage to or destruction of our facility and equipment, prolonged power outage, contamination or shut down by the FDA or other regulatory authority could significantly impair or curtail our ability to produce haNK, taNK, t-haNK and CeNK cells.

We are dependent on third parties to store our aNK, haNK, taNK, t-haNK and CeNK cells, and any damage or loss to our master cell bank would cause delays in replacement, and our business could suffer.

The aNK cells of our master and working cell banks are stored in freezers at a third party biorepository and also stored in our freezers at our production facility. If these cells are damaged at both facilities, including by the loss or malfunction of these freezers or our back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement master and working cell banks, which would impact clinical supply and delay our patients' treatments. If we are unable to establish replacement cell banks, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer.

If we or any of our third party manufacturers that we may use do not maintain high standards of manufacturing, our ability to develop and commercialize haNK, taNK, t-haNK or CeNK cells could be delayed or curtailed.

We and any third parties that we may use in the future to manufacture our products must continuously adhere to cGMP regulations rigorously enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third parties who we may use in the future to produce our products do not pass a pre-approval inspection, the FDA will not grant market approval for haNK, taNK, t-haNK or CeNK cells. In complying with cGMP, we and any third-party manufacturers must expend significant time, money and effort in production, record keeping and quality control to assure that each component of our haNK, taNK, t-haNK or CeNK cell therapies meets applicable specifications and other requirements. We or any of these third-party manufacturers may also be subject to comparable or more stringent regulations of foreign regulatory authorities. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action, which could delay or curtail our ability to develop, obtain regulatory approval of, and commercialize haNK, taNK, t-haNK or CeNK cells. If our component part manufacturers and suppliers fail to provide components of sufficient quality, that meet our required specifications, our clinical trials or commercialization of haNK, taNK, t-haNK or CeNK cells could be delayed or halted, and we could face product liability claims.

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

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

We have not yet developed a validated methodology for freezing and thawing large quantities of taNK and t-haNK cells, which we believe will be required for the storage and distribution of our taNK and t-haNK product candidates.

We have not demonstrated that taNK and t-haNK cells can be frozen and thawed in large quantities without damage, in a cost-efficient manner and without degradation over time. We may encounter difficulties not only in developing freezing and thawing methodologies, but also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze taNK and t-haNK cells for shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw taNK and t-haNK cells in large quantities, we will still need to develop a cost-effective and reliable distribution and logistics network, which we may be unable to accomplish. For these and other reasons, we may not be able to commercialize haNK, taNK or t-haNK cells on a large scale or in a cost-effective manner.

We rely on third party healthcare professionals to administer haNK, taNK, t-haNK or CeNK cells to patients, and our business could be harmed if these third parties administer these cells incorrectly.

We rely on the expertise of physicians, nurses and other associated medical personnel to administer haNK, taNK, t-haNK or CeNK cells to clinical trial patients. If these medical personnel are not properly trained to administer, or do not properly administer, haNK, taNK, t-haNK or CeNK cells, the therapeutic effect of haNK, taNK, t-haNK or CeNK cells may be diminished or the patient may suffer injury.

In addition, if we achieve the ability to freeze and thaw our taNK and t-haNK cells, third party medical personnel will have to be trained on proper methodology for thawing haNK, taNK or t-haNK cells received from us. If this thawing is not performed correctly, the cells may become damaged and/or the patient may suffer injury. While we intend to provide training materials and other resources to these third-party medical personnel, the thawing of haNK, taNK, t-haNK or CeNK cells will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that haNK, taNK, t-haNK or CeNK cells are ineffective or harmful, the desire to use haNK, taNK, t-haNK or CeNK cells may decline, which would negatively impact our business, reputation and prospects. We may also face significant liability even though we may not be responsible for the actions of these third parties.

Even if any of our product candidates receive regulatory approvals, they may fail to achieve the broad degree of market acceptance and use necessary for commercial success.

Any potential future commercial success of any of our product candidates will depend, among other things, on its acceptance by physicians, patients, healthcare payors, and other members of the medical community as a therapeutic and cost-effective alternative to commercially available products. Because only a few cell-based therapy products have been commercialized, we do not know to what extent cell-based immunotherapy products will be accepted as therapeutic alternatives. If we fail to gain market acceptance, we may not be able to earn sufficient revenues to continue our business. Market acceptance of, and demand for, any product that we may develop, if approved for commercial sale, will depend on many factors, including:

- our ability to provide substantial evidence of safety and efficacy;
- convenience and ease of administration;
- prevalence and severity of adverse side effects associated with our product candidates;
- availability of alternative and competing treatments;
- the cost effectiveness of any approved product and competing treatments;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- effectiveness of our marketing and distribution strategy and pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain sufficient third-party coverage and adequate reimbursement.

If haNK, taNK, t-haNK and CeNK cells are approved for use, but fail to achieve the broad degree of market acceptance necessary for commercial success, our operating results and financial condition will be adversely affected. In addition, even if haNK, taNK, t-haNK and CeNK cells gain acceptance, the markets for treatment of patients with our target indications may not be as significant as we estimate.

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 drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary

trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Government authorities also impose mandatory discounts for certain patient groups and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. It may be difficult to promptly obtain coverage and profitable payment rates from both the government-funded and private payors for any of our approved product candidates, and this may have a material adverse effect on our operating results, our ability to raise capital and our overall financial condition.

There are risks inherent in our business that may subject us to potential product liability suits and other claims, which may require us to engage in expensive and time-consuming litigation or pay substantial damages and may harm our reputation and reduce the demand for our product.

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of biopharmaceutical products. We will face an even greater risk of product liability if we commercialize haNK, taNK, t-haNK and CeNK cells. For example, we may be sued if any product we develop allegedly causes or is perceived to cause injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources.

Certain aspects of how haNK, taNK, t-haNK and CeNK cells are processed and administered may increase our exposure to liability. Medical personnel administer haNK, taNK, t-haNK and CeNK cells to patients intravenously in an outpatient procedure. This procedure poses risks to the patient similar to those occurring with infusions of other cell products, such as T-cells and stem cells, including blood clots, infection and mild to severe allergic reactions. Additionally, haNK, taNK, t-haNK and CeNK cells or components of our haNK, taNK, t-haNK and CeNK cell therapy may cause unforeseen harmful side effects. For example, a patient receiving haNK, taNK, t-haNK and CeNK cells could have a severe allergic reaction or could develop an autoimmune condition to materials infused with the haNK, taNK, t-haNK and CeNK cells.

In addition, we have not conducted studies on the long-term effects associated with the media that we use to grow our haNK, taNK, t-haNK and CeNK cells. Similarly, we expect to use media in freezing our haNK, taNK, t-haNK and CeNK cells for shipment. These media could contain substances that have proved harmful if used in certain quantities. As we continue to develop our haNK, taNK, t-haNK and CeNK cell therapy, we may encounter harmful side effects that we did not previously observe in our prior studies and clinical trials. Additionally, the discovery of unforeseen side effects of haNK, taNK, t-haNK and CeNK cells could also lead to lawsuits against us.

Regardless of merit or eventual outcome, product liability or other claims may, among other things, result in:

- decreased demand for any approved products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to clinical trial participants or patients;

- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- loss of revenue;
- a potential decrease in our share price; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We obtained product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing our product candidates, we intend to expand our insurance coverage to include the sale of the applicable products; however, we may be unable to obtain this liability insurance on commercially reasonable terms. If a successful product liability or other claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover these claims and our business operations could suffer.

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

We currently have no sales, marketing or distribution capabilities and have no experience as a company in marketing products. If we develop an internal sales, marketing and distribution organization, this would require significant capital expenditures, management resources and time, and we would have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we expect to pursue collaborative arrangements regarding the sales, marketing and distribution of our products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, their sales forces may not be successful in marketing our products. Any revenue we receive would depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the sales, marketing and distribution efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales, marketing and distribution efforts of our product candidates. There can be no assurance that we will be able to develop internal sales, marketing and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. or overseas.

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the coronavirus pandemic currently having an impact throughout the world; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

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

We have formed, and may in the future form or seek, strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. For example, we entered into an agreement whereby Viracta granted to us exclusive world-wide rights to Viracta's phase II drug candidate, VRx-3996, for use in combination with our platform of NK cell therapies. However, if Viracta fails to raise sufficient capital to complete their pivotal phase II trial, if their trial is unsuccessful, or if our future clinical trial of NK cell therapy in combination with VRx-3996 fails, the value of the Viracta license would be adversely affected.

Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, 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. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches.

Our business model involves the storage and transmission of clinical trial and other data on our systems and on the systems of our consultants and contractors, and security breaches expose us to a risk of loss of this information, governmental fines and penalties, litigation and/or potential liability, in addition to negative publicity. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Our security measures and those of our contractors and consultants may also be breached due to employee error, malfeasance or otherwise. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, 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. Likewise, we rely on affiliated entities and third parties for research and development of our product candidates and to conduct clinical trials and may rely on third parties for the manufacture of our product candidates and similar events relating to their computer systems could have a material adverse effect on our business.

We expect that these risks and exposures related to our internal computer systems will remain high for the foreseeable future due to the rapidly evolving nature and sophistication of cyber threats to our internal computer systems. There can be no assurance that our efforts to implement adequate security measures will remain sufficient to protect the company against future cyber-attacks. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, suffer damage to our reputation, the further development and commercialization of our product candidates could be delayed and our stock price could decline.

Future acquisitions and investments could disrupt our business and harm our financial condition and operating results.

Our success may depend, in part, on our ability to expand our products and services. In some circumstances, we may determine to do so through the acquisition of complementary businesses and technologies rather than through, or in conjunction with, internal development. The identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to successfully complete identified acquisitions. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;

- retention of key employees from the acquired company;
- coordination of research and development functions;
- integration of the acquired company's accounting, management information, human resources and other administrative systems;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, employee disputes, and alleged violations of laws; and
- unanticipated write-offs or charges.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally. Future acquisitions could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses, incremental operating expenses or the write-off of goodwill, any of which could harm our financial condition or operating results.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, acts of terrorism, acts of war and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We may rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster, pandemics, epidemics, or other business interruption, including the recent novel strain of coronavirus (SARS-CoV-2) that originally surfaced in Wuhan, China in December 2019. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain SARS-CoV-2 or treat its impact, among others. If any disaster were to occur, our ability to operate our clinical trials could be seriously, or potentially completely, impaired. Our corporate headquarters are in California near major earthquake faults and fire zones. Our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

A coronavirus pandemic is ongoing in many parts of the world and may result in significant disruptions to our clinical trials, preclinical studies and supply chain which could have a material adverse effect on our business.

A coronavirus pandemic exists as of the filing of this report. As the pandemic continues to evolve, much of its impact remains unknown, and it is impossible to predict the impact it may have on the development of our business.

The coronavirus pandemic may result in significant delays or disruptions in our clinical trials, which could affect or delay the regulatory approval process of our product candidates. If the patients involved with these clinical trials become infected with the coronavirus disease, we may have more adverse events and deaths in our clinical trials as a result. We may also face difficulties enrolling patients in our clinical trials if the patient populations that are eligible for our clinical trials are impacted by the coronavirus pandemic.

Additionally, if our clinical trial patients are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from the coronavirus pandemic, we may experience higher drop-out rates or delays in our clinical trials.

The severity of the coronavirus pandemic could also make access to our existing supply chain difficult or impossible by delaying the delivery of key raw materials used in our product candidates and therefore delay the delivery of such products for use in our clinical trials. Any of these results could materially impact our business and have an adverse effect on our business.

Our employees, affiliates, independent contractors, clinical investigators, CROs, data safety and monitoring boards, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, and insider trading.

We are exposed to the risk of employee fraud, misconduct or other illegal activity by our employees, affiliates, independent contractors, clinical investigators, CROs, data safety and monitoring boards, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent conduct that fails to:

- comply with the laws and requirements of the FDA and other similar foreign regulatory bodies;
- provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse, privacy and security and other laws in the U.S. and similar foreign fraudulent misconduct laws;
- comply with federal securities laws regulating insider trading; or
    - report financial information or data accurately or to disclose unauthorized activities to us.

Our current and future business operations may subject us to fraud and abuse, transparency, health information privacy and security, and other healthcare laws and regulations. Failure to comply with such laws and regulations may result in substantial penalties.

Our current and future business operations may subject us to fraud and abuse, transparency, health information privacy and security, and other healthcare laws and regulations. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also include the collection and/or use of information obtained in the course of patient recruitment for clinical trials. The healthcare laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from the federal government including Medicare and Medicaid, that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional U.S. federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;
- the U.S. federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, which we refer to collectively as ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members by the 90th day of each subsequent calendar year, and disclosure of such information will be made by HHS on a publicly available website; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign laws and regulations that are analogous to the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant compliance guidance promulgated by the federal government; some state laws require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state and local laws that require the registration of pharmaceutical sales representatives; and some state and foreign laws govern the privacy and security of health information in ways that differ, and in certain cases are more stringent than, HIPAA, thus complicating compliance efforts.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not

be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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, including the imposition of civil, criminal and/or administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Competing generic medicinal products or biosimilars may be approved.

In the European Union, or E.U., there exists a process for approval of generic biological medicinal products once patent protection and other forms of data and market exclusivity have expired. Arrangements for approval of biosimilar products exist in the U.S., as well. Other jurisdictions are considering adopting legislation that would allow the approval of generic biological medicinal products. If generic medicinal products are approved, competition from such products may substantially reduce sales of our products.

Public opinion and scrutiny of cell-based immunotherapy approaches may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Our platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals, and no natural killer cell-based immunotherapy has been approved to date. Public perception may be influenced by claims, such as claims that cell-based immunotherapy is unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

Risks Relating to Government Regulation

We may fail to obtain or may experience delays in obtaining regulatory approval to market our aNK platform product candidates, which will significantly harm our business.

We do not have the necessary approval to market or sell aNK platform products in the U.S. or any foreign market. Before marketing aNK platform product candidates, we must successfully complete extensive preclinical studies and clinical trials and rigorous regulatory approval procedures. We cannot offer assurances that we will apply for or obtain the necessary regulatory approval to commercialize aNK platform product candidates in a timely manner, or at all.

Conducting clinical trials is uncertain and expensive and often takes many years to complete. The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. In conducting clinical trials, we may fail to establish the effectiveness of haNK, taNK, t-haNK and Cenk cells for the targeted indication or we may discover unforeseen side effects. Moreover, clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Clinical trials are also often subject to unanticipated delays. In addition, haNK, taNK, t-haNK and Cenk cells are produced in small-scale cell culture systems and we may be unable to adapt the production method to large-scale production systems. In addition, patients participating in the trials may die before completion of the clinical trial or suffer adverse medical effects unrelated to treatment with haNK, taNK, t-haNK and Cenk cells. This could delay or lead to termination of our clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in every stage of clinical trials, even in advanced clinical trials after positive results in earlier clinical trials.

To date, the FDA has approved only a few cell-based therapies for commercialization. The processes and requirements imposed by the FDA may cause delays and additional costs in obtaining regulatory approvals for our product candidates. Because our aNK platform product is novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like our aNK platform products. This inexperience may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our aNK platform products. In addition, the following factors may impede or delay our ability to obtain timely regulatory approvals, if at all:

- potential delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our failure to obtain sufficient enrollment in our clinical trials or participants may fail to complete our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- regulators may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate trials;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- our limited experience in filing and pursuing Biologics License Applications, or BLAs, necessary to gain regulatory approvals related to genetically modified cancer cell line therapies;
- any failure to develop substantial evidence of clinical efficacy and safety, and to develop quality standards and manufacturing processes to demonstrate consistent safety, purity, identity, and potency standards;
- a decision by us, institutional review boards, or regulators to suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulatory inspections of our clinical trials, clinical trial sites or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials if regulators find us not to be in compliance with applicable regulatory requirements;
- our ability to produce sufficient quantities of haNK, taNK, t-haNK and CeNK cells to complete our clinical trials;
- varying interpretations of the data generated from our clinical trials; and
- changes in governmental regulations or administrative action.

Any delays in, or termination of, our clinical trials could materially and adversely affect our development and collaboration timelines, which may cause our stock price to decline. If we do not complete clinical trials for haNK, taNK, t-haNK and CeNK cells and seek and obtain regulatory approvals, we may not be able to recover any of the substantial costs we have invested in the development of haNK, taNK, t-haNK and CeNK cells.

Even if we obtain regulatory approvals for aNK related platform products, those approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could prevent us from realizing the full benefit of our efforts.

If we obtain regulatory approvals, our aNK platform products, and our manufacturing facilities will be subject to continual regulatory review, including periodic unannounced inspections, by the FDA and other U.S. and foreign regulatory authorities. In addition, regulatory authorities may impose significant restrictions on the indicated uses or impose ongoing requirements for potentially costly post-approval studies. aNK platform product candidates would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. These and other factors may significantly restrict our ability to successfully commercialize haNK, taNK, t-haNK and Cenk cell therapies.

Manufacturers of biopharmaceutical products and their facilities, vendors and suppliers are subject to continual review and periodic unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, which include requirements relating to quality control and quality assurance, as well as to the corresponding maintenance of records and documentation. Furthermore, our manufacturing facilities must be approved by regulatory agencies before these facilities can be used to manufacture aNK platform products, and they will also be subject to additional regulatory inspections.

Any material changes we may make to our manufacturing process or to the components used in our products may require additional prior approval by the FDA and state or foreign regulatory authorities. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

We must also report adverse events that occur when our products are used. The discovery of previously unknown problems with aNK, haNK, taNK, t-haNK and Cenk cells and therapies or our manufacturing facilities may result in restrictions or sanctions on our products or manufacturing facilities, including withdrawal of our products from the market or suspension of manufacturing. Regulatory agencies may also require us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our product or obtain further approvals. This may harm our business and results of operations or cause our reputation in the market place to suffer or subject us to lawsuits, including class action suits.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, or other elements to assure safe use;
- 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 the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

In addition, if we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters that can produce adverse publicity;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products or request us to initiate a product recall; or
- pursue and obtain an injunction.

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

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

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

We may seek orphan drug status or breakthrough therapy designation for one or more of our product candidates, but even if either is granted, we may be unable to maintain any benefits associated with breakthrough therapy designation or orphan drug status, including market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for a disease or condition will be recovered from sales in the U.S. for that drug or biologic. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. In 2012, the FDA established a Breakthrough Therapy Designation, which is intended to expedite the development and review of products that treat serious or life-threatening conditions.

We may seek orphan drug status for one or more of our product candidates, but exclusive marketing rights in the U.S. may be lost if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, we may seek breakthrough therapy designation for one or more of our product candidates, but there can be no assurance that we will receive such designation.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A biopharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including review and approval of a brand name. Any

brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the USPTO. The FDA may object to a product brand name if they believe the name creates potential for confusion or inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, market acceptance and sales of our products, if approved, in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third party and/or government payors for any of our products and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish approved lists, known as formularies, and establish payment levels for such drugs. Formularies may not include all FDA-approved drugs for a particular indication. Private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare Part D may result in a similar reduction in payments from non-governmental payors. We cannot be certain that coverage and adequate reimbursement will be available for any of our products, if approved, or that such coverage and reimbursement will be authorized in a timely fashion. In addition, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any of our products, if approved. If reimbursement is not available or is available on a limited basis for any of our products, if approved, we may not be able to successfully commercialize any such products.

Reimbursement by a third party or government payor may depend upon a number of factors, including, without limitation, the third-party or government payor’s determination that use of a product is:

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or to have pricing set at a satisfactory level. If reimbursement of our products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability.

Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use

our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In the U.S., third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers, and other organizations. No uniform policy of coverage and reimbursement for products exists among third-party payors, and third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals.

In some foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our products to other available therapies. If reimbursement of any of our products, if approved, is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

Recent legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for our products, if approved, that could materially affect the opportunity to commercialize.

The U.S. and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products profitably, if approved. Among policy-makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our products, if approved;
- our ability to set a price that we believe is fair for any of our products, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In March 2010, ACA became law in the U.S. The goal of ACA is to reduce the cost of healthcare, broaden access to health insurance, constrain healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry, impose additional health policy reforms, and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what

impact on federal reimbursement policies this legislation will have in general or on our business specifically, ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of any of our products, if they are approved. Provisions of ACA relevant to the pharmaceutical industry include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions to report annually certain financial arrangements with physicians, as defined by such law, and teaching hospitals, as defined in ACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year;
- expansion of healthcare fraud and abuse laws, including the U.S. federal False Claims Act and the U.S. federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected.

The ACA has been modified and amended recently, including the elimination of the individual mandate that individuals purchase healthcare insurance. Furthermore, the current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the ACA, including as a result of current and future executive orders, legislative actions, and litigation, including the pending review by the U.S. Supreme Court of the constitutionality of the ACA. The impact of those changes on us and potential effect on the pharmaceutical and biotechnology industry as a whole is currently unknown.

However, any changes to the ACA are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. may have on our business.

We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products and solutions are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products and solutions outside of the U.S. must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products and solutions in international markets, prevent customers from using our products and solutions or, in some cases, prevent the export or import of our products and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products and solutions could adversely affect our business, financial condition and results of operations.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We have used contract research organizations abroad for clinical trials. In addition, we may engage third party intermediaries to sell our products and solutions abroad once we enter a commercialization phase for our product candidates and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted an anti-corruption policy in connection with the consummation of the IPO of our common stock in July 2015. The anti-corruption policy mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, there can be no assurance that our employees and third party intermediaries will comply with this policy or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other investigations, or other enforcement actions. If such actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and

financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA, the Securities and Exchange Commission, or SEC and other government agencies on which our operations may rely is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be, or may become, subject to data protection laws and regulations, and our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The E.U. has adopted data protection laws and regulations which may apply to us in certain circumstances, or in the future. These laws, which impose significant compliance obligations, are commonly known as the General Data Protection Regulation, or GDPR. The GDPR, which is wide-ranging in scope and applicability, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data, including clinical trials. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. to the U.S., provides an enforcement authority, and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Implementation of the GDPR, as applicable to us, will increase our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, other new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U.S., the E.U. and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Risks Relating to Our Intellectual Property

If our efforts to protect the intellectual property related to our product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and contractual agreements, including confidentiality agreements to protect the intellectual property related to our product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in the market. We believe that we have worldwide commercial rights to the NK-92 cell line and we believe that we control commercial use of our haNK, taNK, t-haNK and Cenk cells in key territories. We have developed and in-licensed numerous patents and patent applications and we possess substantial know-how and trade secrets relating to the development and commercialization of natural killer cell-based immunotherapy product candidates, including related manufacturing processes and technology. Our owned and licensed patent portfolio consists of patents and pending patent applications in the U.S. disclosing subject matter directed to certain of our proprietary technology, inventions, and improvements and our most advanced product candidates, as well as licensed and owned patents and pending applications in jurisdictions outside of the U.S., that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. We believe we have intellectual property rights that are necessary to commercialize haNK, taNK, t-haNK and Cenk cells. However, our patent applications may not result in issued patents, and, even if issued, the patents may be challenged and invalidated. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary property.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc. If we or our current licensors, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the biopharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own or in-license may fail to result in issued patents in the U.S. or foreign countries with claims that cover our product candidates. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable.

Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Furthermore, even if they are unchallenged, our patents

may not adequately protect our product candidates, provide exclusivity for our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidates.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after its earliest effective non-provisional filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product candidates, and our product development processes (such as a manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product candidates, and third parties involved in our clinical trials to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. However, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed despite having such confidentiality agreements. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. If we are unable to prevent unauthorized material disclosure of our trade secrets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the

pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the U.S. had previously enacted and implemented wide-ranging patent reform legislation (e.g., the Leahy-Smith America Invents Act in September 2011) and are currently considering additional legislation that may materially impact our ability to obtain or enforce our patents. Further, recent U.S. Supreme Court rulings and recent decisions from the United States Court of Appeals for the Federal Circuit have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

In addition, changes to U.S. patent laws provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to commercialize our current or future product candidates and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market our current or future product candidates under patent protection would be reduced. Since U.S. patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates, or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application with the USPTO before us could, therefore, be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the U.S. patent laws resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011.

Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

We strive to control cell line distribution, as well as limit commercial use through licenses and material transfer agreements with third parties in addition to our patents and patent applications. However, a company may illicitly obtain our cells or create their own modified variants and attempt to commercialize them in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. For example, we believe that certain companies, including at least one in

China, may be using our NK-92 cell line without our permission. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. and in some cases, may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate or not as strong as that in the U.S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. 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 patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates.

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 and other intellectual property protection, particularly those relating to pharmaceuticals or biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution

process. Periodic maintenance fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

Third-party claims alleging intellectual property infringement may adversely affect our business.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, the intellectual property rights of competitors. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party, for example a competitor in our market, might assert are infringed by our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Nevertheless, we are not aware of any issued patents that we believe would prevent us from marketing our product candidates, if approved. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses, and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (2) obtain one or more licenses from the third party; (3) pay royalties to the third party; and/or (4) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending ourselves or our licensors in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or

administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

For example, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the U.S., 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.

In addition, within and outside of the U.S., there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the biopharmaceutical industry. The Leahy-Smith Act introduced procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including those that patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product candidates. They may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Enforcing our or our licensor's intellectual property rights through litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent

litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

If we fail to comply with our obligation in any of 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.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. We rely on our exclusive license from Hans Klingemann, M.D., Ph.D., one of our founders and the inventor of our aNK and related platform product cell therapies, and subject to our freedom to operate we may or may not rely on our exclusive licenses from Rush University Medical Center, Fox Chase Cancer Research Center, the University Health Network, and other current and future licensors, including Immunity Bio with respect to the Joint COVID-19 Collaboration. If we fail to comply with the diligence obligations or otherwise materially breach our license agreement and fail to remedy such failure or cure such breach, the licensor may have the right to terminate the license.

Our obligation to pay royalties to Dr. Klingemann under the license agreement, as amended, runs until the expiration of the underlying patents and the license agreement may be terminated earlier by either party for material breach. Under the license agreement, we have the right to enforce the licensed patents. Our license agreement with Rush University Medical Center terminated on the 12th anniversary of our first payment of royalties, at which point the license was deemed a perpetual, irrevocable, fully paid royalty-free, exclusive license.

Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships; and
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations.

While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be able to do so in a timely manner, at an acceptable cost, or at all. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could materially harm our business, prospects, financial condition and results of operations. We recently received a notice of termination from Fox Chase Cancer Center alleging breaches of our license. If we are not able to cure these alleged breaches our license will terminate, and we will lose the licensed rights. We do not consider these licensed rights to be material.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of research and development, we rely in part on trade secret protection and confidentiality agreements, including those with our employees and consultants, in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties, which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential intellectual property. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position. Also, third parties, including our competitors, may independently develop substantially equivalent proprietary information and technologies or otherwise lawfully gain access to our trade secrets and other confidential information. In such a case, we would have no right to prevent such third parties from using such proprietary information or technologies to compete with us, which could harm our competitive position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed intellectual property, including trade secrets, confidential information, or other proprietary information, of these third parties or our employees' or consultants' or independent contractors' former or other employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Relating to Our Common Stock

Our Chairman and CEO and entities affiliated with him collectively own a significant majority of our common stock and will exercise significant influence over matters requiring stockholder approval, regardless of the wishes of other stockholders.

As of March 31, 2020, our Chairman and CEO, Patrick Soon-Shiong, M.D., and entities affiliated with him, collectively own approximately 67.2% of the outstanding shares of our common stock. Additionally, Dr. Soon-Shiong holds vested options to purchase an aggregate of 900,000 additional

shares of our common stock, which would give him and his affiliates ownership of approximately 67.5% of our outstanding shares of common stock if they were exercised in full. In addition, pursuant to the Nominating Agreement between us and Cambridge Equities, LP, or Cambridge, an entity that Dr. Soon-Shiong controls, Cambridge has the ability to designate one director to be nominated for election to our board of directors for as long as Cambridge continues to hold at least 20% of the issued and outstanding shares of our common stock. Dr. Soon-Shiong was selected by Cambridge to hold this board seat. Dr. Soon-Shiong and his affiliates will therefore have significant influence over management and significant control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions, such as a merger or other sale of our company or its assets, for the foreseeable future. This concentrated control will limit stockholders' ability to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected.

The market price of our stock may fluctuate significantly, and investors may have difficulty selling their shares.

Prior to our initial public offering in July 2015, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Global Select Market, or Nasdaq, the market for our shares has demonstrated varying levels of trading activity. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock has been and may continue to be volatile.

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;

- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- our ability to effectively manage our growth;
- variations in our quarterly operating results;
- our cash position and the amount and nature of any debt we may incur;
- announcements that our revenue or income are below or that costs or losses are greater than analysts' expectations;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- sales of large blocks of our common stock;
- fluctuations in stock market prices and volumes;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- the perception of our clinical trial results by retail investors, which investors may be subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet;
- general economic slowdowns; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market the market price of our common stock could decline significantly. In addition, as of March 31, 2020 our Chairman and CEO, Dr. Soon-Shiong, and his affiliates beneficially owned approximately 67.5% of our outstanding shares of common stock. Sales of stock by Dr. Soon-Shiong and his affiliates could have an adverse effect on the trading price of our common stock.

Certain holders of approximately 46.2 million shares of our common stock are entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have an adverse effect on the market price of our common stock.

In addition, we expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

As a public company listed in the U.S., and increasingly after we are no longer an "emerging growth company," we have incurred and will continue to incur significant additional legal, accounting and other expenses that we did not incur as a private company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including Sarbanes-Oxley and regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to create a larger finance function with additional personnel to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the U.S., we are required, pursuant to Section 404 of Sarbanes-Oxley, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We must disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we are no longer an "emerging growth company," and if we are not a smaller reporting company at that time, we will need to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting for the year ended December 31, 2019, or for any other period. Accordingly, no such opinion was expressed in 2019. For the year ending December 31, 2020, we may be subject to the auditor attestation requirements of Section 404 of Sarbanes-Oxley. There can be no assurance that we will not discover deficiencies or a material weakness in our internal control over financial reporting or that our auditor will agree with management's assessment of our internal control over financial reporting.

Even after we develop these new procedures, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all

control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or Nasdaq, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

We also expect that being a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

If a restatement of our financial statements were to occur, our shareholders' confidence in the company's financial reporting in the future may be affected, which could in turn have a material adverse effect on our business and stock price.

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to further restate our financial results. In addition, if we are unable to successfully remediate any future material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Because we are relying on the exemptions from corporate governance requirements as a result of being a "controlled company" within the meaning of the Nasdaq listing standards, you do not have the same protections afforded to stockholders of companies that are subject to such requirements.

Our Chairman and CEO, Dr. Patrick Soon-Shiong, and entities affiliated with him, control a majority of our common stock. As a result, we are a "controlled company" within the meaning of the Nasdaq listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and may elect not to comply with certain Nasdaq corporate governance requirements, including (1) the requirement that a majority of the

board of directors consist of independent directors and (2) the requirement 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. Our board of directors is currently comprised of a majority of independent directors. In addition, although not required by the rules of Nasdaq, in August 2019, our board of directors established a nominating and corporate governance committee comprised of three directors, two of which are independent. Accordingly, you do not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements.

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 could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act enacted in April 2012, or the JOBS Act, and may remain an "emerging growth company" for up to five years following the completion of our IPO, or December 31, 2020, although, if we have more than $1.07 billion in annual revenue, the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of June 30 of any year, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31. For as long as we remain an "emerging growth company," we are permitted and intend to continue to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- 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 shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting requirements in our public filings. In particular, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. 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, delaying the adoption of these accounting standards until they would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Investors may find our common stock less attractive as a result of our reliance 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 the market price of our common stock may be reduced or more volatile.

Our ability to use our net operating loss carryforwards, or NOLs, and certain other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2019 we had U.S. federal, state and foreign NOLs of $291.8 million, $255.7 million and $0.2 million, respectively, some of which begin to expire in various years starting with 2022, if not utilized. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $8.5 million and $5.7 million, respectively. These net operating loss and research and development tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We completed an IRC Section 382/383 analysis through March 2019 regarding the limitation of net operating loss and research and development credit carryforwards. The analysis concluded that we have undergone significant ownership changes in previous years. As a result, we derecognized a portion of the deferred tax assets for NOLs and federal and state research and development credits of $0.8 million from our deferred tax asset schedule as of December 31, 2019 as described in more detail in our financial statements.

Since we will need to raise substantial additional funding to finance our operations, we may experience further ownership changes in the future, some of which may be outside of our control. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. In addition, under the legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, or TCJA, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, the amount of NOLs generated in taxable periods beginning after December 31, 2017, that we are permitted to deduct in any taxable year beginning after December 31, 2020 is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The TCJA allows post-2017 unused NOLs to be carried forward indefinitely. Similar rules may apply under state tax laws.

We could be subject to additional income tax liabilities.

We are a U.S.-based company subject to tax in the U.S. and in Korea. Significant judgment is required in determining our global provision for income taxes, deferred tax assets or liabilities, and in evaluating our tax positions on a worldwide basis. While we believe our tax positions are consistent with the tax laws in the jurisdictions in which we conduct our business, it is possible that these positions may be overturned by jurisdictional tax authorities, which may have a significant impact on our global provision for income taxes.

Our business may be materially affected by changes to fiscal and tax policies. Negative or unexpected tax consequences could adversely affect our results of operations.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, that was approved by Congress on December 20, 2017 significantly changed the U.S. Internal Revenue Code. Such changes include a reduction in the corporate tax rate and limitations on certain corporate deductions and credits, among other changes. We have generally accounted for such changes in accordance with our understanding of the TCJA and guidance available as of the date of this filing as

described in more detail in our financial statements. The CARES Act, which was signed into law on March 27, 2020, further modified the TCJA and we will continue to monitor and assess the impact of the federal legislation on our business and the extent to which various states conform to the newly enacted federal tax law. In addition, adverse changes in the financial outlook of our operations or further changes in tax laws or regulations could lead to changes in our valuation allowances against deferred tax assets on our consolidated balance sheets, which could materially affect our results of operations.

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

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts' cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We are not subject to the provisions of Section 203 of the Delaware General Corporation Law, which could negatively affect your investment.

We elected in our amended and restated certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes a merger, asset 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, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. Our decision not to be subject to Section 203 will allow, for example, our Chairman and CEO (who with members of his immediate family and entities affiliated with him owned approximately 67.2% of our common stock as of March 31, 2020) to transfer shares in excess of 15% of our voting stock to a third-party free of the restrictions imposed by Section 203. This may make us more vulnerable to takeovers that are completed without the approval of our board of directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

Some provisions of our charter documents 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.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders. These provisions include:

- a requirement that special meetings of stockholders be called only by the board of directors, the president or the chief executive officer;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.