# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2019**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE TRANSITION PERIOD FROM TO**

**Commission file number: 001-37507**

# NANTKWEST, INC.

**(Exact name of Registrant as specified in its Charter)**

| **Delaware** | **43-1979754** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **3530 John Hopkins Court San Diego, California** | **92121** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (858) 633-0300**

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** | **The Nasdaq Stock Market LLC (Nasdaq Global Select Market)** |

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

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

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Market on June 30, 2019, was approximately $28.8 million.

The number of shares of the Registrant's common stock outstanding as of March 23, 2020 was 98,483,161.

DOCUMENTS INCORPORATED BY REFERENCE

As noted herein, the information called for by Part III is incorporated by reference to specified portions of the Registrant's definitive proxy statement to be filed in conjunction with the Registrant's 2020 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the Registrant's fiscal year ended December 31, 2019.

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**Explanatory Note**

As used in this Annual Report on Form 10-K, or Annual Report, for the year ended December 31, 2019, the terms "NantKwest," "the company," "our," "us" or "we" refer to NantKwest, Inc.

## PART I

***Forward-Looking Statements***

This Annual Report on Form 10-K, or this Annual Report, may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Part I, Item 1A, "*Risk Factors*", in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as "may," "will," "expect," "anticipate," "intend," "plan," "believe," "estimate" or other words indicating future results, though not all forward-looking statements necessarily contain these identifying words. Such statements may include, but are not limited to, statements concerning the following:

- our ability to pioneer immunotherapy, harness the power of the innate immune system, implement precision cancer medicine and change the current paradigm of cancer care;
- our expectations regarding the potential benefits of our strategy and technology;
- our expectations regarding the operation of our product candidates and related benefits;
- our ability to utilize multiple modes to induce cell death;
- our beliefs regarding the benefits and perceived limitations of competing approaches, and the future of competing technologies and our industry;
- details regarding our strategic vision and planned product candidate pipeline, including that we eventually plan to advance therapies for virally induced infectious diseases;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design;
- our expectations regarding our ability to utilize the phase I and II aNK and haNK clinical trials data to support the development of all of our product candidates, including our haNK, taNK and t-haNK product candidates;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including any planned investigational new drug, or IND, filings or pursuit of accelerated regulatory approval pathways or orphan drug status and breakthrough therapy designations;
- our ability to implement an integrated discovery ecosystem and the operation of that planned ecosystem, including being able to regularly add neoepitopes and subsequently formulate new product candidates;
- the ability and willingness of strategic collaborators, including certain affiliates of NantWorks, LLC, or NantWorks, to share our vision and effectively work with us to achieve our goals;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our ability to attract additional third party collaborators;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- our ability to produce an "off-the-shelf" therapy;
- our beliefs regarding the potential manufacturing and distribution benefits associated with our product candidates, and our ability to scale up the production of our product candidates;
- our plans regarding our manufacturing facility and our belief that our manufacturing is capable of being conducted in-house;
- our belief in the potential of our aNK cells as a technology platform, and the fact that our business is based upon the success of our aNK cells as a technology platform;
- our aNK platform and other product candidate families, including genetically modified taNK, haNK and t-haNK product candidates, will require significant additional clinical testing;

- even if we successfully develop and commercialize our aNK product candidate, we may not be successful in developing and commercializing our other product candidates either alone or in combination with other therapeutic agents;
- the ability to obtain and maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates and not infringe upon the intellectual property of others;
- regulatory developments in the United States, or U.S., and foreign countries; and
- our expectations regarding the period during which we qualify as an "emerging growth company" under the JOBS Act, and a "smaller reporting company," as defined in Rule 12b-2 of the Securities Exchange Act of 1934.

In addition, you should refer to Part I, Item 1A, "*Risk Factors*" of this Annual Report for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

## Item 1. Business.

### Overview

As a pioneering clinical-stage immunotherapy company, we are focused on harnessing the power of the innate immune system by using its natural killer cells, 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, 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 hold the exclusive right to commercialize aNK cells, a commercially viable natural killer cell line, and a wide range of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States, or U.S., and foreign composition and methods-of-use patents and applications covering the cells, improvements, methods of expansion and manufacture and use of aNK cells and their improvements as therapeutics to treat a spectrum of clinical conditions.

We also license exclusive commercial rights to a high-affinity CD16 receptor expressing enhancement of our aNK cell platform, covered in a portfolio of U.S. and foreign composition and methods-of-use patents and applications covering both the clinical use as a therapeutic to treat cancers in combination with antibody products, as well as the non-clinical use in laboratory testing of monoclonal antibodies.

We believe our proprietary NK cell platform, coupled with our integrated discovery ecosystem, positions us to implement precision cancer medicine by taking advantage of the advances that have evolved during the past decade and addressing newly discovered challenges of cancer. Cancer is only recently understood to be a complex of rare diseases, with hundreds of cancer specific proteins. We believe proteins, selectively expressed on the cancer cells and not on the essential normal tissue, represent large untapped targeting opportunities for immune effector cell products derived from our aNK cell platform.

**Our Approach**

***Multiple Modes of aNK Directed Tumor Cell Killing.*** Our NK platform has demonstrated the ability to induce cell death in cancers and virally infected cells through a variety of concurrent mechanisms including:

i. *Innate Killing*, whereby all of our NK platforms, aNK, haNK, taNK and t-haNK, recognize the abnormal proteins typically found on the surfaces of metabolically stressed cells, which upon binding, release toxic granules to immediately kill their targets;

ii. *Antibody-Mediated Killing* with our haNK and t-haNK platforms, which are aNK cells engineered to express antibody receptors that can bind to therapeutically administered antibody products or to antibodies naturally produced in the body, thereby enhancing the cancer cell killing effects of those antibodies through Antibody Dependent Cellular Cytotoxicity, or ADCC; and

iii. *CAR-Directed Killing* with our taNK and t-haNK platforms, which are aNK cells engineered to express chimeric antigen receptors, or CARs, that target tumor-specific proteins commonly found only on the surfaces of cancer cells and upon binding, induce cell death through the release of toxic granules directly into their targets and by the release of cytokines and chemokines, which recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells.

All three modes of killing; *Innate Killing*, *Antibody-Mediated Killing*, *and CAR-Directed Killing*, are employed by our proprietary t-haNK platform, which combines all the enhanced NK killing functions of aNK, haNK and taNK into a single product platform.

Our primary target therapeutic area is cancer, with a heavy emphasis on solid tumors. According to the National Cancer Institute, there was an estimated 1.7 million newly diagnosed cases of cancer in the U.S. in 2019, adding to the 16.9 million already living with cancer. In addition, we plan to advance therapies for hematologic malignancies and virally induced infectious diseases.

***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 typical 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 can also 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 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 ADCC. 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 commercialization going forward. We have optimized our haNK product manufacturing process partly through the successful development of a product that does 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 has been approved 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 and B7-H4;

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

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 demonstrates that taNK cell activation through the binding of its CAR receptors to these cancer specific proteins is 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 products under this platform avails itself to all three modes of killing: *innate*, *antibody-mediated* and *CAR-directed killing*. These products 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 products 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, authorized to commence phase I testing, a pipeline of prominent CARs for t-haNK, including HER2, which is nearing IND submission, and EGFR, which is advancing through human enabling studies, among others will enable us to address an even broader range of cancers as part of a chemotherapy-free combination regimen.

***The Nant Cancer Vaccine.*** The Nant Cancer Vaccine, or NCV, program is a personalized therapy regimen, which utilizes our "off-the-shelf" NK cell platform as the backbone of the regimen. NCV consists of an initial tumor-conditioning regimen followed by a molecularly-informed immunologic conditioning therapy. More specifically, NCV combines tumor and peripheral blood genomic and transcriptomic data derived from our affiliates NantOmics' and NantHealth Labs' sequencing and analytical services with the novel delivery of metronomic, albumin-bound low-dose chemotherapy in conjunction with certain other agents, followed by a sequenced administration of tumor-associated antigen vaccines and a unique IL-15 cytokine, all of which potentiate our NK cell therapy to potentially drive immunogenic cell death while avoiding the ravages of toxic high-dose chemotherapy. By inducing immunogenic cell death and enhancing a patient's innate and adaptive immune system, NCV is designed to attain a long-term, durable response in multiple cancer types with a potential for lower toxicity and improved efficacy and quality of life in comparison with current standards of care. We believe ultimately that employing our NK cell therapy in the context of NCV will be a highly effective combination for long term clinical success over available standards of care that employ maximum tolerated dose, tolerogenic cell death and immune system compromise.

***Our Integrated Discovery Ecosystem for Precision Medicine.*** In order to effectively target newly discovered neoepitopes, we plan to eventually integrate the following ecosystem to help drive the utility of our NK cell therapies against these unique cancer markers, including the use of our haNK platform in conjunction with cancer vaccines that induce *in vivo* antibody formation directed against these mutated proteins, as well as the development of t-haNK cells that directly target these mutated proteins:

i. a high-speed supercomputing infrastructure to help identify both known antigens on the surface of tumor cells and neoepitopes in clinical patients suffering from cancer, in a timely manner and at large scale;

ii. a next-generation genomic and transcriptomic sequencing infrastructure to verify the expression of the neoepitopes in the tumor cell, developed by our affiliate entity NantOmics;

iii. delivering the neoepitope via an adenoviral or yeast platform developed by an affiliate entity to induce production of IgG1-type antibodies in the body, which would in turn combine with our haNK cells to accelerate ADCC tumor killing;

iv. a diverse library of human antibodies from which to interrogate and extract an antibody to construct a CAR for genetic incorporation into our t-haNK platform; and

v. CAR-targeted t-haNK cells potentially capable of being produced as a scalable cell-based "off-the-shelf" therapy, without the need for patient compatibility matching.

We expect to regularly add newly discovered neoepitopes and novel antibody/CAR targets from our discovery engine and we believe the thousands of newly discovered antigens selectively expressed on the cancer cells and not on the essential normal tissue will provide us with the ability to create new libraries of cancer-specific antibodies and their corresponding CARs to be potentially delivered as living drugs for selective targeting of metastatic cancer cells and cancer stem cells.

***Potential Advantages of Our aNK Platform Over T-Cell and Other Current Immunotherapies***

The immune system has two components: innate immune cells, such as natural killer cells, which are always primed and ready to attack diseased cells, and adaptive immune cells, such as T-cells, which are recruited and educated through a series of antigen presentation and clonal expansion, eventually mounting a delayed response. Our proprietary aNK platform is specifically designed to potentially address many of the limitations associated with current adaptive autologous cellular immunotherapies. We believe key limitations of adaptive autologous immunotherapy are the need to isolate adequate amounts of naive T-cells from a cancer patient in a lengthy procedure called leukapheresis and the requirement for a complex individualized genetic transfection and expansion campaign to manufacture each patient's therapy. As a consequence, current autologous CAR-T cell therapies, in large part, are limited to patients from highly selected hematological cancers and leave many patients ineligible for treatment. Additionally, patients must undergo lympho-depleting chemotherapy prior to receiving CAR-T therapy and rely on engraftment, thereby exposing themselves to life-threatening serious adverse events for extended periods. For instance, recipients of CD19 CAR-T therapy develop life-long B-cell aplasia and hypogammaglobulinemia, requiring immunoglobulin infusion therapy. Acutely, patients may develop cytokine release syndrome or acute or chronic neurotoxicities. Due to these and other events, treatment with CAR-T requires intensive inpatient and long term monitoring. In contrast, our allogeneic "off-the-shelf" NK cells can be infused in the outpatient setting and do not rely on the patient as the source of suitable immune cells for processing, thereby availing every cancer patient as a potential candidate for on-demand treatment. In addition, our NK cell therapy is intended to be combined with immune potentiating agents, rather than immuno-depleting agents with the interest of driving a more natural and long-lasting adaptive immune response. This is largely due to the unique versatility of our cell products, which more closely approximates the characteristics of a drug rather than a transplant. Most cell-based immunotherapies are limited to one or a constrained number of doses due to product limitations and cost burdens, thereby driving the need for immune-ablative therapies and reliance on long-term engraftment to achieve clinically meaningful results. In comparison, our NK cell based therapies can be re-dosed regularly throughout the year and at much higher dose levels without the same product limitations, cost burdens, reliance on long-term engraftment and potential exposure to long-term toxicities.

For these reasons, we believe that our approach includes the following advantages:

- ***Innate immune response.*** aNK platform products are always activated and can naturally detect and rapidly destroy a wide variety of diseased cells without prior exposure to antigens or activation by stimulatory molecules.
- ***Promotion of adaptive immune response.*** aNK platform products stimulate the adaptive component of the immune system by producing chemokines and other molecules that recruit and activate T-cells directly and through dendritic cells to attack cancers.
- ***Enhancement of ADCC effect with CD16 expressing haNK cells.*** Our haNK product candidates may have significant market potential as a combination therapy with approved monoclonal antibodies, or mAbs, targeting tumor associated antigens, as well as neoepitope induced antibodies, potentially addressing a large number of patients who have poor responses to antibody products.
- ***Wide therapeutic potential across multiple tumor types and even late-stage disease.*** In preclinical studies and phase I and II clinical trials to date, aNK, haNK and t-haNK cells have demonstrated activity in a spectrum of cancers, including bulky hematological cancers and solid tumors, as well as late-stage cancer patients who have failed multiple rounds of chemotherapy, radiation and stem cell transplantation.
- ***Ability to attack cancer stem cells.*** aNK cells have been shown in preclinical studies to preferentially attack cancer stem cells, which have demonstrated resistance to conventional chemotherapy.
- ***Applications in diseases beyond cancer.*** We believe aNK platform products have the potential to treat diseases beyond cancer, such as viral infectious diseases because of the inherent ability of natural killer cells to kill virally infected cells. Preclinical studies in HIV, HCV, EBV and Ebola viruses demonstrate this capability.
- ***Well tolerated.*** aNK platform products are hypo-immunogenic and have shown no dose limiting toxicities in over 900 patient infusions, including in recipients who have received long-term repeat infusions beyond a year.
- ***Ease of administration.*** aNK platform products may be administrable in outpatient facilities, offering physicians the flexibility to re-dose therapy in the ambulatory setting for extended periods and in large practices.
- ***Virtually universal patient compatibility.*** aNK platform products do not require patient-donor matching or a minimum level of patient immuno-competence.
- ***Low-cost, efficient and scalable manufacturing.*** aNK, haNK, taNK and t-haNK cells have the potential to be expanded on a large scale and readily supplied on demand from what we believe is the world's only cGMP compliant aNK, haNK and t-haNK cell banks, proprietary assets of our company.

***Experienced Management Team***

Since the founding of our company in 2002, we have assembled a team of proven, experienced and visionary leaders in biotechnology. Our team is led by Patrick Soon-Shiong, M.D., FRCS (C), FACS, our Chairman and Chief Executive Officer, or CEO. Dr. Soon-Shiong was first introduced to us in 2007 when our technology was at a very early stage of development and he provided us with advice and scientific development strategies, including demonstration of activity in the clinical setting following irradiation of the cells and demonstration of safety and activity following multiple infusions in patients with both end-stage solid and liquid tumors. Dr. Soon-Shiong made an equity investment in our company in December 2014, joined as our Chief Medical Officer in January 2015, and became our Chairman and CEO in March 2015. Dr. Soon-Shiong, a renowned surgeon and scientist, has pioneered novel therapies for both diabetes and cancer, published over 100 scientific papers in the U.S., and has been issued over 230 worldwide patents on groundbreaking advancements spanning a myriad of fields. He performed the first encapsulated islet stem cell transplant in a diabetic patient in the U.S. He invented, developed and launched the first nanoparticle delivery system of human albumin, abraxane. Dr. Soon-Shiong was founder, Chairman and CEO of American Pharmaceutical Partners (sold to Fresenius SE for approximately $4.6 billion in 2008), Abraxis BioScience (sold to Celgene Corporation for approximately $3.8 billion in 2010), and NantWorks, an ecosystem of companies to create a transformative global health information and next generation pharmaceutical development network.

Barry Simon, M.D., our President and Chief Administrative Officer, who was our CEO from May 2007 until March 2015 and our President and Chief Operating Officer from March 2015 to December 2016, brings decades of drug development and executive leadership experience from Roche Labs, F. Hoffmann-La Roche, Connetics Corp. and Immunomedics, having successfully contributed to Biologics License Applications, or BLAs, and drug launches for Xeloda, Pegasys, Kytril, Fortovase, Valcyte, Fuzeon and Tamiflu.

Since 2015, we have recruited seasoned executives to lead manufacturing, clinical development, regulatory affairs, medical affairs, quality and other critical staff as we continue to build our management and manufacturing infrastructure.

***Company Vision***

We aspire to be the premier immunotherapy company, with the ultimate goal of harnessing the power of the innate immune system—with the NK cell at its core—to pioneer precision medicine in treatments for cancers and viral infectious diseases.

**Our Core Strategies**

Our goal of becoming the world leader in immunotherapy for cancers and other diseases can be realized through a major reframing of how we apply the collective knowledge amassed in this field to date. This starts with precisely determining the 'molecular address' of the target disease and leveraging this knowledge in the selection and staging of both tumor and immune conditioning agents in accordance with our understanding of biological mechanisms of action and the natural order of immune biology. Metronomic, low-doses of certain agents would be utilized to potentiate cellular stress and boost tumor immunogenicity, while an array of other agents would be applied selectively and sequentially to propagate a meaningful and lasting adaptive immune response. We believe that by utilizing the NK cell as the backbone and central coordinator as we engage and sequentially orchestrate the entire ecosystem of immune cells, we can effectively empower the patient's own immune system to regain control by becoming its own 'drug factory' that can establish and once again maintain a cancer-free environment in the body. The key elements of our strategy include:

- ***Pursuit of both accelerated regulatory pathways and large market opportunities.*** We are pursuing a comprehensive clinical development plan designed to maximize the commercial potential of our haNK and t-haNK platforms as the backbone in the treatment of cancers in a streamlined combination with a PD-L1 checkpoint inhibitor and a highly selective and molecularly enhanced IL-15 cytokine immunotherapy. We intend to pursue accelerated regulatory approval pathways and seek indications that can lead to orphan drug status and breakthrough therapy designation, as well as pursue large market opportunities in select solid tumors in the shortest feasible timeframe.
- ***Progress our lead haNK product through phase II and registration trials.*** We are leveraging the combined human safety and activity data accumulated to date on haNK therapy to conduct our multi-center phase II trial in patients with Merkel cell carcinoma who have relapsed on checkpoint therapy.
- ***Advance our next-generation t-haNK products towards phase II and registration trials.*** Our broadly applicable t-haNK product, PD-L1.t-haNK, is expected to conclude phase I clinical testing by June 30, 2020, and the first phase II trials in pancreatic and PD-L1 expressing non-small cell lung cancers have recently been filed with the FDA, with an additional phase II trial submission in lung cancer with concurrent chemotherapy in preparation for submission. Additionally, our CD19.t-haNK IND application has been approved by the FDA for a dose escalation phase I study in patients with CD19 expressing diffuse large B-cell lymphomas and our Her2.t-haNK IND application is nearing completion and being readied for submission with the FDA during the first half of 2020. Additions to our pipeline of IND-ready t-haNK product candidates may include EGFR and BCMA t-haNK products during the second half of 2020.
- ***Leverage our exclusive co-development agreement with ImmunityBio for N-803.*** As with the emergence of dozens of CAR-T companies following the success of a select few, more and more natural killer cell therapy companies are forging ahead into the cancer immunotherapy space. Due to the lack of market access to suitable companion products for co-development, such as cytokine therapies, many natural killer cell therapy developers are following the path of CAR-T sponsors in the use of myeloablative therapies that support engraftment, but at the same time suppresses immune recruitment and the recipient's ability to mount an adaptive immune response. N-803 is an experimental IL-15 superagonist, currently in late stage registration trials by ImmunityBio, Inc., an affiliated entity. Our utilization of N-803 in combination with our NK therapies across our clinical program affords us an additional distinction and competitive advantage where we combine systemic activation of recipient natural killer and T-cells with chemotherapy-free treatment regimens for maximal immune response and memory T-cell formation.
- ***Pursue partnering opportunities with pharmaceutical companies for commercially approved antibodies and select late-stage antibodies in development.*** Numerous biopharmaceutical companies have previously licensed our research-grade haNK cells through an affiliated entity for non-therapeutic applications that facilitate the discovery, selection and validation of their antibody candidates for development. A growing number of these biopharmaceutical companies have also licensed our cells for use in their antibody manufacturing and testing procedures in order to satisfy requirements by the FDA and comparable foreign regulatory agencies. There may be multiple opportunities to leverage these biopharmaceutical business relationships to forge therapeutic collaborations to conduct clinical studies with our haNK and t-haNK product candidates in combination with their late-stage and commercial antibody products to demonstrate enhanced activity when used in combination.

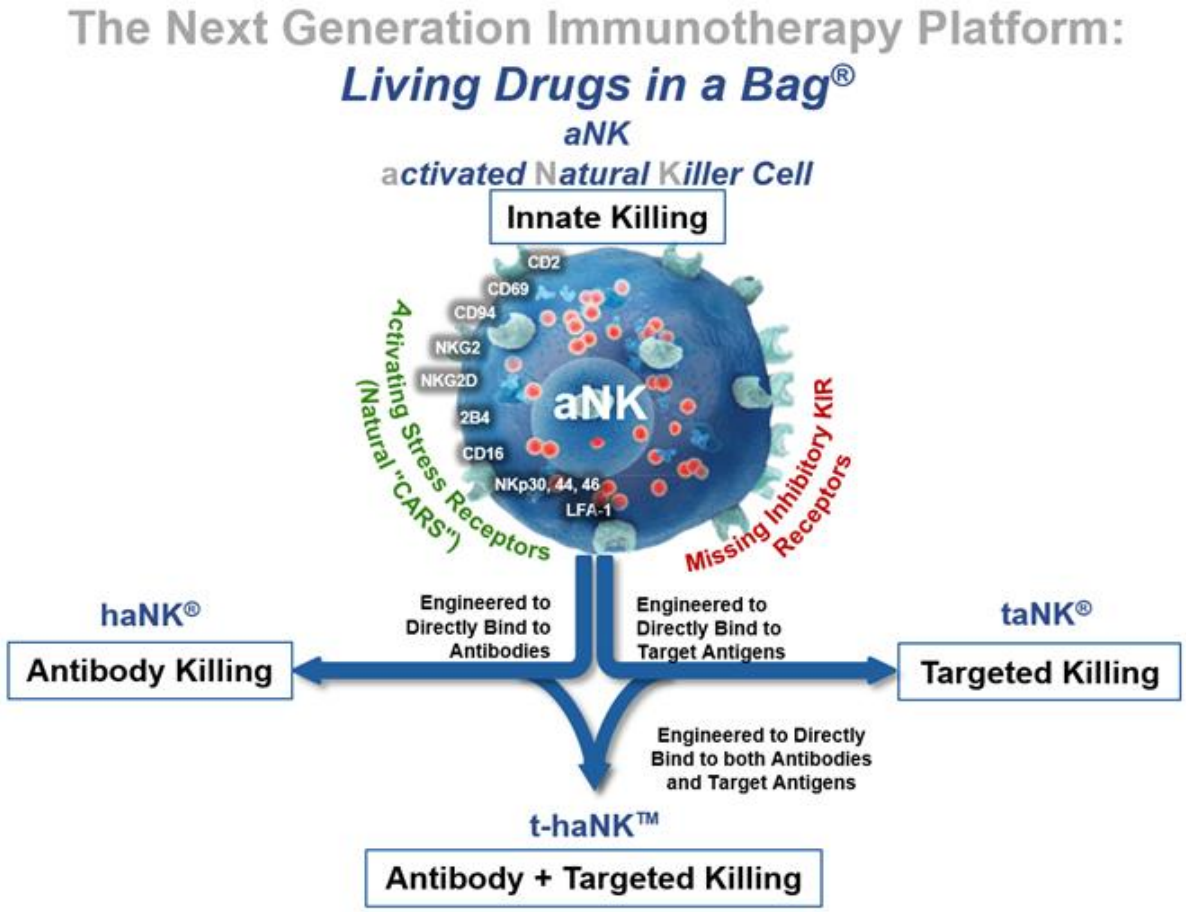
- ***Accelerate clinical development of our t-haNK products by implementing phase Ib/II basket trials.*** A growing number of antibody and other anti-cancer products are being marketed for multiple cancer types that share the same molecular abnormality. We plan to accelerate clinical development of our PD-L1.t-haNK, CD19.t-haNK and Her2.t-haNK product candidates by designing trials that permit the enrollment of patients whose cancers demonstrate high levels of PD-L1, CD19 and HER2, respectively, from a number of select cancer types. We believe this approach will enhance the development potential of our t-haNK product pipeline.
- ***Employ an adaptive approach to our clinical trials designs.*** As we explored complex combinations in our NCV trials that combined tumor conditioning agents, IL-15 cytokine activation, adenoviral and yeast vaccine driven dendritic cell activation and antibody therapy together with our haNK cell therapy across multiple tumor types, we continued to optimize the treatment design over time after accumulating sufficient outcome observations through IND amendments and new IND filings. By doing so, we were able to considerably condense the development time frame while providing patient access to the enhanced protocol designs much sooner than would have otherwise been possible.
- ***Establish low-cost, scalable manufacturing capabilities to support late-stage clinical trials and global commercialization.*** We believe our aNK platform products offer unique advantages of a simplified, on-demand manufacturing process that is relatively easy to scale and requires minimal handling at the site of infusion. We opened our state-of-the-art commercial production facility in El Segundo, California, at the beginning of 2019 and transferred all of our manufacturing operations from our pilot facility in Culver City, California. We believe this new facility is capable of producing clinical product for all our clinical trials for multiple product lines and well into commercialization. We have developed novel manufacturing methods, including the use of proprietary equipment that employs state-of-the-art optics, as well as proprietary media, designed to maximize the attributes of our NK product lines. We have eliminated the need for IL-2 media supplementation in all of our bioreactors and product lines, thereby simplifying the expansion process and shortening the culturing times while significantly reducing production costs. We have also implemented proprietary cryopreservation methods that enable large-scale production yields that can be easily processed into final frozen dose forms for long-term storage and simple, on-demand shipping. Cryopreservation allows for significant cost efficiencies and the establishment of a substantial commercial pipeline supply, much like shelf-stable pharmaceutical drugs. We have effectively eliminated reliance on third party contract manufacturers, with the associated risks to cost, time and reliability. We plan to continue to improve our costs as we scale up production to larger capacity bioreactors that can support serial harvests, the utilization of consumables that will support fully automated production lines from harvest to cryopreserved product and establish additional efficiencies across products pipelines.
- ***Pursue opportunities with vaccine combination partnerships that drive in vivo production of anti-cancer antibodies for ADCC killing with haNK and t-haNK cells.*** Upon achieving initially anticipated BLAs for our haNK and PD-L1.t-haNK products in simple combinations with N-803 and a monoclonal antibody, we plan to initiate a wide range of combination therapy studies that incorporate adenoviral and yeast vaccine platforms to deliver tumor associated antigens which induce the natural production of IgG1-type antibodies in patients, and when combined with our haNK and t-haNK products, would be expected to potentiate ADCC killing.
- ***Extend our NK platform to address diseases beyond cancer.*** We believe our aNK platform has the potential to address diseases beyond cancer such as viral infectious diseases because of the innate ability of natural killer cells to kill virally infected cells. Preclinical studies in HIV, HCV, EBV and Ebola viruses demonstrate this capability. Preclinical efforts are underway to evaluate the role of haNK in combination with select broadly neutralizing antibody, or bNAb, candidates in clearing HIV reservoirs as part of a novel immunotherapy combination regimen. Additionally, exploratory efforts are proceeding with the evaluation of haNK cells, as well as other variants, in the treatment of moderate to severe respiratory infections due to Coronaviruses, such as SARS-CoV-2.

**Our Therapeutic Platforms**

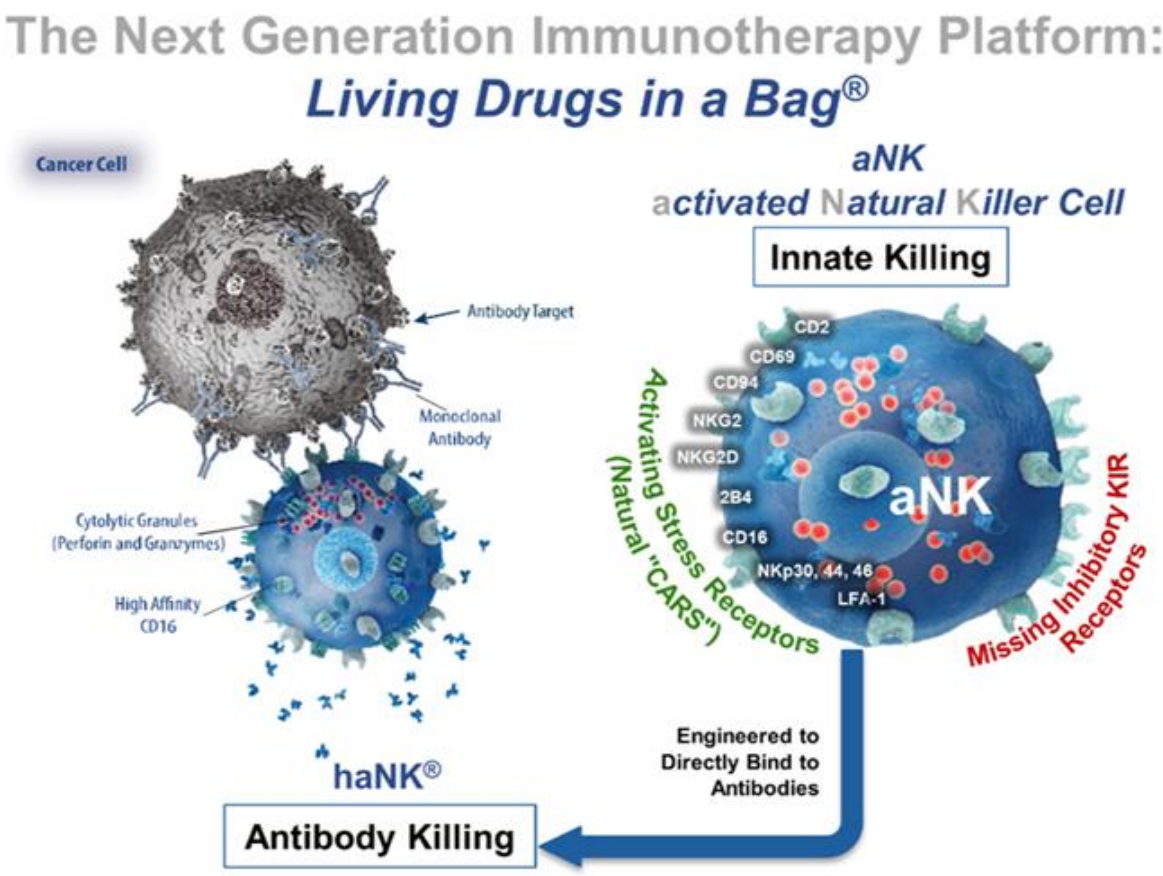
***Leveraging Our Assets***

We have developed a pre-clinical portfolio of t-haNK products based on the combined attributes of our existing haNK and taNK platforms. We have also advanced our haNK product into clinical trials across several solid-tumor types, which incorporates a comprehensively orchestrated tumor and immune-conditioning regimen known as the Nant Cancer Vaccine, or NCV, and generated compelling safety and activity data. We now plan to advance our lead clinical candidates from the haNK and t-haNK platforms into checkpoint inhibitor and IL-15 combination trials in select cancer indications.

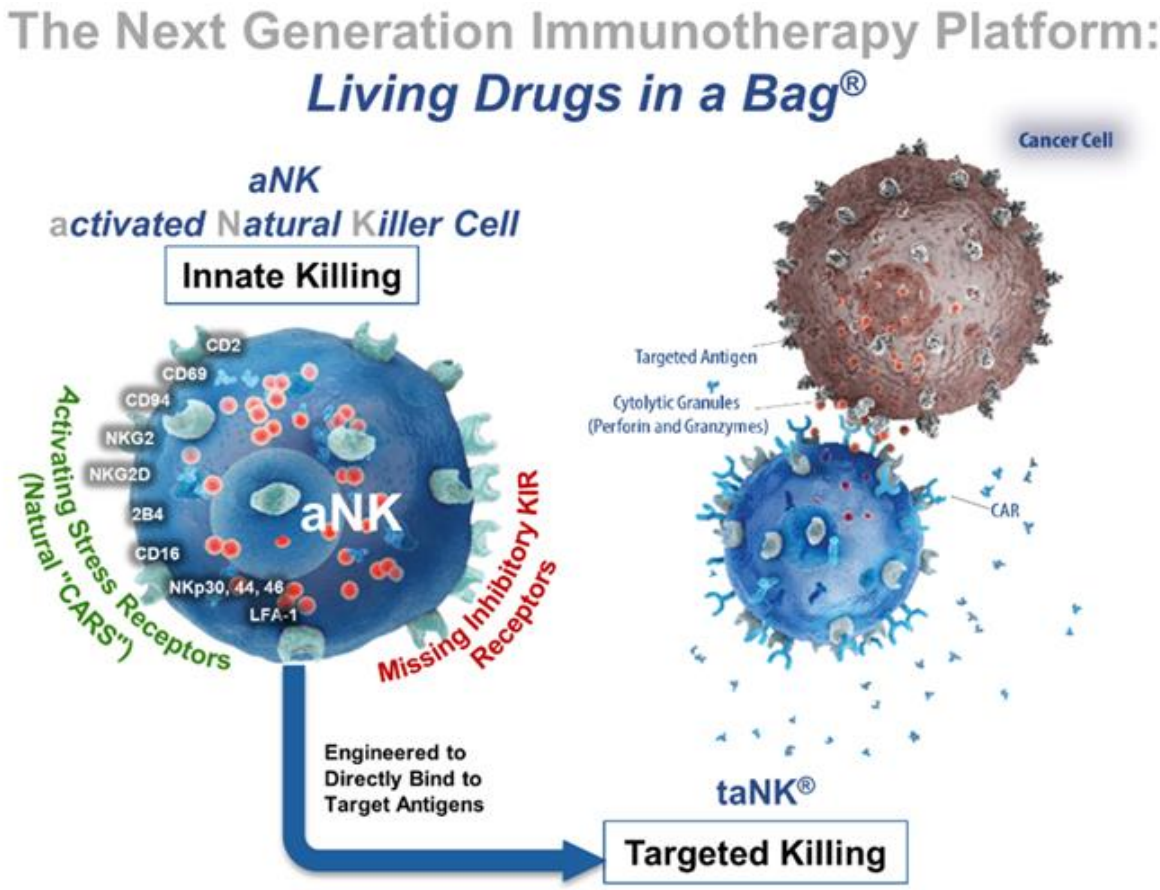
***Our aNK Platform is the Foundation for Our haNK, taNK and t-haNK Product Candidates.*** Based on the unique characteristics of our aNK cells, we continue to expand the potential therapeutic applications of this platform through molecular engineering designed to leverage the multiple modes of killing available to aNK cells, including (1) innate plus antibody-mediated killing, the haNK platform; (2) innate plus antigen targeted killing, the taNK platform; and (3) a combination of all three, the t-haNK platform, as illustrated below.



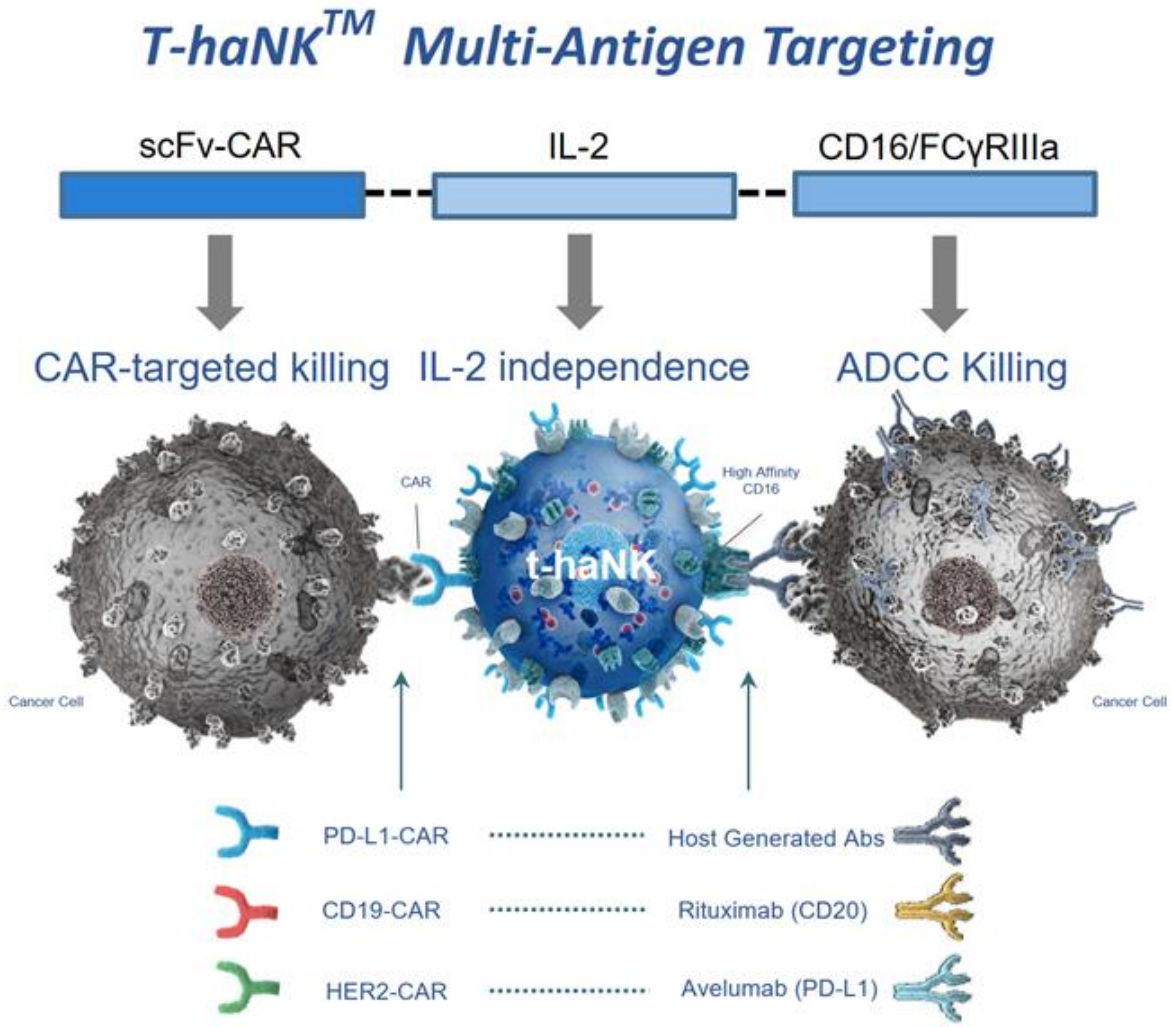
***Antibody-Mediated Killing - the haNK Platform.*** We have genetically engineered our aNK cells to both overexpress high-affinity CD16 receptors and the IL-2 cytokine. These haNK cells are well suited to directly bind to concurrently administered therapeutic antibodies such as avelumab, trastuzumab, cetuximab and rituximab to potentially enhance their targeted cancer killing effects through ADCC, as illustrated below.



***CAR-Directed Killing - the taNK Platform.*** We have genetically modified our aNK cells to incorporate CARs that target cancer specific proteins typically found on the surface of cancer cells. These taNK cells are designed to directly bind to these surface proteins in a variety of solid and hematological cancers and induce cell death through the release of toxic granules directly into the tumor cell and the release of cytokines and chemokines, which recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells. CARs are complex molecules that are designed to traverse the cell membrane and are comprised of four elements: (1) the antibody-derived single-chain Fv fragment, or scFv, which appears on the external membrane surface of the taNK cell, where it is exposed and available to bind to cancer specific antigens; (2) a transmembrane hinge region; (3) a CD28 co-stimulatory domain; and (4) one of several signaling domain segments which resides on the internal surface of the membrane where, upon external scFv binding, it is available to signal the activation cascade to release cytotoxic compounds to destroy the targeted cancer cell. Unlike CAR-T and T-cell receptor therapies, taNK killing is human leukocyte antigen, or HLA, independent for “off-the-shelf” applications and does not depend on additional (second generation) co-stimulatory domains, such as 4-1BB or OX40, which are often necessary in CAR-T cells for immune cell activation and survival.



***CAR-Directed and Antibody-Mediated Killing - the t-haNK Platform.*** We have genetically engineered our aNK cells to exhibit all three mechanisms of killing, thereby imparting CAR targeted killing via cancer specific antigens, ADCC based killing as mediated by antibody products, innate killing inherent to natural killer cells, as well as independence from IL-2 supplementation for expansion and viability. Based on this unique arrangement, t-haNK cells can target two distinct cancer antigens at once: one via its CD16 receptor together with an antibody such as rituximab (CD20), and the other through its CAR receptor (i.e. PD-L1), as illustrated below.




In the taNK and t-haNK cell lines, the activation signaling that results from the binding of the CARs to the tumor-specific antigens can be strong enough to overcome both cancer escape mechanisms and suppressive factors present in the tumor microenvironment. 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 and B7-H4;

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

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.

The table below is a partial list of CAR modified aNK products in the literature and their intended tumor types.

**CAR taNKs Have Been Created & Published**

| Target | Indication | Literature |
|---|---|---|
| HER2 | Glioblastoma | J Natl Cancer Inst. 2015 Dec 6;108(5) |
| CD19 | Non-hodgkin Lymphoma | Leukemia. 2019 Nov 26 |
| EGFRVIII | Glioblastoma | Oncoimmunology. 2016. Dec 5(4): p. e1119354 |
| CD123 | Acute Myeloid Leukemia | Haematologica. 2018. Oct;103(10): p. 1720-1729 |
| GD2 | Neuroblastoma | Cancer Immunol Immunother. 2015. May;64(5): p. 621-34 |
| EpCAM | Breast carcinoma | Cancer Immunol Immunother. 2012 Sep;61(9):1451-61 |
| CD138 | Multiple Myeloma | Mol Oncol. 2014 Mar;8(2):297-310 |
| NKG2D | Enhancement of NK cytotoxicity | Cancer Res. 2013 Mar 15;73(6):1777-86 |
| CS1 | Multiple Myeloma | Clin Cancer Res. 2014 Aug 1;20(15):3989-4000 |
| CD20 | Lymphoma and leukemia | Cancer Immunol Immunother. 2008 Mar;57(3):411-23 |

***Non-Clinical Validation of Lenti- and Retroviral Generated taNK Cell Lines; a Compelling Case for Virus-Free t-haNK-Based Therapies.*** We are preparing a novel lineup of virus-free t-haNK product candidates that are cryopreserved, CAR expressing cell lines based on our haNK cell therapeutic, one of which is progressing towards phase II clinical trials. Our rapid advancement of the virus-free t-haNK platform has enabled us to discontinue all use of viral vectors as a means to genetically enhance our platforms. These next-generation products avoid the safety concerns associated with the use of retro- and lentivirus sequences, incorporate the high-affinity CD16 receptor for enhanced antibody-mediated killing, as well as IL-2 for IL-2 growth independence, which can potentially reduce production costs and enhance clinical efficacy.

**Clinical Experience With Our Unmodified aNK Platform as a Cell Therapy Candidate**

Our clinical experience with single and multiple intravenous infusions of aNK monotherapy across a range of relapsed and refractory solid and hematological malignancies has been consistently encouraging from both a safety and activity standpoint. We have demonstrated single-agent safety with dose escalations in both single and repeat dosing schedules to doses as high as 1 x $10^{10}$ cells/$m^2$ and as many as 18 infusions over a six-month period, corresponding to a cumulative dose of as high as 15 x $10^{10}$ cells in an individual patient. Infusion-related toxicities remained generally mild across all studies and dose levels, with the exception of one grade 3 fever and one grade 4 hypoglycemic episode, neither of which resulted in dose reduction or study discontinuation. A minority of subjects that proceeded with additional testing were found to have detectable levels of anti-HLA antibodies, but none were required to withdraw from study and some continued to receive additional infusions without sequelae.

While many cell-based adaptive immunotherapy trials impose heavy pre-screening protocols to cherry-pick likely responders, our subjects were not pre-selected, but rather we accepted all-comers after meeting simple eligibility criteria, including patients who had very advanced disease, having failed multiple rounds of standard chemotherapy, radiation, surgery and even stem cell transplantation. Additionally, none of these patients received lympho-depleting or pre-conditioning regimens in order to enhance therapeutic effects.

Although aNK is not intended as a monotherapy, clinical activity was recorded in all studies conducted to date:

i. Among the three Merkel cell cancer patients receiving aNK cell monotherapy, one subject achieved a radiologic complete response.

ii. Among the four lung cancer patients treated, three subjects had clinically significant responses including one with a resolved supraclavicular lymph node metastasis, the second with a nearly resolved mediastinal lung metastasis and the third with a 23-month disease stabilization with thoracic pain resolution.

iii. Among 12 patients with advanced melanoma and renal cell carcinoma, one melanoma patient went on to have a mixed response with several lesions resolving, and five renal cell carcinoma patients achieved disease stabilization after having breakthrough progression on their prior therapies.

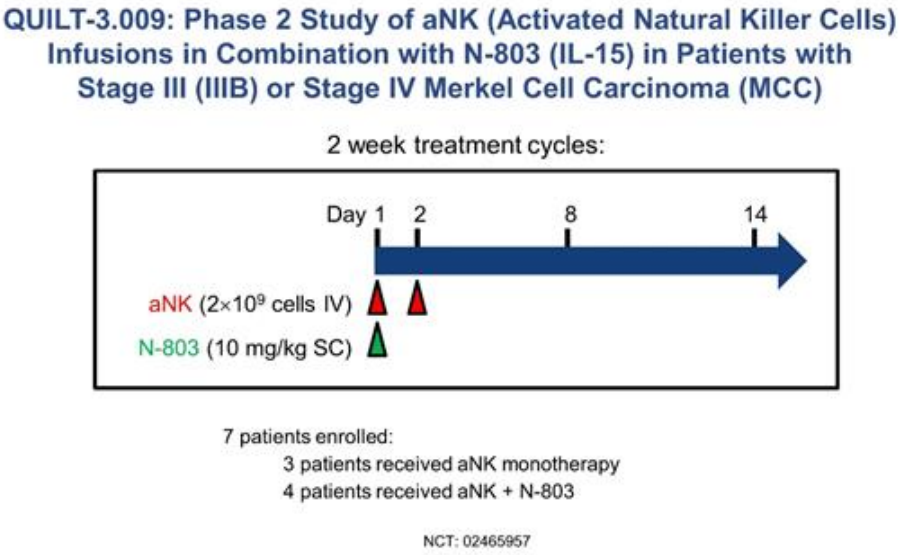
iv. Among 12 subjects with advanced hematological malignancies, two subjects, one with Hodgkin's lymphoma and the other with multiple myeloma, achieved a complete response. A third subject achieved a partial response, another subject achieved a clinical-transient response, and a fifth subject achieved a mixed-transient response.

v. Among six patients with acute myeloid leukemia, one subject achieved a significant reduction in percentage of blasts and two subjects achieved a stable percentage of blasts present in their peripheral blood.

Additional detail on each of these studies follows:

***i. Merkel Cell Carcinoma: QUILT 3.009 (NantKwest Sponsored)***

This completed multi-center, nonrandomized, open-label phase II study was conducted in patients 18 years and older with histologically confirmed stage IIIB or stage IV inoperable Merkel cell carcinoma. The primary endpoint was a four month progression-free survival rate, and the secondary endpoints were overall response rate, time to disease progression, median overall survival, safety, and quality-of-life assessment. The study employed a Simon's two-stage design where upon if at least one patient from the first stage of treatment with aNK monotherapy achieved progression-free survival for 16 weeks or more, the second stage would initiate and proceed to full enrollment. Shortly after the first patient reached the 16 week progression-free survival metric, the protocol was amended such that all second stage patients would receive aNK in combination with N-803. The aNK dose of $2 \times 10^9$ cells/$m^2$ was administered intravenously on two consecutive days every two weeks (one cycle). N-803 was administered subcutaneous at 10 µg/kg on the first day of every aNK infusion (prior to aNK infusion) every two weeks. Patients were withdrawn from the trial if there was evidence of disease progression at any time after the fourth cycle.



A total of three subjects received treatment with aNK monotherapy and a total of four subjects were treated with aNK plus N-803, all having previously received and failed treatment with multiple lines of therapy that included checkpoint inhibitors. There were no serious adverse events of grade 3 or higher that were considered to be related to treatment with the study drugs. All adverse events that may have been related to study drug administration were grade 2 or milder and included chest tightness, chills, fatigue, upper respiratory infection, strep throat, redness at the injection site, hypokalemia, hypotension, anorexia, mucosal infection, and hyponatremia.

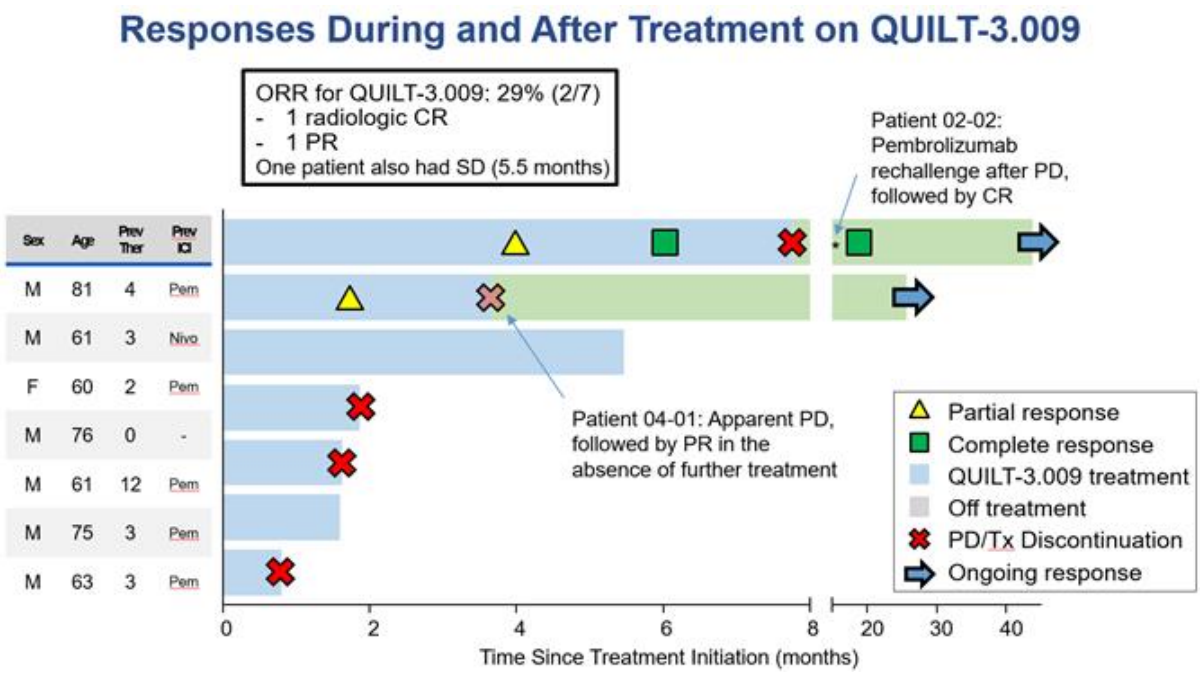
## QUILT-3.009 Safety: No Treatment-Related Grade ≥3 AE/SAEs

### AEs by System Organ Class Occurring in > 1 Subject

| | aNK (n=3) | | aNK + N-803 (n=4) | | All Subjects (n=7) | |
|---|---|---|---|---|---|---|
| Grade | Grade 0-2 | Grade ≥ 3 | Grade 0-2 | Grade ≥ 3 | Grade 0-2 | Grade ≥ 3 |
| Subjects With at Least 1 Treatment-Related AE | 2 (67%) | 0 | 4 (100%) | 0 | 6 (86%) | 0 |
| General Disorders | 2 (67%) | 0 | 4 (100%) | 0 | 6 (86%) | 0 |
| Chest discomfort | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Chills | 2 (67%) | 0 | 3 (75%) | 0 | 5 (71%) | 0 |
| Fatigue | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Flushing | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Injection site erythema | 0 | 0 | 3 (75%) | 0 | 3 (43%) | 0 |
| Injection site irritation | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Injection site rash | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Injection site reaction | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Night sweats | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Pyrexia | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Infections | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Oral candidiasis | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Pharyngitis streptococcal | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Upper respiratory tract infection | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Investigations | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Lymphocyte count | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Platelet count decreased | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Weight decreased | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Metabolism and Nutrition Disorders | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Decreased appetite | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Hypokalemia | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Hyponatremia | 0 | 0 | 1 (25%) | 0 | 1 (14%) | 0 |
| Vascular disorders | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |
| Hypotension | 0 | 0 | 2 (50%) | 0 | 2 (29%) | 0 |

As reported at the November 2019 Society for Immunotherapy Conference and subsequently updated, of the seven subjects enrolled, three having received aNK monotherapy and four having received aNK plus N-803, three experienced a clinical benefit. The objective response rate was 29%, with two of seven patients experiencing a complete response or partial response:

- One heavily pretreated patient that progressed on pembrolizumab, received aNK monotherapy and achieved and maintained a radiologic complete response until progressive disease was confirmed by biopsy at eight months. Re-challenge with pembrolizumab after aNK therapy resulted in an ongoing durable complete response at 44 months.
- A second patient receiving aNK plus N-803 experienced pseudo-progression at three and a half months after initially responding and was taken off therapy with no subsequent intervention. This patient subsequently went on to experience a durable partial response with more than 86% tumor regression that is still ongoing at 29 months.
- A third patient experienced an ongoing stable disease, now beyond five and a half months.
- Intriguing changes were noted clinically in superficial tumors in several patients within hours of aNK infusion.
- Three of the remaining four patients showed progressive disease at the first imaging assessment. The final patient was discontinued from treatment due to clinical disease progression prior to the first imaging assessment.




Results from this study show that treatment with aNK and N-803 is well-tolerated, as no treatment-related serious adverse events were associated with aNK monotherapy or with aNK plus N-803 combination therapy. Treatment with both aNK monotherapy and aNK plus N-803 combination therapy were associated with anticancer activity as evidenced by increased antigen presentation, IFN-γ and other immune response gene expression, as well as CD8+ and CD4+ immune cell infiltration in the tumor microenvironment in addition to measurable tumor responses. Moreover, evidence that aNK cell treatment may reverse refractoriness to immune checkpoint inhibitors was observed with a patient that previously progressed while on pembrolizumab, only later to experience a durable complete response to pembrolizumab re-challenge after completing aNK cell therapy. These results suggest treatment with aNK and N-803 at doses sufficient to elicit tumor regression is associated with manageable and relatively modest adverse events and provides a foundation upon which to investigate the use of our "off-the-shelf" haNK product in QUILT 3.067, a phase II trial investigating a chemotherapy-free combination of haNK, N-803 and the checkpoint inhibitor avelumab.

***ii. Advanced Solid Tumors (Investigator Sponsored)[1]***

This phase I, single-arm, open-label, dose-escalation study conducted at the University Hospital in Frankfurt, evaluated the safety and efficacy of aNK cell monotherapy in 15 pediatric and adult patients with advanced cancer resistant to standard therapies. The objectives of the study were to evaluate safety and clinical outcomes. The three aNK dose levels were $1 \times 10^9$ cells/m$^2$, $3 \times 10^9$ cells/m$^2$, and $1 \times 10^{10}$ cells/m$^2$ ($1 \times 10^{10}$ cells/m$^2$ was administered in adults only). Two infusions of aNK were administered intravenously on days one and three.

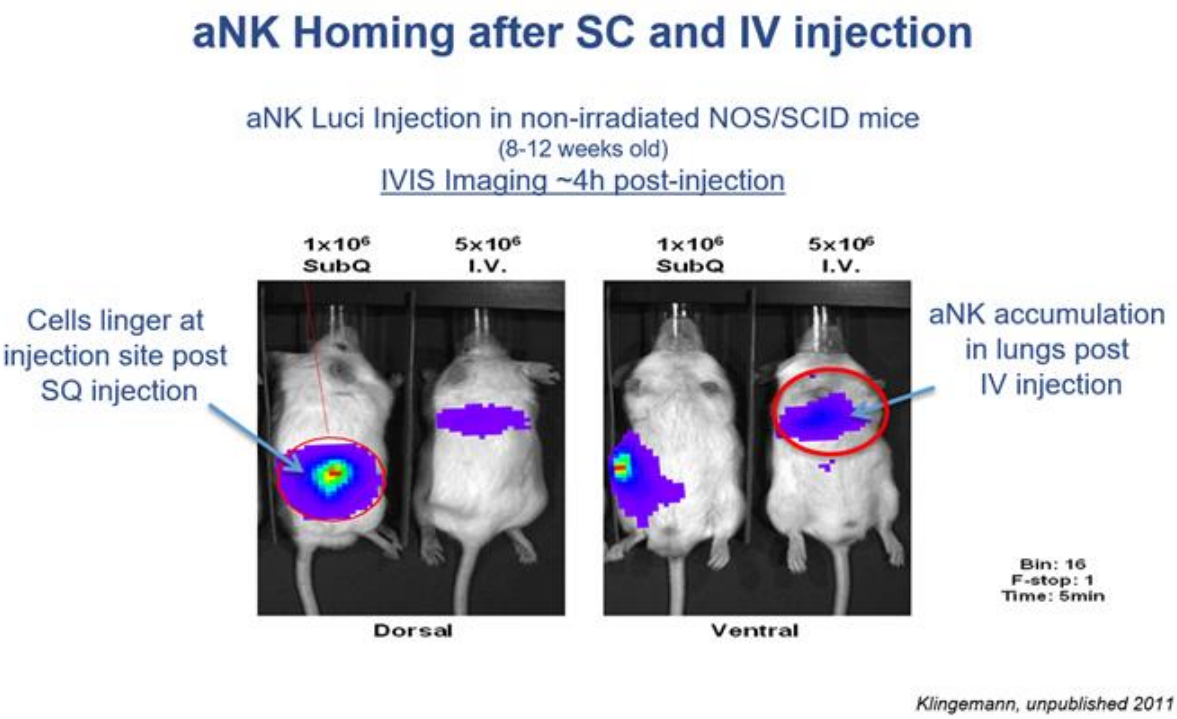
All infusions were well tolerated by all patients, even at the highest dose level, with the exception of one patient whose second transfusion was discontinued after he reported lower back pain. No effect on bone marrow function was observed in any patient as stable blood cell counts observed were over the first four weeks after aNK treatment. Likewise, no changes in renal and hepatic functions were noted. One of seven tested patients had an antibody response to HLA antigens expressed by aNK at the time of testing, one- and four-weeks after aNK infusions; this patient had received blood transfusions after aNK infusion with potential transmission of antibodies.

1 Tonn et al, Cytotherapy. 2013 Dec;15(12):1563-70

Three patients with advanced lung cancer had clinically significant responses after two doses of aNK:

- One patient had a diagnosis of non-small cell lung cancer with multiple lung metastases resistant to conventional chemotherapy, radiation and surgery. After treatment with two infusions of $1 \times 10^{10}$ cells/m$^2$, the patient experienced stable disease. Four months after receiving two initial infusions, the patient received four additional infusions of aNK cells ($5 \times 10^9$ to $1 \times 10^{10}$ cells/m$^2$) over a period of six months, with no adverse events from either the initial or subsequent treatments. The patient had an overall survival of 23 months after receiving the initial two infusions of aNK.
- One patient had a diagnosis of small cell lung cancer with a supraclavicular lymph node metastasis, also resistant to conventional chemotherapy, radiation and surgery. After treatment with two infusions of $3 \times 10^9$ cells/m$^2$, the patient's lymph node metastasis could no longer be detected. This patient experienced a mixed response and went on to have an overall survival of nearly 18 months.
- Another patient had a diagnosis of small cell lung cancer with multiple metastases in the liver and a one inch single metastasis in the lung just behind the sternum. After two infusions of $3 \times 10^9$ cells/m$^2$, there was significant regression in the lung metastasis as verified by lateral imaging before and 14 days after aNK treatment with no regression of the liver metastases. This patient was recorded as having a mixed response and an overall survival of eight months.

Such beneficial effects of aNK cell therapy in three of four lung cancer patients may not be surprising as we better understand aNK biodistribution upon intravenous administration. After circulating through the right heart and pulmonary vasculature, murine models of aNK trafficking reveal that the cells demarginate and reside in the lungs within the first hours after infusion before circulating systemically to distant organs, including spleen, kidney, bladder and peripherally implanted tumor.[2]




This could potentially make tumors of the lung the most readily accessible among solid tumors to serial infusions of aNK cells and provide a foundation upon which to investigate the use of our "off-the-shelf" PD-L1.t-haNK product in QUILT 59, a late-stage trial investigating a chemotherapy-free combination of PD-L1.t-haNK, N-803 and a checkpoint inhibitor.

2 NantKwest, Klingemann H., et al., data on file

***iii. Advanced Melanoma or Renal Cell Carcinoma (Investigator Sponsored)[3]***

This phase I, open-label, single-arm, single-center, dose-escalation study, conducted at Rush University Medical Center, Chicago, evaluated the feasibility and safety of a single cycle consisting of three infusions of aNK monotherapy administered on days one, three and five in 12 patients 18 years and older with measureable refractory or relapsed advanced renal cell carcinoma and melanoma. The primary endpoints were the feasibility and safety of aNK cells. The four dose levels were $1 \times 10^8$ cells/$m^2$, $3 \times 10^8$ cells/$m^2$, $1 \times 10^9$ cells/$m^2$, and $3 \times 10^9$ cells/$m^2$ administered intravenously.

Three patients developed grade 1 fever and one patient developed grade 3 fever, all possibly related to aNK infusions. One patient with renal cancer, who had extensive liver metastases, developed a transient grade 4 hypoglycemia possibly related to aNK. The patient responded to a 5% dextrose intravenous infusion, and went on to receive two subsequent infusions of aNK uneventfully. Four adverse events were considered not related to aNK and included three exacerbations of tumor pain (grade 2 neck pain, grade 2 chest pain, and grade 3 back pain) and one grade 2 rheumatoid arthritis pain. There were no serious infections reported for patients at the one-year follow-up. Six patients had elevations in lactate dehydrogenase enzymes, and four patients had elevated cytokines, potentially due to tumor lysis reaction.

**Adverse Events in patients receiving NK-92 infusions. Severity of adverse events was graded according the ECOC scale.**

| Subject | Diagnosis | Cell dose/$m^2$x3 doses | Adverse Event w/grade (possibly related) |
|---|---|---|---|
| 1 | RCC | $1x10^8$ | 0 |
| 2 | RCC | $1x10^8$ | 0 |
| 3 | RCC | $1x10^8$ | 0 |
| 4 | RCC | $3x10^8$ | 0 |
| 5 | RCC | $3x10^8$ | 0 |
| 6 | RCC | $3x10^8$ | 0 |
| 7 | RCC | $1x10^9$ | 0 |
| 8 | RCC | $1x10^9$ | 1-fever |
| 9 | RCC | $1x10^9$ | 1-fever |
| 10 | Melanoma | $3x10^9$ | 3-fever |
| 11 | RCC | $3x10^9$ | 4-hypoglycemia |
| 12 | RCC | $3x10^9$ | 1-fever |

RCC=renal cell cancer

Six of the 12 patients, or 50%, experienced a clinical benefit in this single-course dose escalation study in a dose-dependent fashion with:

- Zero of three experiencing a clinical benefit in the lowest dose cohort,
- One of three at the second dose cohort,
- Two of three at the third dose cohort, and finally
- Three of three at the highest dose cohort.

Two patients had a mixed response, four patients had stable disease, and six patients had progressive disease, all assessed four weeks post-infusion. Of note, the one patient with renal cell carcinoma that had a mixed response was observed to have a significant reduction in lung masses, but progressed in the mediastinum. Also, the one patient with advanced melanoma that had a mixed response had a striking reduction in a target lesion in the upper neck on CT imaging noted at two weeks post-infusion. Overall survival in the patients achieving stable disease ranged from seven to 35 months. These encouraging results became the basis to further investigate repeat course therapy at a recommended phase II dose.

3 Arai et al, Cytotherapy. 2008;10(6):625-32

***iv. Hematologic Malignancies (Investigator Sponsored)[4]***

This phase I, open-label, single-arm, single-center, dose-escalation study conducted at the Princess Margaret Hospital in Toronto, evaluated the safety of aNK monotherapy in patients 18 years and older with histologically confirmed, refractory hematologic malignancies who relapsed after autologous hematopoietic cell transplantation. The primary endpoint was safety and the secondary endpoints were efficacy, immune responses to aNK, and kinetics of infused aNK. The three aNK dose levels were $1 \times 10^9$ cells/$m^2$, $3 \times 10^9$ cells/$m^2$, and $5 \times 10^9$ cells/$m^2$ administered intravenously on days one, three, and five of each cycle of treatment. Patients could receive up to six monthly cycles, for a total of 18 infusions.

A total of 12 patients were enrolled in the study and included Hodgkin's, mantle cell and diffuse large B-cell lymphoma, chronic lymphocytic leukemia with Richter's transformation and multiple myeloma. Some patients experienced grade 1 fever, chills, fatigue, blurry vision, and nausea. There was a single grade 2 adverse event of fever and chills that occurred during an aNK infusion. No grade 3 or 4 adverse events were observed. There were no clinically significant alterations in hemoglobin, platelets, white cell counts, creatinine, or liver function tests. Six patients developed either class I or II anti-HLA antibodies, typically after the second cycle of aNK, however, this did not interfere with repeat dosing, with most receiving 15 or more infusions without incident. Cytokine release was not observed in any of the patients, although there was a transient rise in IL-10 and IL-6 in two patients.

Five of 12 patients had responses to aNK cell therapy: two durable complete responses, one partial response, one clinical-transient response, and one mixed-transient response.

- One complete response was observed in a patient with relapsed, refractory Hodgkin's lymphoma, which was maintained for more than ten years with no subsequent therapy.
- The second complete response was observed in a patient with IgA kappa myeloma who received concomitant lenalidomide-dexamethasone therapy during and after aNK cell infusions, and this patient remains on maintenance therapy with an ongoing complete response two years after aNK cell therapy.
- An additional three patients experienced partial or transient responses. One patient diagnosed with Hodgkin's lymphoma had a partial response after one cycle of aNK cell infusion. This patient elected to undergo allotransplantation and subsequently died of allotransplant-related complications.
- A patient diagnosed with chronic lymphocytic leukemia showed clinical improvement and subsequently progressed after completing six monthly cycles of aNK infusion.
- A patient with diffuse large B-cell lymphoma, or DLBCL, also showed a transient clinical improvement that was followed by progressive disease.

4 Williams et al, Oncotarget. 2017 Jul 12;8(51):89256-89268

## NK-92 Dosing and Clinical Outcomes

| Patient # | Dose Level | Number of Cycles | Number of Cells Administered (Total x10^9) | Response | Diagnosis |
|---|---|---|---|---|---|
| 1 | 1 | 1 | 6 | MR | HL |
| 2 | 1 | 3 | 15.93 | PD | MCL |
| 3 | 1 | 5 | 30 | CR* | HL |
| 4 | 2 | 1 | 14.49 | PD | DLBCL |
| 5 | 2 | 3 | 51.84 | CI** | DLBCL |
| 6 | 2 | 6 | 109 | MR | CLL-Richter's to DLBCL |
| 7 | 3 | 5 | 150 | PD | DLBCL |
| 8 | 3 | 1 | 27.42 | PD | MM |
| 9 | 3 | 3 | 77.68 | PD | MM |
| 10 | 1 | 6 | 24.67 | PD | MM |
| 11 | 1 | 6 | 25.11 | CR*** | MM |
| 12 | 1 | 5 | 23 | PD | MM |

*Patient 03 had increase in lymphadenopathy/splenomegaly interpreted as progression, with subsequent resolution to CR X 10 years after NK-92 therapy.
**Patient 05 had clinical improvement after 2 cycles of NK-92.
**Patient 11 achieved complete response after NK-92 therapy and also received concomitant Lenalidomide-Dexamethasone therapy during and after the infusions.
Abbreviations: PD: progressive disease; CR: Complete Response, MR: Minor Response, CI: Clinical Improvement in symptoms.

Results from this trial demonstrated that it was feasible to safely administer to patients serial dosing of aNK in excess of 7 x $10^{10}$ cells across 18 infusions administered over a six month timeframe. Interestingly, both of the complete responses occurred in the lowest dose cohort, though these patients received 15 or more doses of aNK, indicating that dose-exposure over time could potentially overcome shortcomings a smaller individual dose may have. These observations helped to lay the foundation for subsequent phase Ib/IIa trials with modified aNK cells in combination with an immuno-conditioning regimen that includes N-803 and a checkpoint inhibitor, with repeat NK cell dosing out to 12 months or for as long as the patient is responding to treatment.

***Acute Myeloid Leukemia: QUILT 3.018 (NantKwest Sponsored)[5]***

This phase I, open-label, single-arm, dose-escalation/de-escalation study evaluated the safety in patients 18 years and older with refractory or relapsed acute myeloid leukemia, or AML. The primary endpoints were the maximum tolerated dose and safety of aNK monotherapy and the secondary endpoints were therapeutic efficacy and aNK cell phenotype, cytotoxic activity, presence in bone marrow, and effects on patient immune systems. Two dose levels of aNK were used: $1 \times 10^9$ cells/$m^2$ and $3 \times 10^9$ cells/$m^2$. One course of aNK treatment comprised a total of two intravenous infusions of the same cell dose with each intravenous infusion administered 24 hours apart (i.e., days one and two). Patients underwent bone marrow biopsy 21 days after each course of therapy. Patients who had stable disease or a reduction of leukemia blasts after the initial course were eligible to receive additional aNK infusions.

Seven patients were enrolled in the study with three having received the lower dose level and the remaining patients received the higher dose level of aNK cells. None of the seven patients experienced a dose-limiting toxicity during administration of the aNK cell infusions or during the 21-day observation period post-infusion. There were no grade 3 or grade 4 toxicities related to aNK cell infusions. One patient developed grade 2 fever and chills following each aNK infusion that resulted in inpatient observation. These known aNK-related effects were reversible with supportive care.

Of the six patients that were evaluable for response 21 days after therapy, three experienced clinical benefit. One patient had a reduction of the percentage of blasts from 70% to 48% and went on to receive a second course. The other two patients achieved disease stabilization, one of which went on to receive two additional courses. This trial demonstrates early evidence of single agent activity and safety in heavily pretreated relapsed or refractory AML patients and serves as a basis to study modified aNK cell therapy in combination with an immuno-conditioning regimen that includes N-803 and a checkpoint inhibitor, with repeat NK cell dosing for as long as a clinical response is maintained.

5 Boyiadzis et al, Cytotherapy. 2017 Oct;19(10):1225-1232

**Our Clinical Pipeline**

**haNK Product Candidate**

***Overview***

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

i. A natural, high-affinity antibody engager, FcγRIIIa/CD16 receptor, which binds to therapeutically administered cancer-targeting antibodies, resulting 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.

Our internal research efforts have demonstrated that these high affinity CD16 receptors on our haNK cells are cleaved during ADCC-mediated killing of target cancer cells, thereby enabling them to engage in serial killing of multiple cancer targets, rather than remaining bound to the first target cell it encounters, a key drawback of non-cleavable CD16 receptors. Additionally, internal research efforts have demonstrated that high affinity CD16 receptor expression rebounds and recovers more rapidly in haNK cells after attacking its target when compared to other types of natural killer cells. This unique feature distinguishes our haNK cell product as exceptionally well suited for serial killing.

Our haNK cell product retains all the innate killing receptors present on aNK, such as NKG2D and NKp44, and therefore preserves the innate ability to detect and bind a diverse range of ligands unique to cancers through this diverse array of receptors, thereby making it a highly versatile killer product suitable for clinical testing. In preclinical studies, the combination of haNK cells with a number of different therapeutic antibody products resulted in significantly enhanced tumor cell killing when compared to the use of the antibody as a single agent, or the antibody in combination with low affinity expressing CD16 receptors, thereby providing strong scientific support for our therapeutic approach of combining haNK plus N-803 together with a commercially available therapeutic antibody.

A growing body of published and internal research on our haNK cells consistently support its continued study as a therapeutic product for the treatment of cancers. Select highlights from this research include:

i. Utilization of haNK over a low-affinity natural killer cell allows for a one-third lower concentration of herceptin to achieve half of its maximal effect.

ii. haNK demonstrates impressive CD16 receptor expression stability after innate pathway activation and degranulation when compared to that of healthy donor natural killer cells.

iii. haNK also demonstrates CD16 receptor expression stability after chemically induced activation and degranulation whereas healthy donor natural killer cells undergo CD16 depletion and potential exhaustion.

iv. haNK cells also demonstrate rapid and full recovery of CD16 expression after ADCC activation, which may be promoted by its endogenous IL-2 production.

v. Irradiated haNK cells have a higher innate killing frequency than healthy donor natural killer cells.

vi. Irradiated haNK cells are efficient killers of a wide range of cancer types through their innate killing mechanism without reliance on their ADCC killing mechanisms.

vii. Hypoxemic conditions of the tumor microenvironment that abolishes the killing ability of healthy donor natural killer cells can be overcome by haNK cells.

viii. Addition of commercial antibody products to haNK cells adds an ADCC mechanism for killing tumors that would otherwise be resistant to innate killing, and does so in a dose dependent manner.

ix. Synergy was demonstrated when combining two antibody products together with haNK cells.

x. haNK enhances the killing capacity of the PD-L1 checkpoint inhibitor, avelumab.

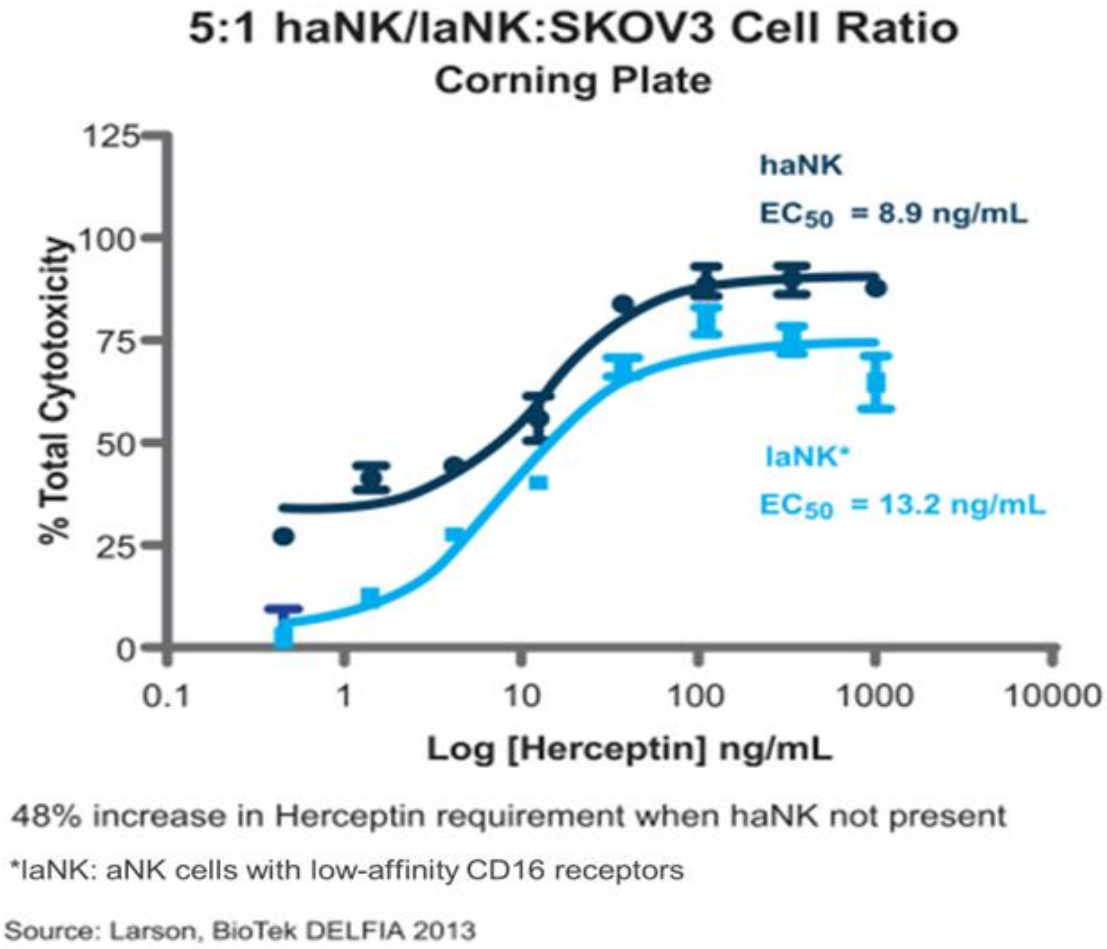
xi. haNK and avelumab in combination exhibits potent killing across a variety of cancer types.

xii. A compelling rationale for developing our haNK product in combination with approved and late-stage antibody products that utilize the ADCC killing pathway resides in the fact that only a small subgroup of antibody recipients can benefit from the full potential of antibody products due to CD16 gene variations and natural killer cell dysfunction which haNK therapy could potentially abrogate.

These findings are further detailed in the ensuing sections.

***haNK as the Current 'Gold-Standard' in Non-Clinical Characterization of Commercial Antibody Products.*** Our haNK cells have been widely utilized by numerous biopharmaceutical companies, including many well-known large-pharma companies, under non-exclusive licenses for *in vitro* ADCC testing of their antibodies in development, as well as to release-test their commercially available antibody products. For example, our haNK cells have been adapted for use in commercial assays such as BioTek's automated Delfia ADCC assay system and Agilent's xCELLigence system.

***Utilization of haNK Over a Low-Affinity Natural Killer Cell Allows for a One-Third Lower Concentration of Herceptin to Achieve Half of its Maximal Effect.*** In the Delfia ADCC assay system it was determined that the concentration of herceptin which achieves the half-maximum response (EC50) is 48% higher for the low-affinity natural killer cells than for haNK, thereby demonstrating how haNK potentiates herceptin in achieving its peak killing capacity.



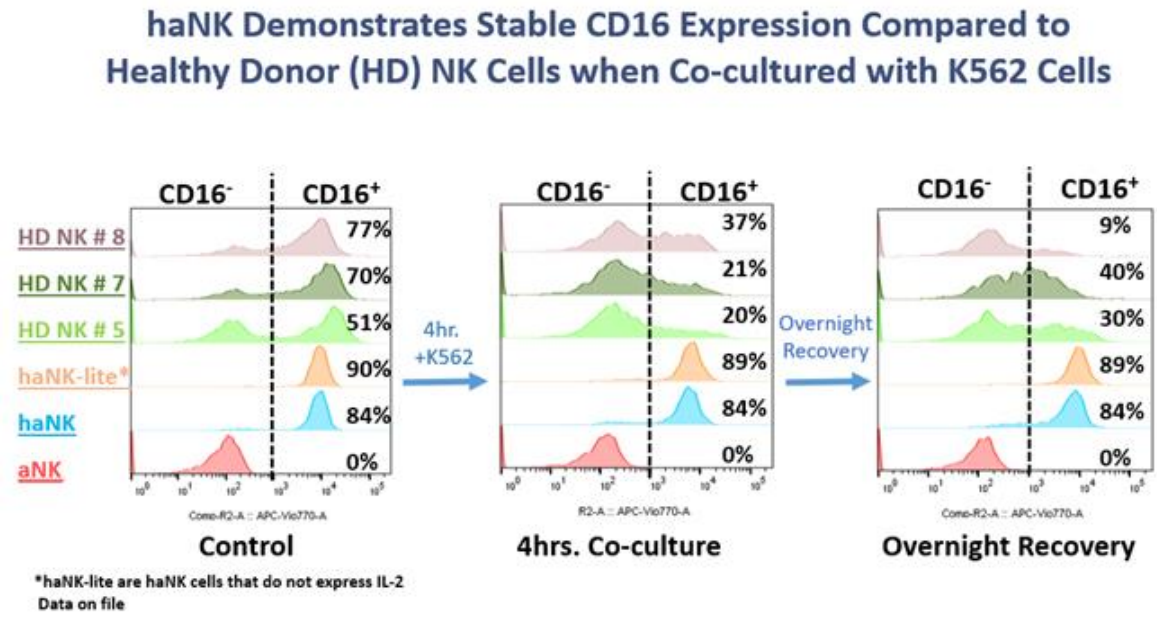

48% increase in Herceptin requirement when haNK not present

*laNK: aNK cells with low-affinity CD16 receptors

Source: Larson, BioTek DELFIA 2013

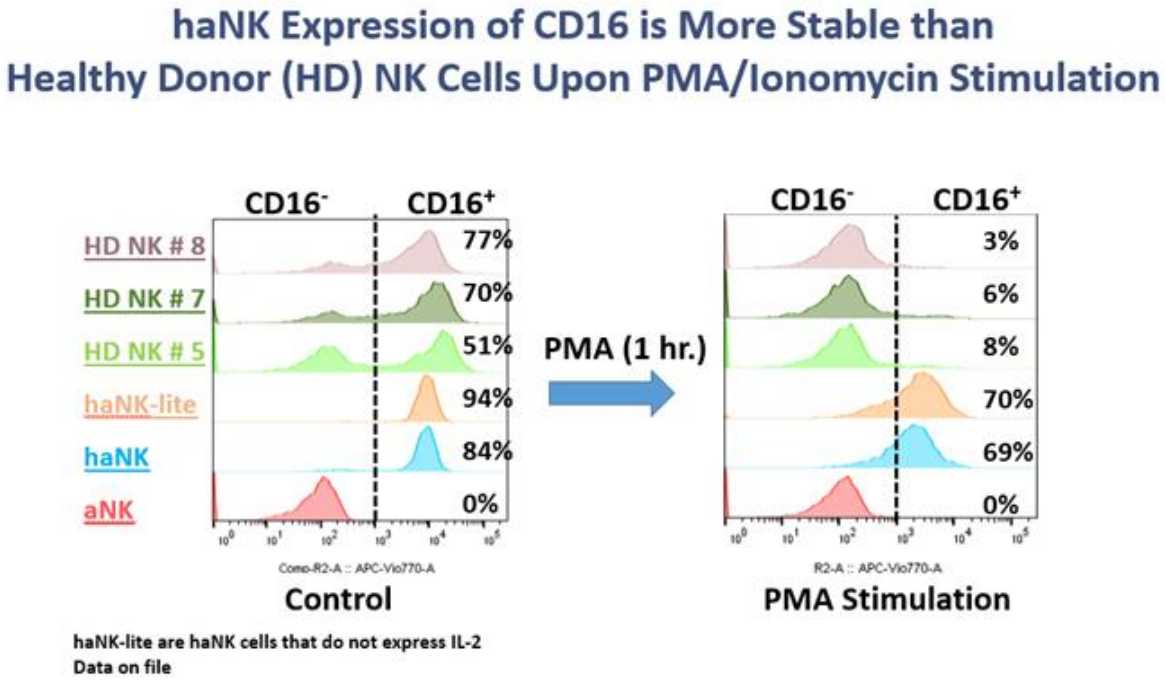
***Natural Killer Cell Numbers, Function and CD16 Expression Levels Are Deficient Among Cancer Patients and Correspond with Clinical Outcomes.*** Immunologic surveillance studies in human subjects have revealed a series of related trends in natural killer cell numbers, function and their CD16 receptor expression levels in cancer patients that undergo antibody-based treatment regimens. One observation is that event free survival in diffuse large B-cell lymphoma, or DLBCL, patients corresponded directly with natural killer cell counts at diagnosis, whereas CD4+, CD8+ and B-cell counts did not.[6] Also, when comparing natural killer cells from DLBCL patients with that of healthy donors, fewer natural killer cells from DLBCL patients express CD16 and of those that do, express CD16 at far lower levels and that these cells demonstrate significantly reduced ADCC-mediated degranulation.[7] Another noteworthy observation was seen in DLBCL patients receiving antibody-based treatment regimens where during and within a month of completing therapy, there was a marked depletion of CD16+ natural killer cells and that these cells exhibited markedly diminished ADCC activity.[8] The same diminished ADCC activity was noted in natural killer cells from ovarian[9] and esophageal[10] cancer patients, when compared to that of healthy donor natural killer cells. It is therefore reasonable to conclude that efforts to address the diminished and exhausted population of natural killer cells in the setting of cancer could have broad therapeutic value and is the underlying driver to forge ahead with clinical research on haNK replacement therapy, particularly in combination with the natural killer cell induction agent, N-803, targeted antibody products and checkpoint inhibitors.

***haNK Demonstrates Superior CD16 Receptor Stability After Innate Pathway Activation and Degranulation When Compared to That of Healthy Donor Natural Killer Cells.*** Four hours after co-culture with the feeder cell line, K562, which serves to activate the innate pathway of killing, CD16 expression on natural killer cells from healthy donors dropped precipitously and only partially recovered after resting overnight whereas that of haNK was maintained at peak levels throughout the study duration.

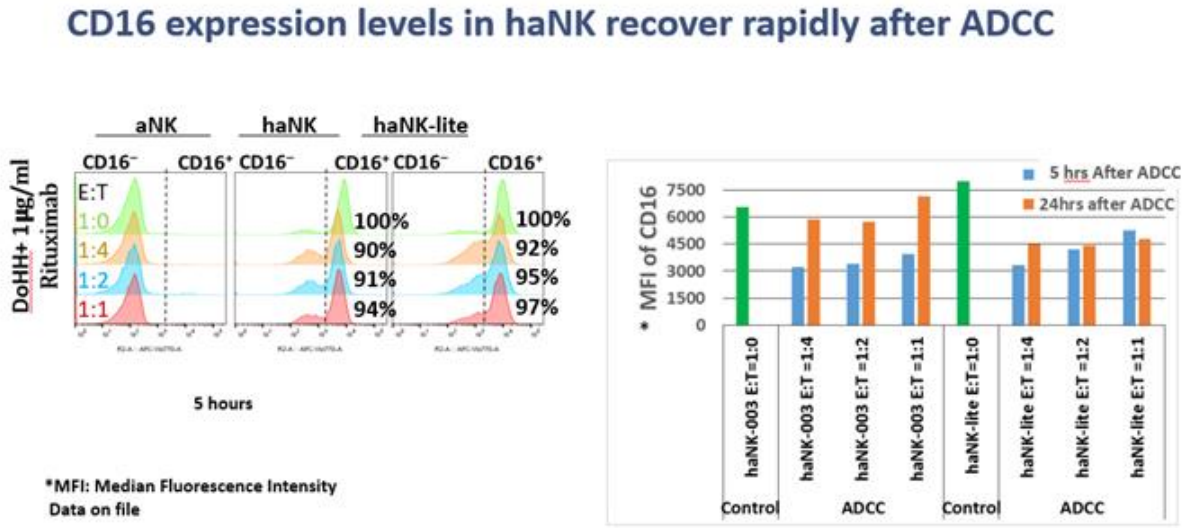



***haNK Demonstrates CD16 Receptor Expression Stability After Chemically Induced Activation and Degranulation Whereas Healthy Donor Natural Killer Cells Undergo CD16 Depletion and Potential Exhaustion.*** Using flow cytometric analysis of CD16 expression after employing a more robust chemical induction model of degranulation, natural killer cells from healthy donors were observed to have a 94% drop in CD16 expression compared to 18% in haNK. Of note, CD16 expression levels in haNK only dropped to average pre-activation levels in healthy donor natural killer cells.

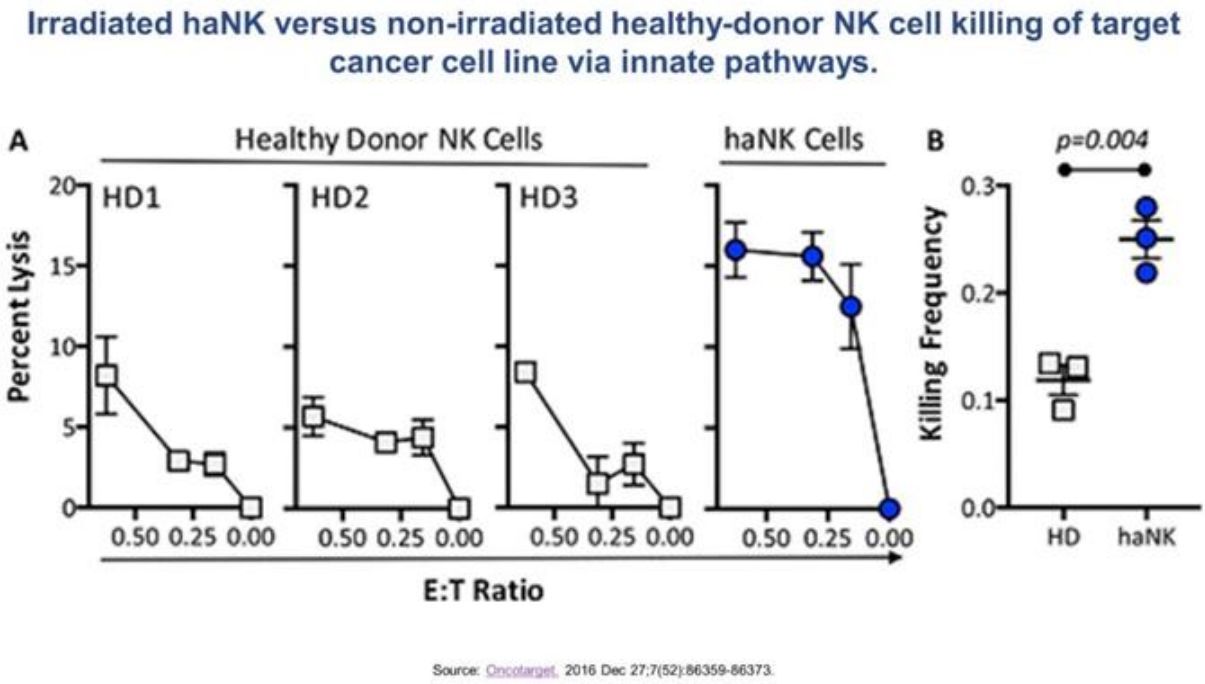
6 Plonquet et al, Ann Oncol. 2007 Jul;18(7):1209-15
7 Danielou-Lazareth et al, Eur J Immunol. 2013 May;43(5):1383-8
8 Cox et al, Oncoimmunology. 2015 Jan 7;4(3):e990773
9 Carlsten et al, J Immunol. 2009 Oct 15;183(8):4921-30
10 Watanabe et al, Dis Esophagus. 2010 Nov;23(8):675-81




***haNK Demonstrates Rapid and Full Recovery of CD16 Expression by 24 Hours Post-ADCC Activation.*** The bottom figure on the left shows the percent CD16 expression five hours after ADCC activation in haNK cells using rituximab and deoxyhypusine hydroxylase, or DoHH, cells. We observed that there is only a modest drop in expression at this time point and that it appears to correspond proportionately with the target burden. haNK CD16 levels dropped slightly more than in the IL-2 dependent haNK-lite cells, possibly due to the greater degree of target killing. The bottom figure on the right shows the shift in CD16 median fluorescence intensity of expression in haNK versus IL-2 dependent haNK-lite cells from five to 24 hours after ADCC activation. We observed that haNK recovery at 24 hours is nearly complete, whereas haNK-lite recovery requires more time, possibly due to its lack of endogenous IL-2 production, possessed by haNK cells. Collectively, these findings indicate that our selected haNK clone is a promising candidate to advance into clinical testing.



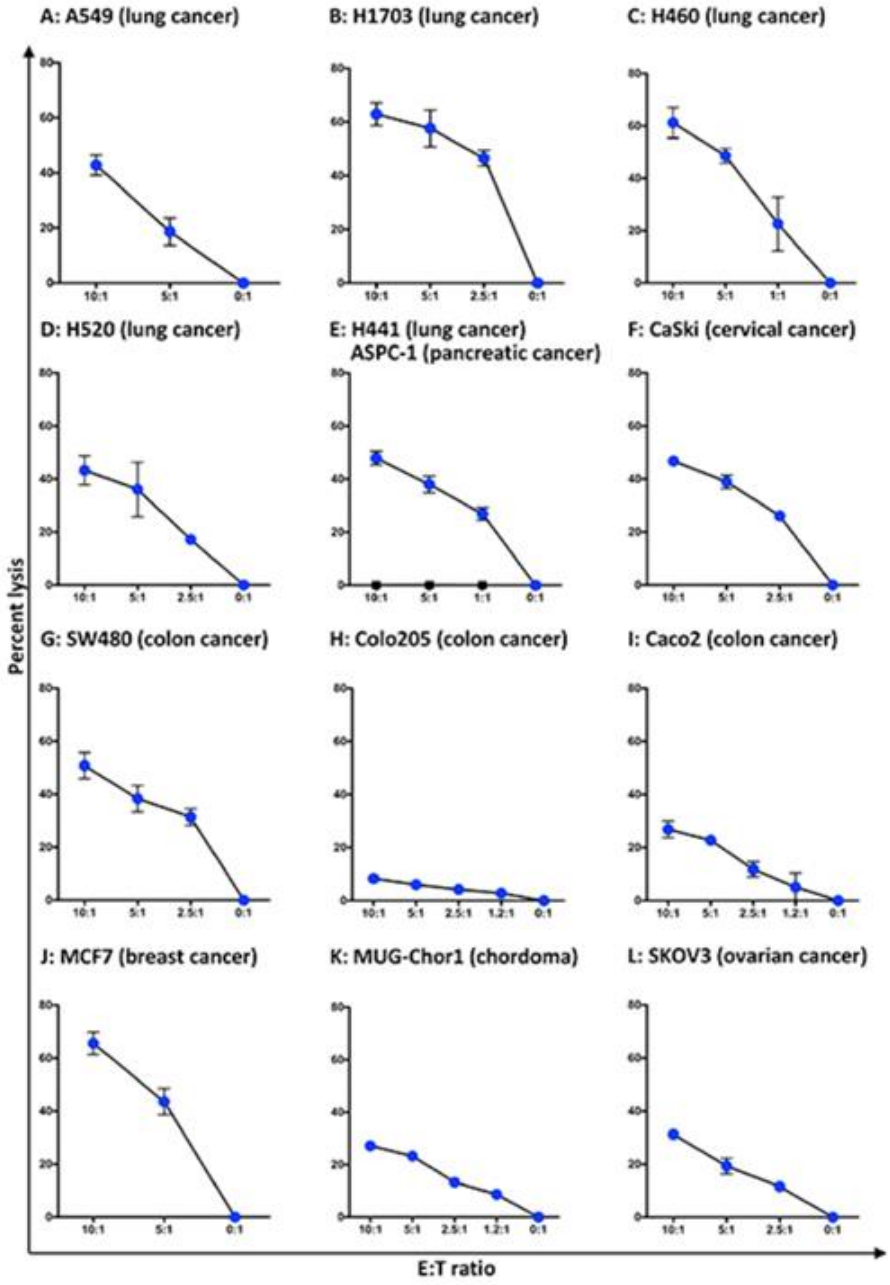
***Irradiated haNK Cells Have a Higher Innate Killing Frequency than Healthy Donor Natural Killer Cells.*** The following graph compares innate killing of target breast cancer cells by healthy donor natural killer cells versus irradiated haNK cells. Irradiated haNK cells have a three-fold higher killing frequency (on a per cell basis) than the average killing frequency of healthy donor natural killer cells, thereby demonstrating substantially greater levels of lysis from irradiated haNK cells across a range of effector-to-target cell ratios. Quantitative analysis of the killing frequency demonstrated that, on average, it took three healthy donor natural killer cells to kill the same amount of tumor target as one irradiated haNK cell, thereby implying serial killing activity.




Source: Oncotarget. 2016 Dec 27;7(52):86359-86373.

***Irradiated haNK Cells are Efficient Killers of a Wide Range of Cancer Types Through Their Innate Killing Mechanism Without Reliance on Their ADCC Killing Mechanisms.*** In the graphs that follow, irradiated haNK cells exhibit an ability to efficiently kill 13 human tumor cell lines via innate mechanisms such as NKG2D-NKG2DL receptors, without the addition of antibodies. This was demonstrated in innate killing assays against lung, colon, breast, cervical, ovarian, pancreatic and chordoma cancer lines. With the exception of ASPC-1, target killing was consistently observed in an effector-to-target, or E:T, dependent manner.

# Irradiated haNK cells efficiently kill lung, colon, breast and other cancer cell lines without the addition of antibodies via innate pathways.




Source: Oncotarget. 2016 Dec 27;7(52):86359-86373.

***Hypoxemic Conditions of the Tumor Microenvironment That Abolishes the Killing Ability of Healthy Donor Natural Killer Cells Can Potentially be Overcome by haNK Cells.***[11] Current research on healthy donor natural killer cell function in the hypoxemic tumor microenvironment supports our understanding of the various mechanisms involved in natural killer cell dysfunction:

i. Exposure to hypoxemia decreases surface expression of NKG2D, the primary receptor needed for innate killing;

ii. Exposure to hypoxemia decreases surface expression of CD16 receptors, necessary for ADCC-mediated killing;

iii. Intracellular perforin and granzyme B levels are also diminished when exposed to hypoxemic conditions, as well as the total percentage of degranulating natural killer cells in a given population; and

iv. Natural killer cell activation by IL-2 can restore NKG2D levels and restore cytotoxicity against a number of hypoxemic cancer cell types.

By contrast, haNK cells possess several inherent features that impart *in-vivo* advantages over healthy donor natural killer cells including:

i. haNK produces its own supply of intracellular IL-2 thereby maintaining itself in a perpetual state of activation;

ii. haNK cells are naturally larger in diameter and therefore volume when compared with donor natural killer cells and within that larger volume, pack a greater density of perforin and granzyme containing granules; and

iii. haNK cells start off with a high density of surface CD16 and NKG2D receptors and since it can be frequently re-dosed with relative ease at a cell number per dose that is equivalent to an average person's total natural killer cell population, it is feasible to maintain the equivalent of a fully active population of natural killer cells for extended periods to supplement the recipient's dysfunctional and exhausted resident population of natural killer cells.

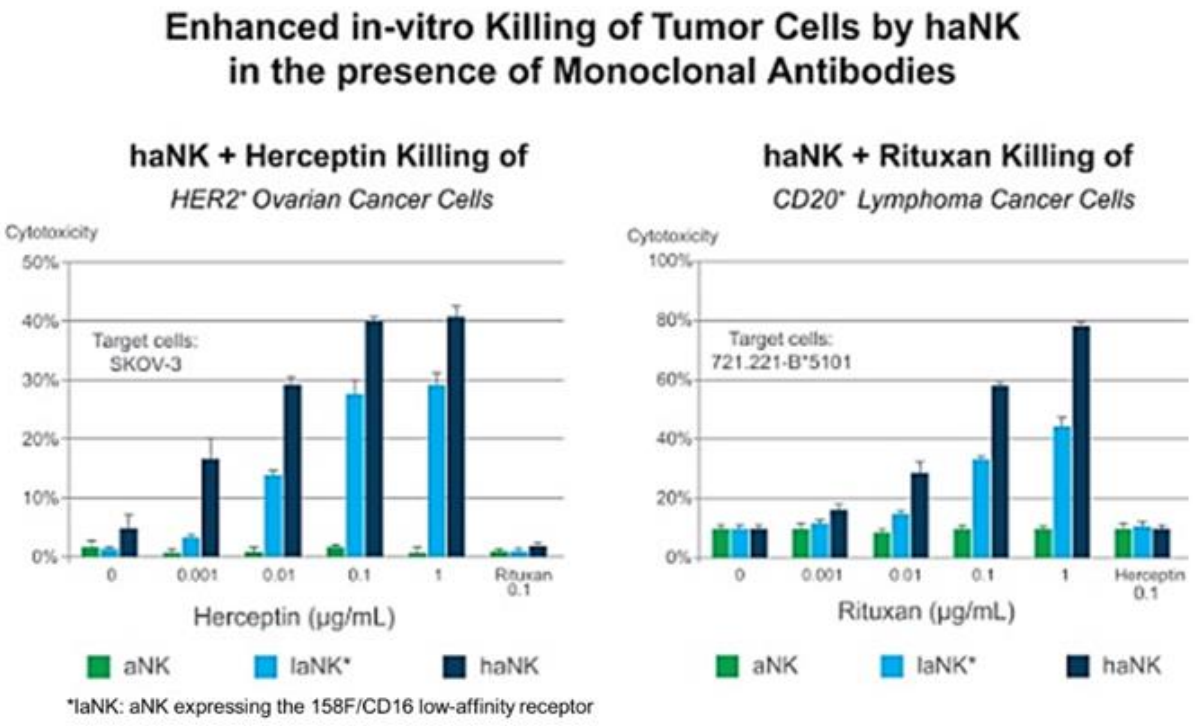
New research conducted internally and by collaborators confirming that irradiated and cryopreserved haNK cells maintain optimal performance under hypoxemic conditions, is expected to publish in the near term.

***Addition of Commercial Antibody Products to haNK Cells Adds an ADCC Mechanism for Killing Tumors that would Otherwise Be Resistant to Innate Killing, and Does so in a Dose-Dependent Manner.*** The graphs that follow depict the increasing ADCC killing activity of haNK cells in the presence of increasing concentrations of either herceptin or rituxan observed in *in vitro* studies. The comparative killing activity of aNK alone, low-affinity CD16 receptor expressing aNK cells, or laNK, cells, and haNK with a non-relevant antibody as a negative control, are included for direct comparison purposes.

In the first graph below, aNK, laNK, and haNK cells were tested separately in killing assays against SKOV-3 ovarian cancer cells in the presence of logarithmically increasing concentrations of herceptin. The assay was performed by loading the tumor cells with radioactive chromium-51 and measuring the release by cytotoxicity in a four-hour assay. haNK cells responded to a lower dose of herceptin (0.001 ug/mL) and exhibited stronger maximal killing response as compared to cells expressing the low affinity 158F variant. Parental aNK cells, which lack CD16 expression, and haNK cells in combination with non-relevant antibody did not exhibit any ADCC response toward the SKOV-3 cells.

11 Sarkar et al, PLoS One. 2013 May 28;8(5):e64835

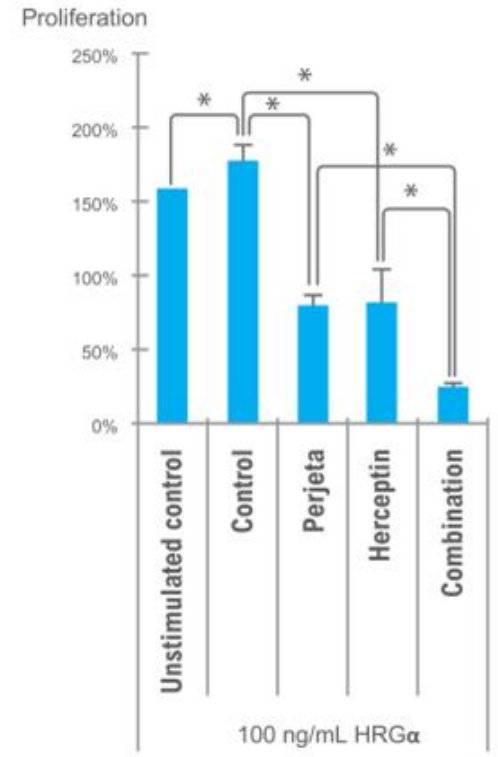
In the second graph below, haNK cells responded to a lower dose of rituxan (0.001 ug/mL) and exhibited stronger maximal killing response, as compared to laNK cells. Parental aNK cells, lacking CD16 expression, did not exhibit any ADCC response toward the 721.221 B-cell lymphoma cells and haNK cells together with non-relevant antibody did not trigger any ADCC response.




Source: J Immunol. 2008 May 1;180(9):6392-401.

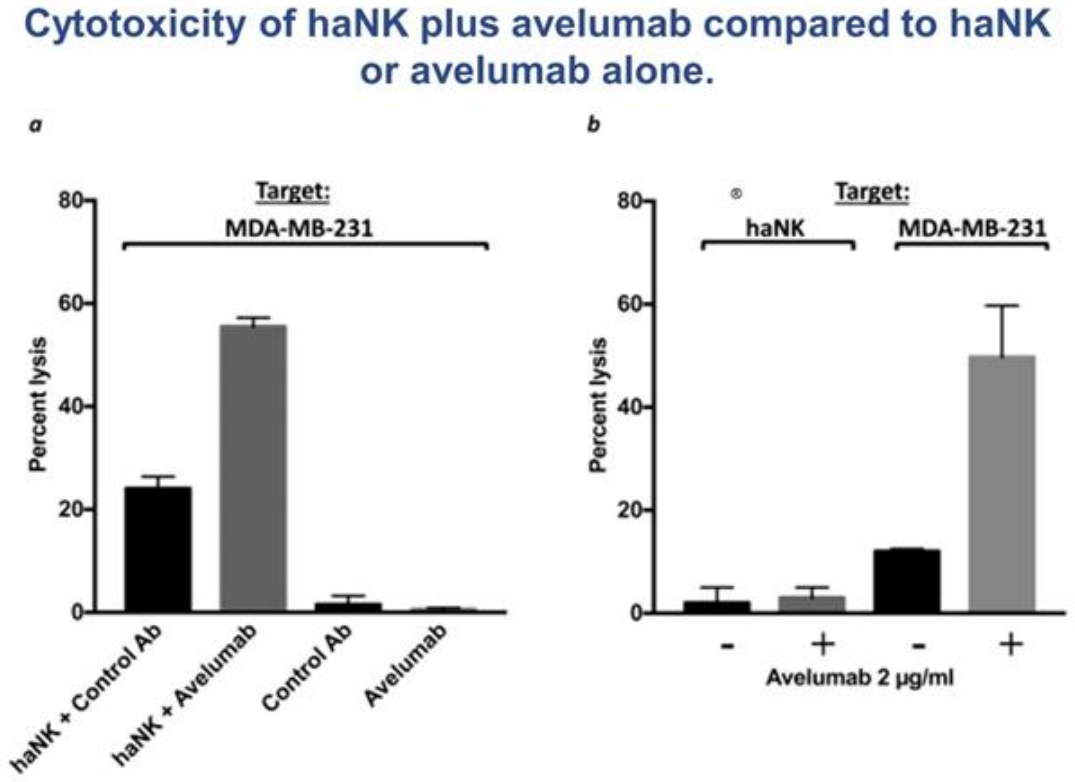
***Synergy Demonstrated When Combining Two Antibody Products together with haNK Cells.*** The graph below depicts the synergistic activity of the combination of herceptin and perjeta (HER2/HER3) to mediate ADCC killing observed in *in vitro* studies. Through the application of haNK cells to kill HER2 positive gastric carcinoma cells, the activity observed in the combination of herceptin and perjeta was significantly greater than with either agent alone.

**Proliferation Inhibition of HER2+ Gastric Carcinoma Cells in the Presence of haNK + mAbs**



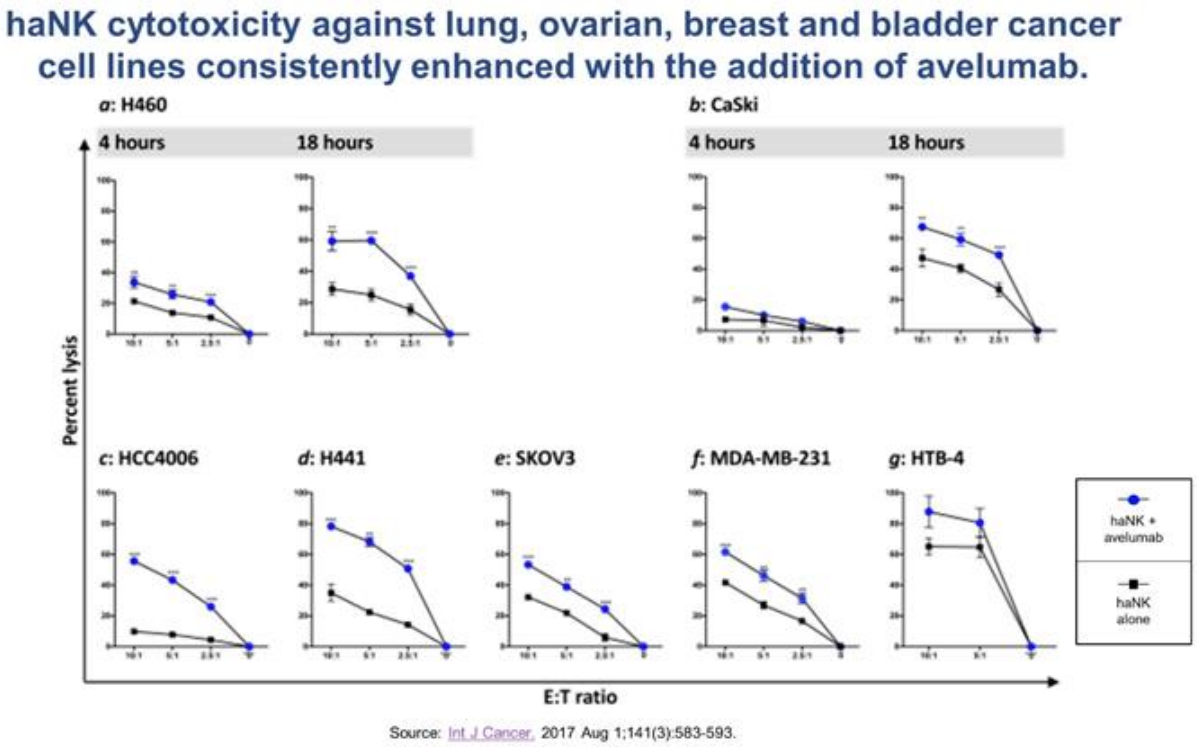

Source: Clin Cancer Res, 2011 August 1;17(15) 5060-5070

***haNK Enhances the Killing Capacity of the PD-L1 Checkpoint Inhibitor, Avelumab.*** Irradiated haNK cells and MDA-MB-231 (human breast carcinoma) cells were used as a target at an E:T ratio of 7.5:1. haNK innate killing (black bars) and innate + ADCC killing mediated by avelumab (grey bars) are shown in the graphs below. While avelumab alone and control Ab alone show no killing and haNK alone demonstrates some killing via innate mechanisms, the combination of haNK and avelumab yields the highest degree of killing, attributable to targeting the PD-L1 checkpoint protein as a target **(a)**. Separately, it was demonstrated that irradiated haNK cells do not exhibit cytotoxic activity against other haNK cells (fratricide) **(b)**.



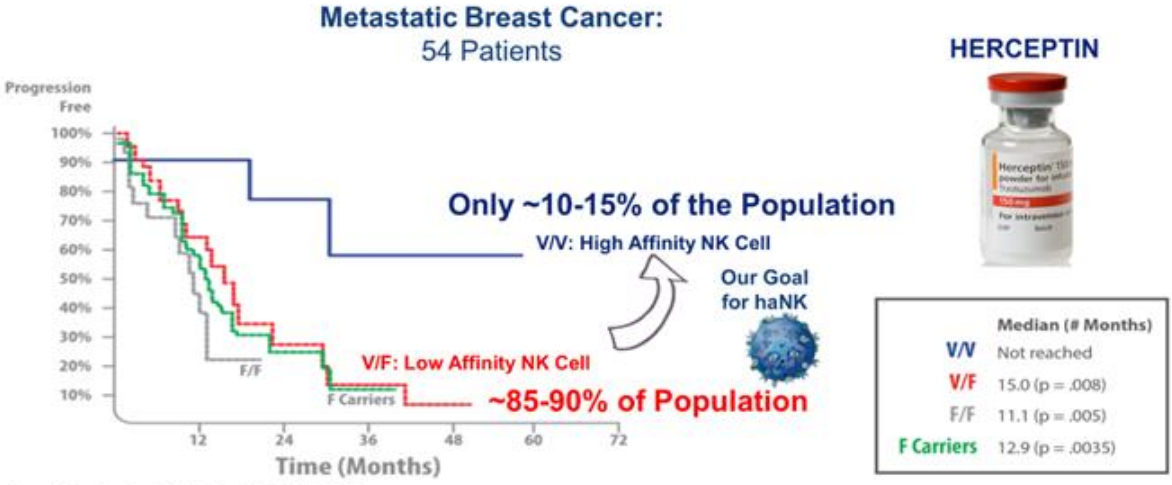

Source: Int J Cancer. 2017 Aug 1;141(3):583-593.

***haNK and Avelumab Combination Exhibits Potent Killing Across a Variety of Cancer Types.*** As illustrated in the graphs below, avelumab-mediated ADCC by haNK cells demonstrated enhanced killing against a variety of cancer types in four-hour assays, which was even more pronounced in 18-hour assays. Both haNK with isotype control (black squares) and haNK with avelumab (blue circles) mediated lysis of H460 human lung carcinoma cells in an E:T dose dependent manner (**a**). Similar results were also seen with several other human cell lines including cervical cancer CaSki cell (**b**); HCC4006: lung carcinoma (**c**); H441: lung carcinoma (**d**); SKOV3: ovarian carcinoma (**e**); MDA-MB-231: breast carcinoma (**f**); and HTB-4: bladder carcinoma (**g**).




Source: Int J Cancer. 2017 Aug 1;141(3):583-593.

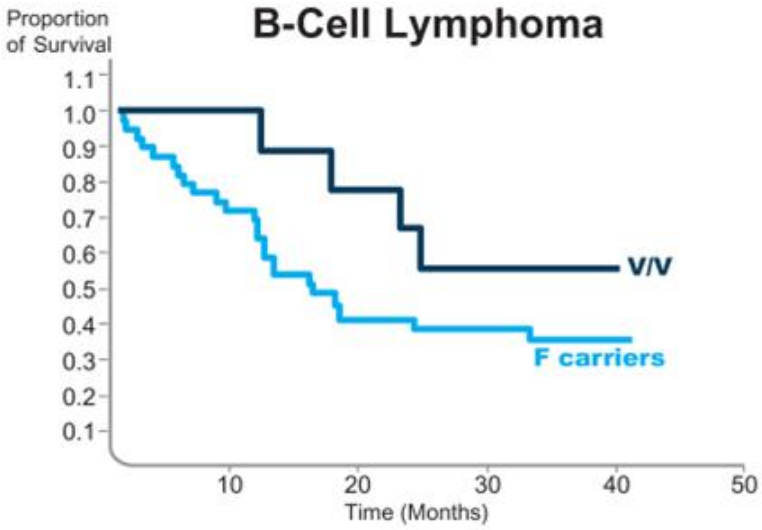
***Rationale for Developing Our haNK in Combination with Approved and Late-Stage Antibody Products That Utilize the ADCC Killing Pathway.*** In multiple clinical trials conducted by third parties, patients who were homozygous for high-affinity CD16 (158V/V) generally experienced better responses to antibody therapies than patients who were carriers of at least one low affinity CD16 allele (158F/F or V/F). The illustration from one study below shows the difference in progression-free survival between HER2 positive breast cancer patients treated with herceptin who have the homozygous high-affinity form of CD16 and those who are carriers for the low affinity form to be far in excess of 20% at 48 months.




Source: Musolino et al, J. Clin Oncol, 26, 1789, **2008**

*A p-value is the probability that the reported result was achieved purely by chance, such that a p-value of less than or equal to 0.05 or 0.01 means that there is a 5.0% or 1.0% or less probability, respectively, that the difference between the control group and the treatment group is purely due to chance. A p-value of 0.05 or less typically represents a statistically significant result.

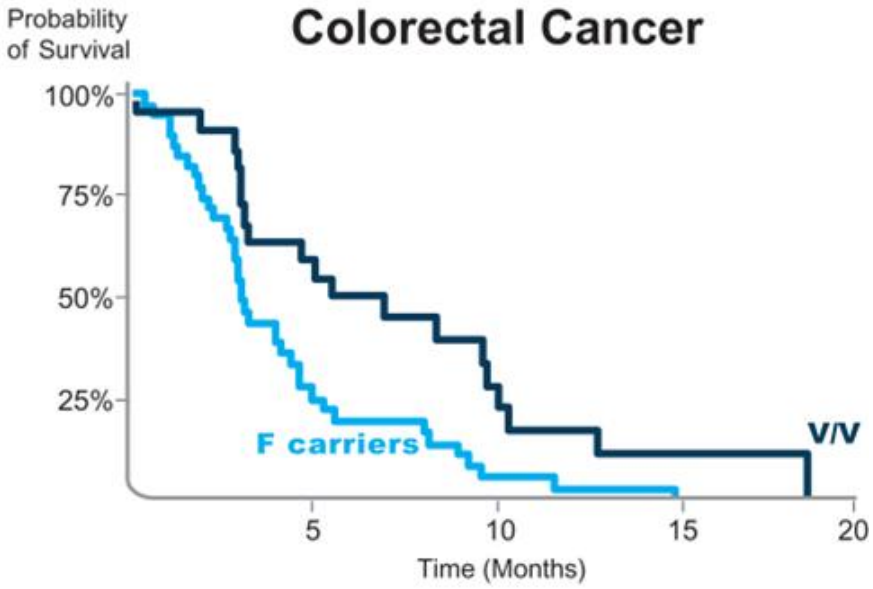
Data from two additional clinical trials demonstrating the same point are shown below. The rationale therefore favors combining haNK with rituxan, herceptin and erbitux in patients that carry the low affinity CD16 allele (both homozygous 158F/F and heterozygous carriers 158F/V and 158V/F) in order to improve the killing effect of these antibody products to approximate the results seen in patients that are homozygous (158V/V) for the high affinity alleles.




**49 patients treated with Rituxan**

Response rates at months 2 and 12 were 100% and 90% respectively for V/V patients.

Source: Cartron et al, Blood, 99, 754-758, 2002




**69 patients treated with Erbitux**

Patients with V/V had longer PFS (5.5 v 3.0 months; P = 0.005).*

Source: Bibeau et al, J. Clin Oncol, 27, 1122, 2009

Antibodies are prevalently used and it is estimated that they generate over $100 billion in reported global annual sales. It has been reported that only approximately 10% to 15% of the addressable patient population for antibody therapies carry high-affinity CD16 receptors. This implies that our haNK product candidates may have significant market potential for these and possibly all IgG1-type antibody products that kill via the ADCC pathway as a combination therapy to address a large number of patients who would otherwise have poor responses to their antibody treatments.

***haNK Single Agent Phase I Trial***

QUILT 3.028 (NCT03027128) was our open-label, phase I study of haNK for infusion in subjects with metastatic or locally advanced solid tumors. As a first-in-human trial for haNK cells, our aim was to evaluate safety and single agent activity, determine the maximum feasible dose or highest dose with acceptable toxicity of haNK infusions in up to 16 subjects. The study was conducted in two parts, the first being a standard dose escalation protocol using a 3 + 3 design and the second, an expansion of the highest dose level with acceptable toxicity to further characterize safety and activity. The final treatment was administered during the first quarter of 2019, the same quarter that the trial concluded, and the clinical study report is being finalized for April 2020. Solid tumor types included a wide range of cancers including colorectal, ovarian, head and neck squamous cell and adenoid cystic carcinomas. Patients were highly treatment experienced, with up to seven prior courses of therapy and had progressed on their most recent regiment. A preliminary look at the first two cohorts that received repeat haNK infusions revealed no grade 3 or higher toxicities related to haNK and no dose limiting toxicities. Grade 1 or 2 fever, fatigue, nausea, infusion-related reactions and pain have been reported for most patients. One patient experienced grade 3/4 hyponatremia and another reported grade 4 hyperbilirubinemia, but neither was considered to be related to the administration of the study drug. Transient disease stabilizations were observed in half of the patients treated, though with the absence of concurrent antibody treatment, significant responses were not anticipated. A recommended phase II dose level of 2 x $10^9$ was determined and utilized in our subsequent phase Ib/II and phase II combination trials.

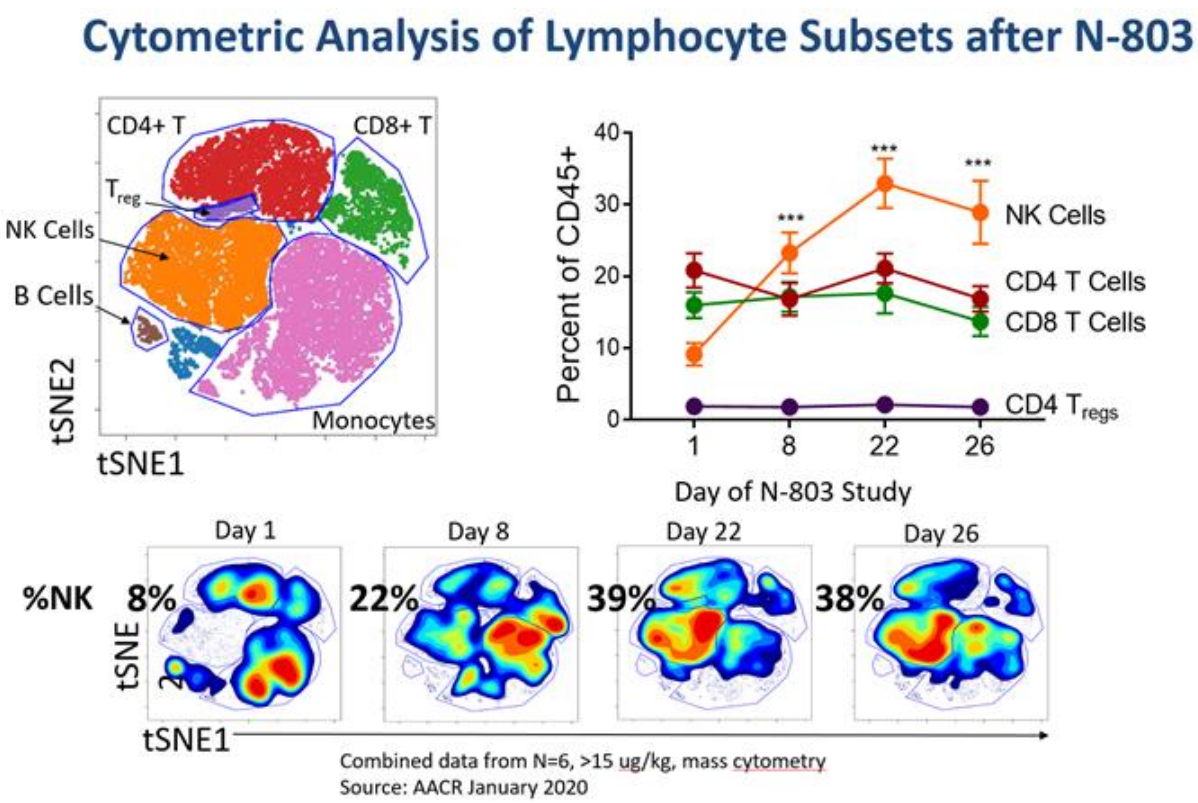
***Transition to Cryopreserved haNK Product Candidate.*** During the QUILT 3.028 study, our haNK product for infusion was changed from fresh irradiated haNK to frozen irradiated, “off-the-shelf” haNK product. The administration of both products was found to be equally safe and tolerable. The early favorable safety profile established from this first-in-human study paved the way for numerous successful IND submissions to the FDA for our phase Ib/II haNK combination trials, which we designated as NCV trials.

***The Distinction of Exclusively Combining Our NK Therapies with a Systemically Administered IL-15 Superagonist.***

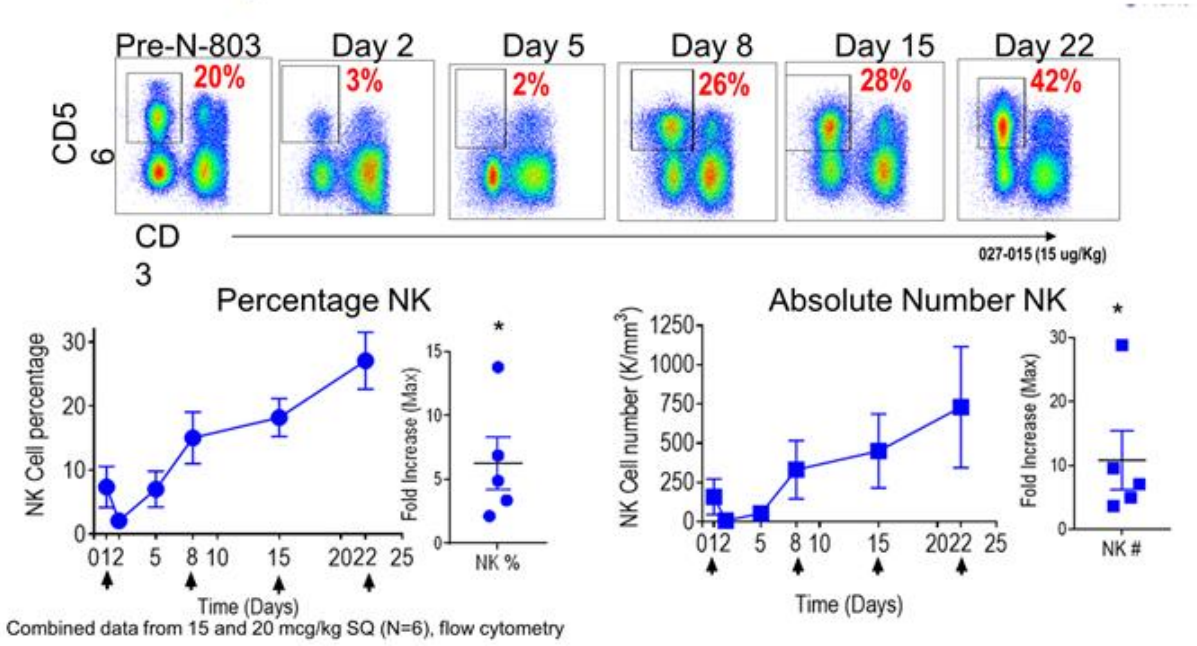
An expansive scientifically-based rationale has evolved that justifies the pairing of our NK cell therapeutic platforms with a selective IL-15 activator of the patient’s own natural killer and T-cells, while avoiding bystander activation of deleterious inhibitory immune cells. We anticipate that such a combination in conjunction with a tumor conditioning regimen, which promotes tumor immunogenicity, would be most effective at inducing immunogenic cell death, memory immune cells and cancer remissions. We selected N-803 for use in our combination trials since it is the only IL-15 superagonist agent that is in late-stage clinical development, has an evolving dossier of clinical safety and has demonstrated consistent synergism when combined with haNK and PD-L1.t-haNK cells in *in vitro* and *in vivo* experiments both internally and with various research collaborators.

It is generally known that natural killer cell counts at the time of cancer diagnosis corresponds directly with event free survival and that existing natural killer cell populations in these patients are both low in number and dysfunctional due to impaired innate and ADCC killing mechanisms. It is also known that cancer patients receiving an antibody therapeutic demonstrate marked depletion of ADCC competent natural killer cells both during and up to one month after completing therapy. The administration of an “off-the-shelf” replacement natural killer cell therapy such as haNK or t-haNK, at numbers that readily approximate a patient’s normal natural killer cell count over an extended period through repeat dosing, would be expected to make available iterative waves of innate and ADCC competent natural killer cells until the patient’s own immune system is able to reconstitute and defend itself. N-803 is a stimulating cytokine that promotes the expansion and activation of the patient’s own natural killer and CD8+ T-cell populations, a finding that has been demonstrated in numerous preclinical and clinical studies in cancer patients. Moreover, cross reactivity with CD4+ T-regulatory and MDSC cells does not occur with N-803, thereby sparing patients from the counterproductive immune inhibitory effects of this immunologic compartment. Pairing these features with the finding that N-803 acts synergistically to enhance the anti-cancer effects of haNK and t-haNK sets the foundation for our combination approach to innate natural killer therapeutics for cancers, where these agents can form the backbone of any combination cancer regimen.

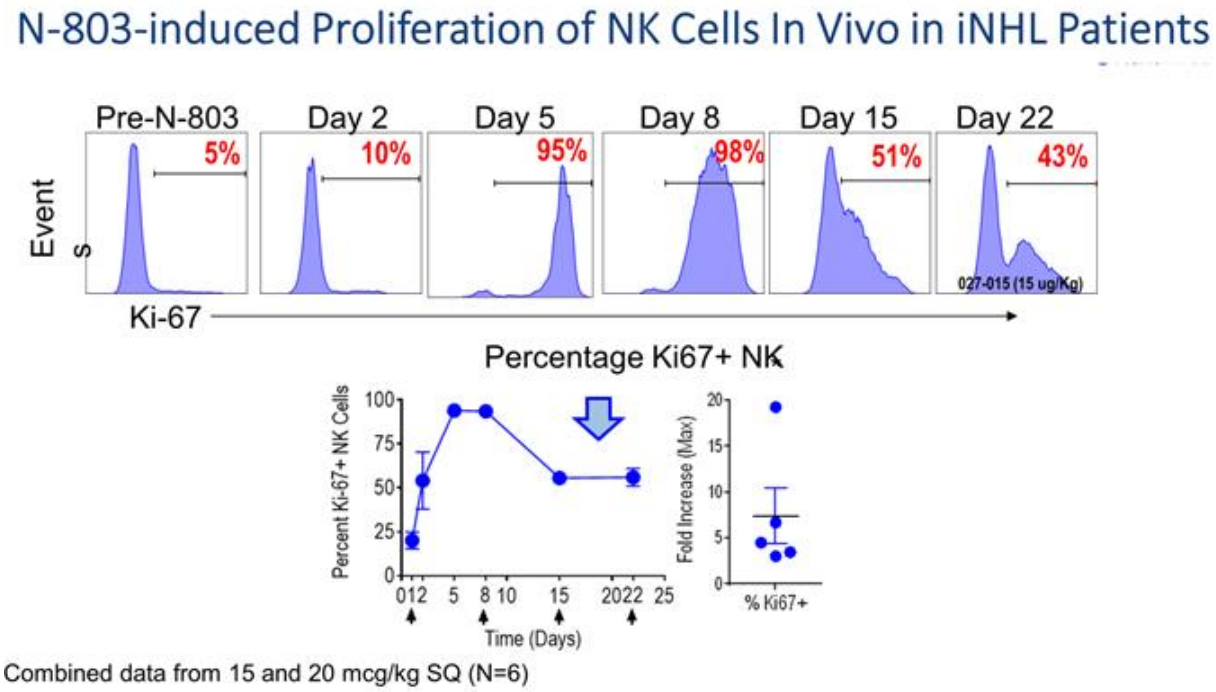
The following graphs illustrate how the lymphocyte compartments in human recipients respond to N-803 administration. A recently reported clinical study that investigated the combination of N-803 and rituximab in indolent non-Hodgkin's lymphoma patients who relapsed or were refractory to rituximab therapy demonstrated that N-803 induced expansion of the patient's own natural killer cell compartment while avoiding regulatory T-cell stimulation.




Natural killer cells, which typically represents 10% of the overall lymphocyte population, expanded three fold to approximately 30% in these recipients, reaching absolute counts averaging 750 cells/µL.




N-803 administration also markedly increased the proliferation marker, Ki67+ on natural killer cells over the full three weeks of patient monitoring.



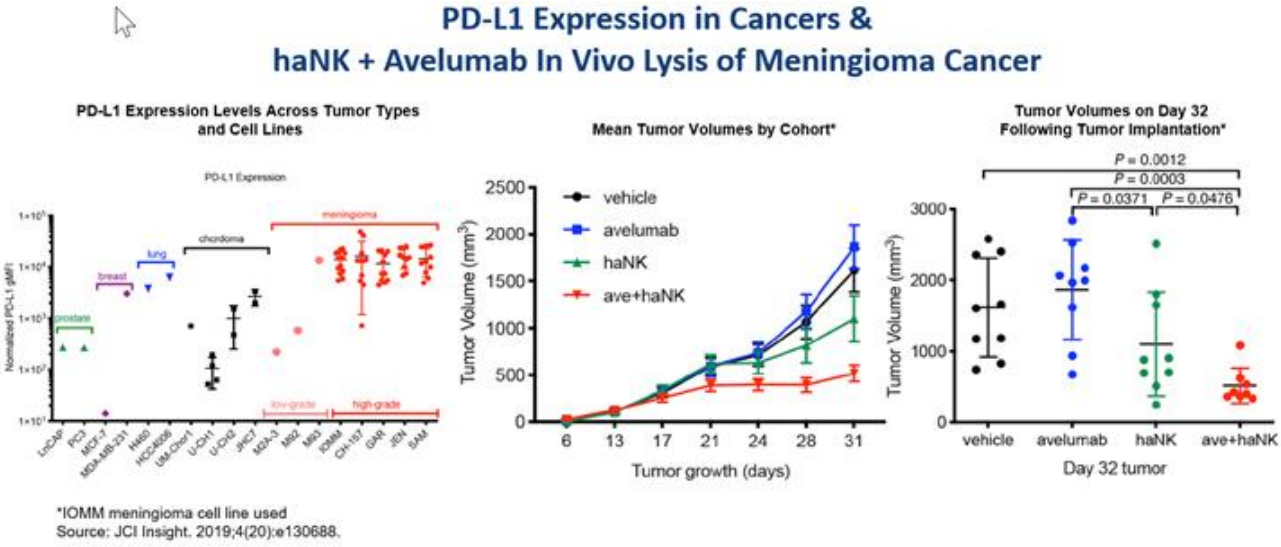
Another recent study in patients with metastatic non-small cell lung cancer who received a checkpoint inhibitor, also demonstrated increased numbers of natural killer cells when administered N-803 therapy. The ability of N-803 to drive potent expansion of natural killer cells was identified to potentially have particular value as major histocompatibility complex, or MHC, class I is lost on a substantial frequency of non-small cell lung cancer tumors, thereby making these tumors potentially susceptible to natural killer cell-mediated killing.[12]

These foundational data suggest that IL-15-based immunomodulation using N-803 has broad effect on patient natural killer cells and indicate that combination therapy with our NK cell therapies can potentially deliver more productive natural killer cell driven responses than would be possible with either alone.

***Combining haNK and Avelumab as a Versatile Treatment for a Wide Range of Cancer Types.***

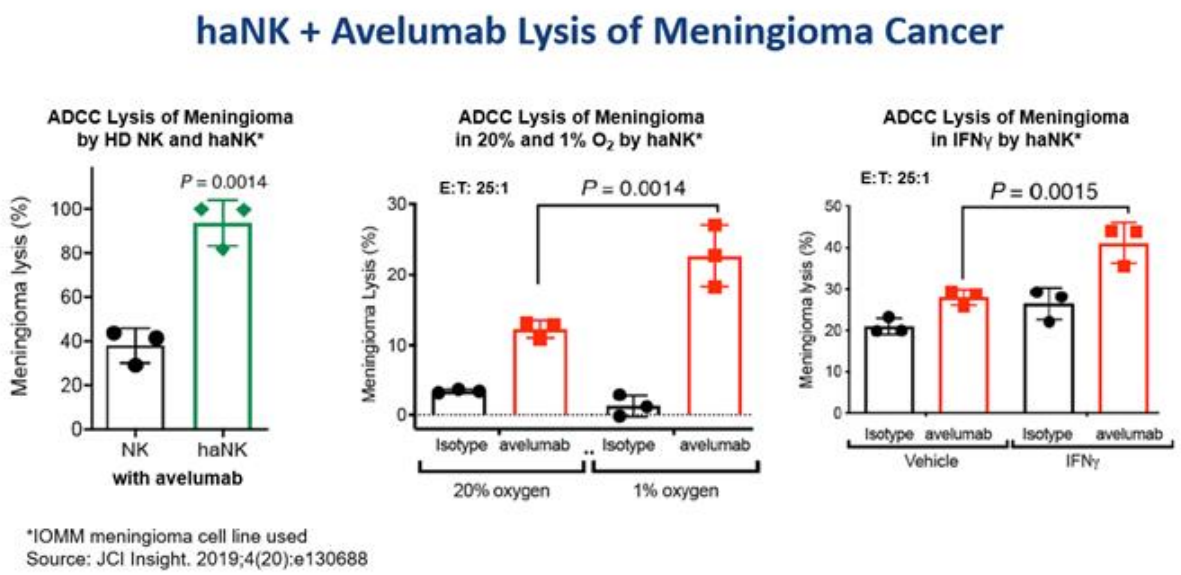
Programmed cell death ligand-1, or PD-L1, which hinders anti-tumor immunity, has been detected on a wide range of tumor types and contributes to cancer escape. Antibody-mediated PD-L1 blockade has already demonstrated clinical benefit in metastatic cancers such as non-small cell lung cancer, bladder cancer, melanoma, renal cell and ovarian cancers. The human anti-PD-L1 antibody, avelumab, is a commercially available IgG1 antibody product with a fully functional Fc segment that can engage CD16 receptors on natural killer cells, thereby mediating ADCC killing of PD-L1 expressing cancer cells. Avelumab combinations with haNK, the high affinity CD16 and IL-2 expressing aNK cell line, could therefore be considered an ideal pairing of agents for a number of highly prevalent cancer types.

In the graphs below, we see that PD-L1 is expressed, to the greatest extent, in high-grade meningioma, but also in lung, breast, prostate cancers and chordoma. Additionally, the combination of haNK and avelumab has a synergistic effect at controlling meningioma tumor growth by volume in mouse models, when compared with either agent alone. Not shown, is the finding that the combination of haNK and avelumab extended survival in both orthotopic and subcutaneous meningioma mouse models in conjunction with increased cytotoxic immune infiltration and tumor necrosis.




12 Wrangle et al, Lancet Oncol. 2018 May;19(5):694-704

Also, the data below demonstrates that the haNK and avelumab combination more efficiently lysed meningioma cells when compared with healthy donor natural killer cells and avelumab. PD-L1 expression on meningioma cancer cell lines has been shown to increase under conditions of increasing hypoxemia and in the presence of IFN-γ. This can help explain why the observations below were made of heightened ADCC mediated lysis by haNK cells with avelumab under a hypoxemic condition and in the presence of IFN-γ.

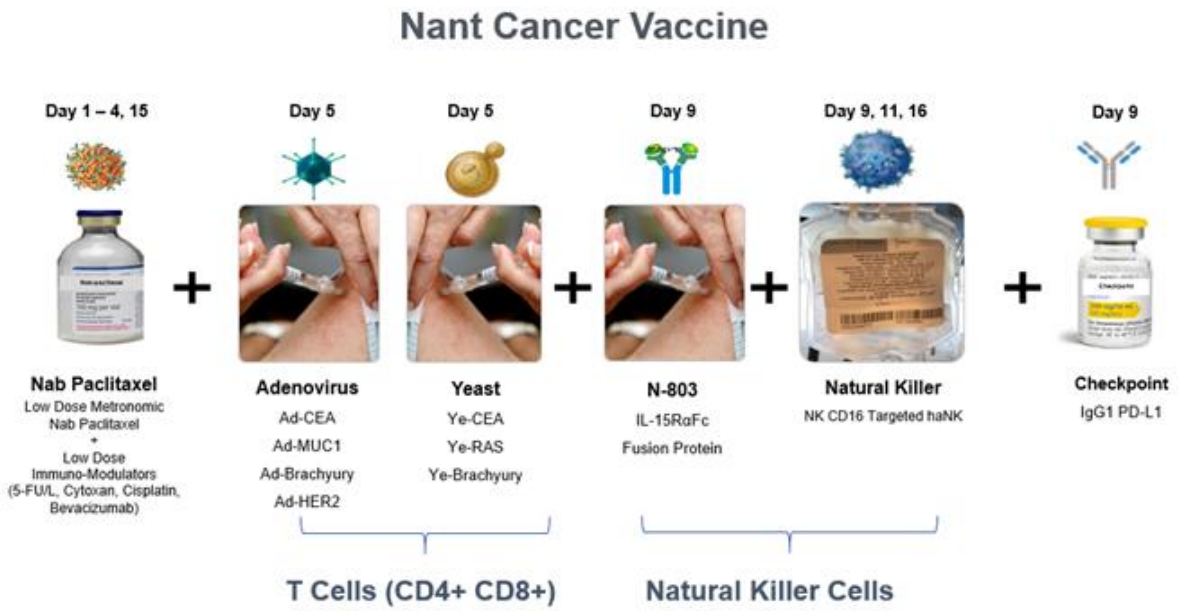



Combined with our knowledge about haNK's ability to function in the hypoxemic tumor microenvironment and the ability of haNK to express IFN-γ, the potential for clinical applications have become increasingly clear.

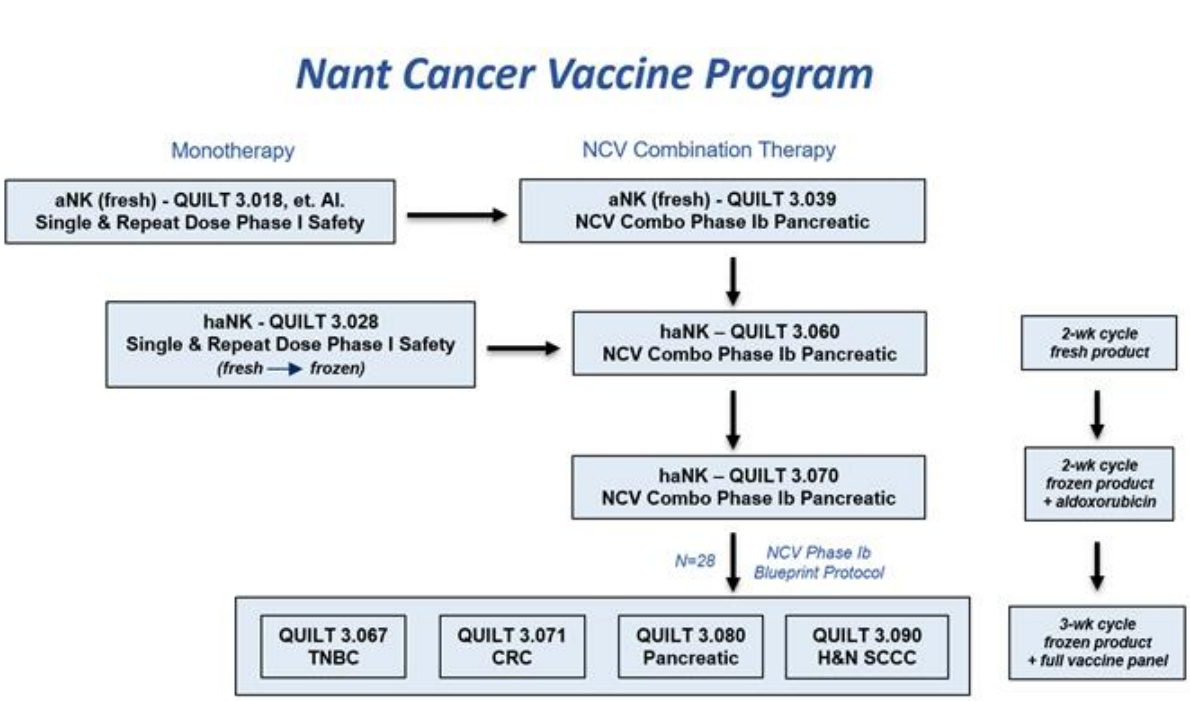
***Building a Blueprint for the Nant Cancer Vaccine (NCV) Treatment Program***

***QUantum Immuno-Oncology Lifelong Trial***, or QUILT, is a master clinical trial protocol designed under cooperative research and development agreements between pharmaceutical/biotechnology companies and the National Cancer Institute, in accordance with published FDA guidance. QUILT studies are designed to harness and orchestrate all of the elements of the immune system, including natural killer cell, T-cell and dendritic cell therapies, by testing novel combinations of cell-based immunotherapy (i.e., haNK and t-haNK), cytokines (i.e., N-803), immunomodulators, including checkpoint inhibitors, vaccines, metronomic chemotherapy (i.e., abraxane and aldoxorubicin) and low dose radiotherapy as a 'triangle offense' in patients who have undergone next generation whole genomic and transcriptomic analysis, with the goal of achieving durable, long-lasting remission for patients with cancer.

## The Triangle Offense: Orchestrating the Innate and Adaptive Immune Systems

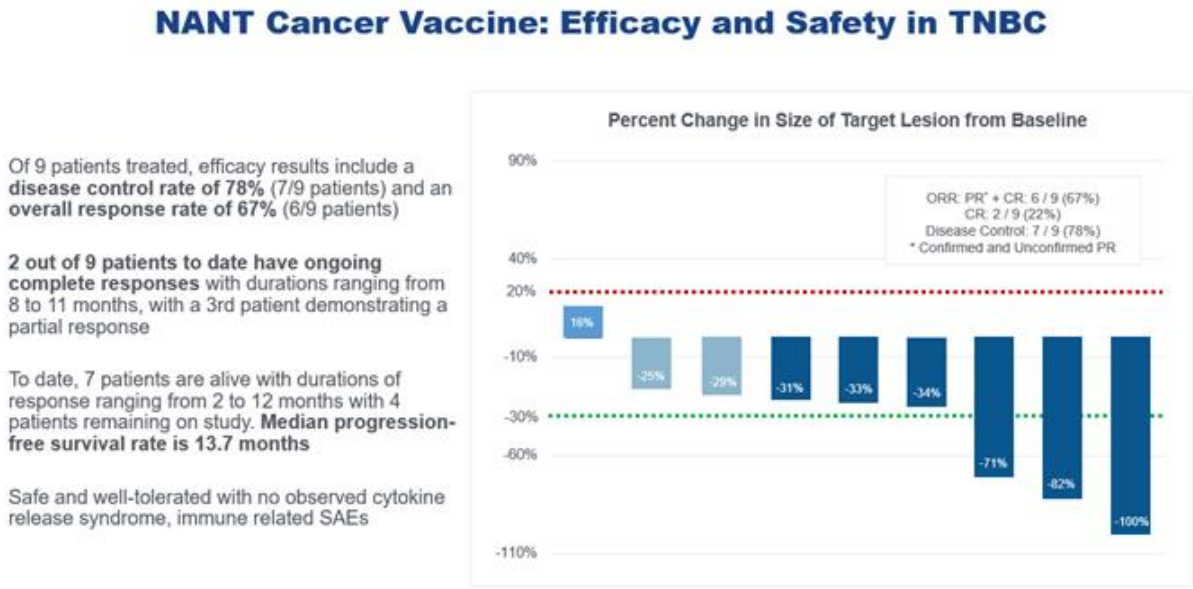


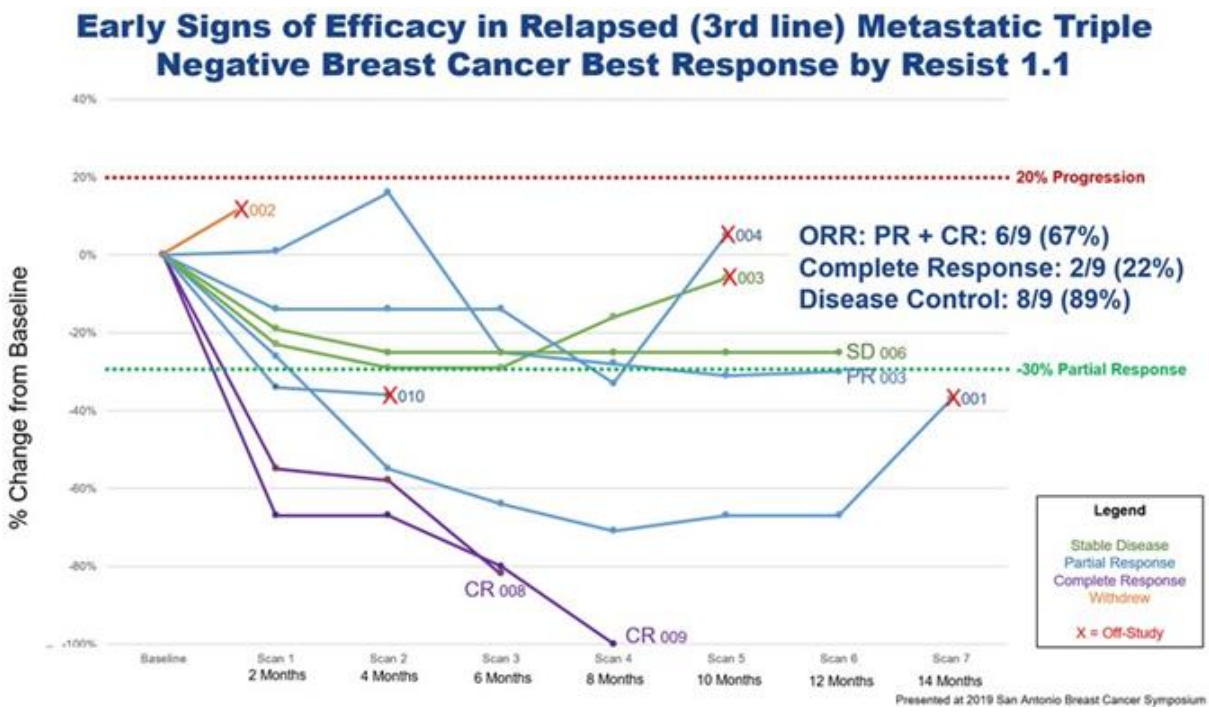

After demonstrating phase I safety and activity of single and repeat-dosing of fresh aNK monotherapy in several phase I trials, including QUILT 3.018, we demonstrated the same for both fresh and frozen haNK monotherapy in our QUILT 3.028 study. We next demonstrated safety and activity of the combination of fresh aNK with NCV agents in pancreatic cancer patients in our QUILT 3.039 study and demonstrated the same for both fresh and frozen haNK with NCV agents in our QUILT 3.060 study for patients with pancreatic cancer who have progressed on or after standard-of-care therapy. Then we introduced our cryopreserved haNK formulation together with the addition of low-dose aldoxorubicin and a design change to extend the length of each treatment cycle to three weeks, in our QUILT 3.070 study. Based on the encouraging safety and activity findings, we proceeded to implement this refined NCV design in a new program to better assess responsiveness across several tumor types, which included triple negative breast, colorectal, pancreatic and head and neck squamous cells cancers in QUILT 3.067, 3.071, 3.080 and 3.090, respectively.




These phase Ib studies all investigated haNK in combination with metronomic chemotherapy, N-803, cytokine therapy, cancer vaccines, and stereotactic body radiation therapy and continue to have patients in active follow-up. The primary endpoint is to determine safety and activity of the combination treatment. By March 15, 2020, approximately 540 doses of haNK cells have been administered to subjects. No immune-related adverse effects or cytokine release syndrome attributable to haNK have been observed. Transient low-grade fevers have been reported in these haNK recipients when administered in this NCV combination therapy.

***QUILT 3.067*** study of haNK cells in combination with NCV agents in subjects with triple negative breast cancer who have progressed on or after standard-of-care therapy continues to follow two long-term complete responders on maintenance therapy at 15 and 18 months.






We have now concluded enrollment for this phase Ib first-generation NCV program, and while we have demonstrated the safety of this approach, we will continue treatment of patients still on study, analyze data and prepare clinical study reports in select indications.

**t-haNK Programs**

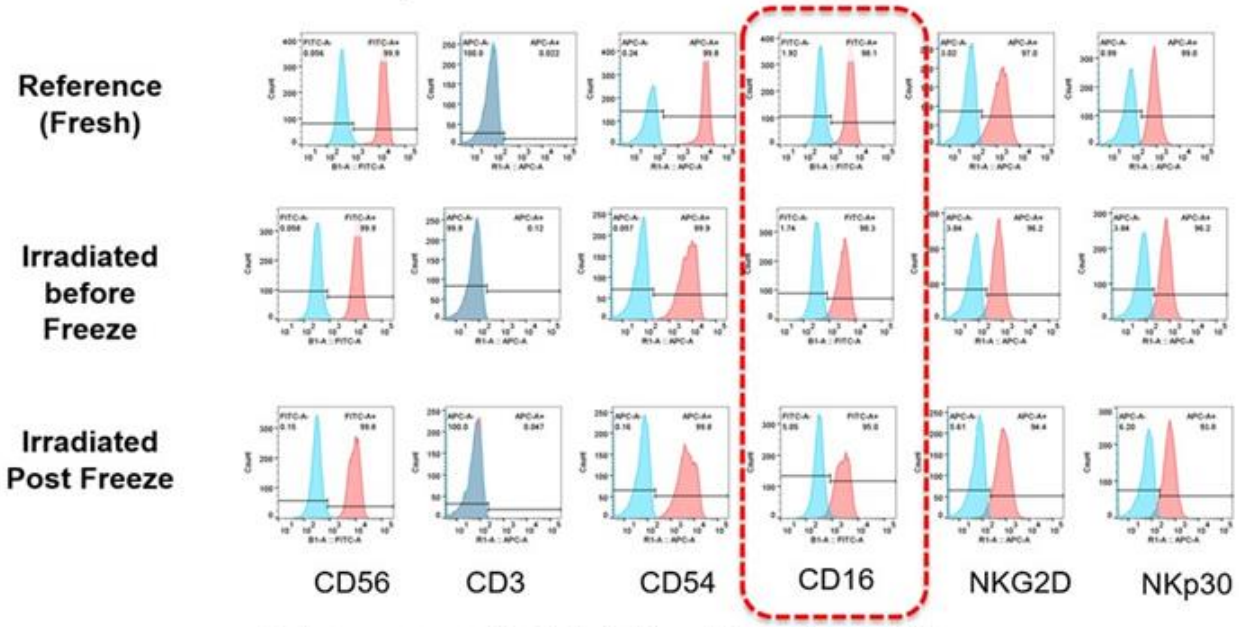
***Novel, First-in-Class PD-L1.t-haNK Product Candidate for Solid Tumors.***

***Introduction.*** PD-L1.t-haNK is a human, allogeneic, stable clonal NK cell line generated from our parental clinical-grade aNK master cell bank. This product combines the potent cell killing mechanism mediated through PD-L1 CAR targeting with the well-known and potent FcgRIIIa/CD16 mediated ADCC killing mechanism. Internal research has demonstrated that such a dual expression is not only stable, but that each component contributes synergistically when used in conjunction with the appropriate therapeutic IgG1 therapeutic antibody. Our PD-L1.t-haNK product is highly potent and selectively active through the stable expression of three primary proteins: (1) a human PD-L1–targeted CAR; (2) the high-affinity variant of the human IgG1 Fc receptor, FcγRIIIa/CD16 for enhanced ADCC; and (3) a variant of the human IL-2 cytokine for enhanced function, IL-2 growth independence and limited extracellular leakage of IL-2 for improved safety.

***In Vitro Research.*** Our PD-L1.t-haNK master cell bank is a uniform cell population that can be easily and stably expanded in continuous culture. It has demonstrated exceptionally potent and specific *in vitro* activity against PD-L1–expressing tumors via CAR-directed cytotoxicity. Likewise, it exhibited potent killing through innate mechanisms, including NKG2D and NKp30 receptors. Moreover, since PD-L1.t-haNK retains a high expression of the high-affinity CD16 allele, the engineered enhancement of haNK cells, even after irradiation and thawing, it can also mediate antitumor activity via ADCC when administered in combination with a monoclonal antibody. As such, a tri-targeting approach may be more effective at potentiating antitumor activity in all PD-L1–expressing solid malignancies, particularly when the appropriate IgG1-type antibody is added to the therapeutic regimen. The receptor expression profiles and *in vitro* killing plots of our PD-L1.t-haNK cells against cancer cell lines utilizing CAR, innate and ADCC mechanisms are illustrated in the following slides. Several NCI manuscripts on PD-L1.t-haNK from our collaboration disclosing new and compelling *in vitro* and *in vivo* data are expected to publish in the very near term.

# PD-L1.t-haNK™ Cells Maintain Critical Receptor Profiles After Irradiation and Thawing

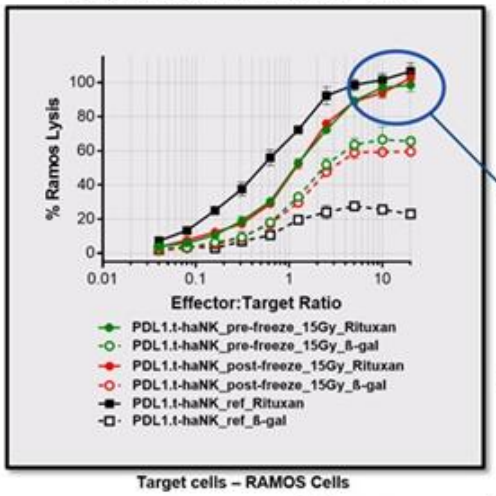
## PD-L1.t-haNK expresses CD-16 and other activation markers

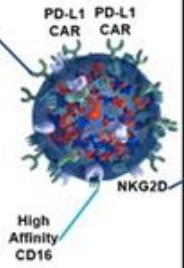



*Cells were processed to initiate testing within one hour post-thaw.*
*Phenotypic assays were run for 4-5 hours post-thaw of cells.*

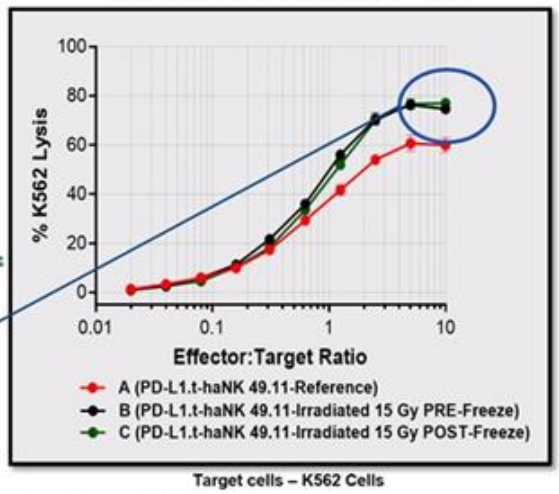
# PD-L1.t-haNK™ Cells Maintain Normal Cytotoxicity and ADCC Activities

*CD-16 Activated ADCC Activity of Cryopreserved PD-L1.t-haNK™ cells*



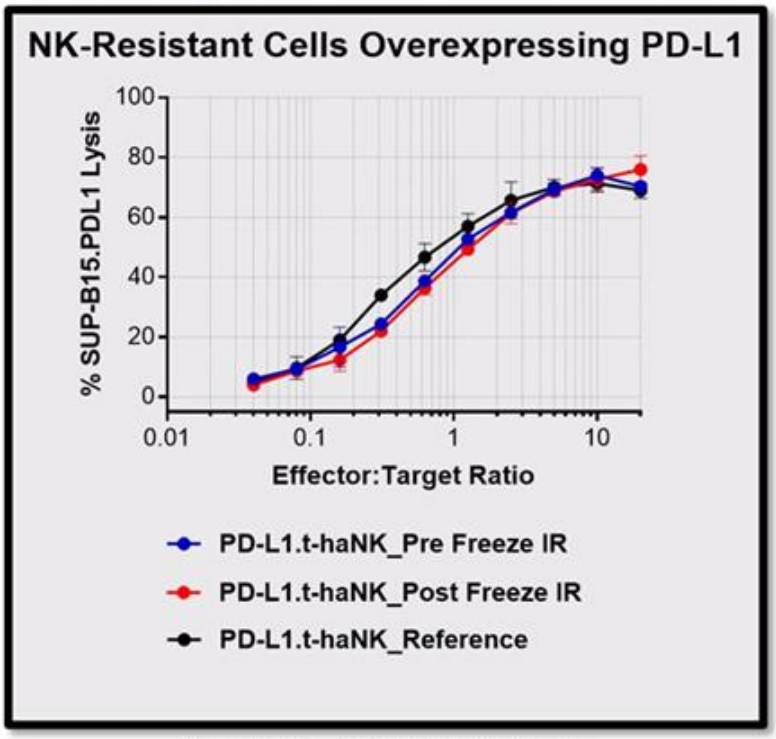




*NKG2D & NKp30 Direct Cytotoxicity Activity of Cryopreserved PD-L1.t-haNK™ Cells*




*Cells were processed to initiate testing within one hour post-thaw.*
*Cytotoxicity assays are run for 6-7 hours post-thaw of cells.*

# PD-L1.t-haNK™ Cells Maintain ADCC Activity and Innate Cytotoxicity after Irradiation and Thawing




**Target cells – SUP-B15.PDL1+ Cells**

*Cells were processed to initiate testing within one hour post-thaw.*
*Cytotoxicity assays are run for 6-7 hours post-thaw of cells.*

***In Vivo Research.*** Nonclinical testing was performed to determine the pharmacologic and toxicologic effects of PD-L1.t-haNK, which may be predictive of its clinical safety and efficacy in humans. The nonclinical *in vivo* studies employed immunocompromised mouse models in order to mitigate rejection of PD-L1.t-haNK cells by the xenogenic host species. Nonclinical pharmacology data demonstrated that PD-L1.t-haNK cells possess potent *in vivo* antitumor efficacy as demonstrated in PD-L1–positive xenograft models. PD-L1.t-haNK administration was able to markedly decrease metastatic disease burden and inhibit tumor growth in these tumor-bearing animals.

A repeat-dose biodistribution study evaluated the dispersion and persistence of the PD-L1.t-haNK cell line following repeated administration in the presence of PD-L1-expressing tumors. PD-L1.t-haNK cells were detected at very low frequency in the liver and lungs of PD-L1 tumor-bearing mice six-hours after dosing and were completely undetectable 48-hours after dosing. This study also indicated that the presence of the PD-L1-targeted CAR construct does not affect the biodistribution pattern of the PD-L1.t-haNK cells. Likewise, the presence of a PD-L1–targeted CAR does not affect the biodistribution of the cells, which circulate through the blood with accumulation occurring in the liver and lungs, and with limited persistence.

A pivotal toxicity study showed that repeat-dose administration of irradiated PD-L1.t-haNK cells in an immunocompromised mouse model was well tolerated and did not result in any significant toxicities, pathological changes, or tumor formation. Additionally, no weight loss, distress, or other treatment-related adverse reactions were observed in any animals. Importantly, the tolerability of repeat-dose administration of PD-L1.t-haNK cells was comparable to treatment with other aNK-derived cell lines. In summary, the nonclinical data demonstrated a favorable risk-benefit ratio for PD-L1.t-haNK.

***Development Plan.***

***QUILT 3.064*** is a phase I, first-in-human, open label study to evaluate safety, preliminary efficacy, determine the maximum feasible dose and designate the recommended phase II dose of PD-L1.t-haNK for infusion in subjects with locally advanced or metastatic solid cancers. This study opened mid-2019 and is being conducted in two parts: the first being a standard dose escalation protocol using a 3 + 3 design, and the second, an expansion of the highest dose level with acceptable toxicity to further characterize safety and efficacy. As of March 15, 2020, we have completed the first two dose levels of 2 x $10^9$ and 4 x $10^9$ cells and are enrolling the fourth patient for our expansion cohort. Since the observation hold period between each patient only applied to the dose escalation potion of the trial, we anticipate study completion during the second quarter of 2020. Patient tumor types so far included head and neck squamous cell carcinoma, breast and triple negative breast cancers, colon cancers, glioblastoma, urothelial cancer and leiomyosarcoma. One-hundred doses at the 2 x $10^9$ dose level and fifty-six doses at the 4 x $10^9$ dose level have been administered as of March 2, 2020. One dose limiting toxicity was reported at the 4 x $10^9$ dose level that did not require dose-reduction and all but one patient are still alive, two stable diseases were noted, one at an early time point and one at four months and several additional patients are scheduled to undergo imaging studies to assess their tumor responses. We anticipate reporting on this trial at the upcoming American Society of Clinical Oncology conference in June 2020.

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 leading with pancreatic and non-small cell lung cancers. 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.

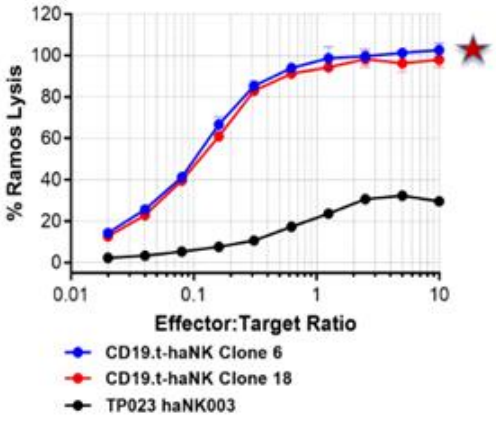
On a related note, a patient with late stage pancreatic cancer was enrolled to a special IND to receive PD-L1.t-haNK cells in combination with N-803 and aldoxorubicin. This patient has been confirmed to have a complete response by Positron Emission Tomography CT at three months. QUILT 88, a phase II/III protocol that was recently filed with the FDA and described in further detail later in this section, will investigate this combination of agents further.

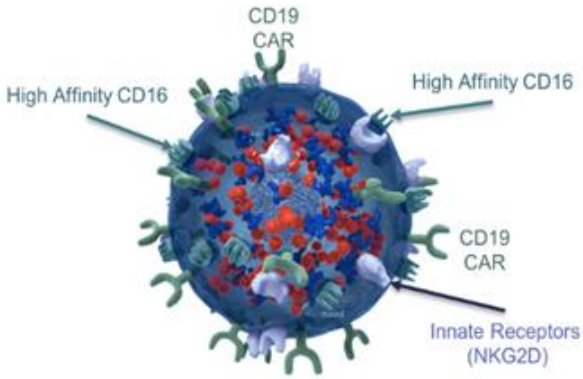
***Novel, First-in-Class CD19.t-haNK Product Candidate for Liquid Tumors.***

***Introduction.*** CD19.t-haNK is a human, allogeneic, stable clonal NK cell line generated from our parental clinical-grade aNK master cell bank. This product combines the potent cell killing mechanism mediated through CD19 CAR targeting of the B-cell marker CD19 with the well-known and potent FcγRIIIa/CD16 mediated ADCC killing mechanism. Internal research has demonstrated that such a dual expression is not only stable, but that each component contributes synergistically when used in conjunction with the appropriate therapeutic IgG1-type monoclonal antibody. Our CD19.t-haNK product is highly potent and selectively active through the stable expression of three primary proteins: (1) a CD19–targeted CAR; (2) the high-affinity variant of the human IgG1 Fc receptor, FcγRIIIa/CD16 for enhanced ADCC; and (3) a variant of the human IL-2 cytokine for enhanced function, IL-2 growth independence and limited extracellular leakage of IL-2 for improved safety.

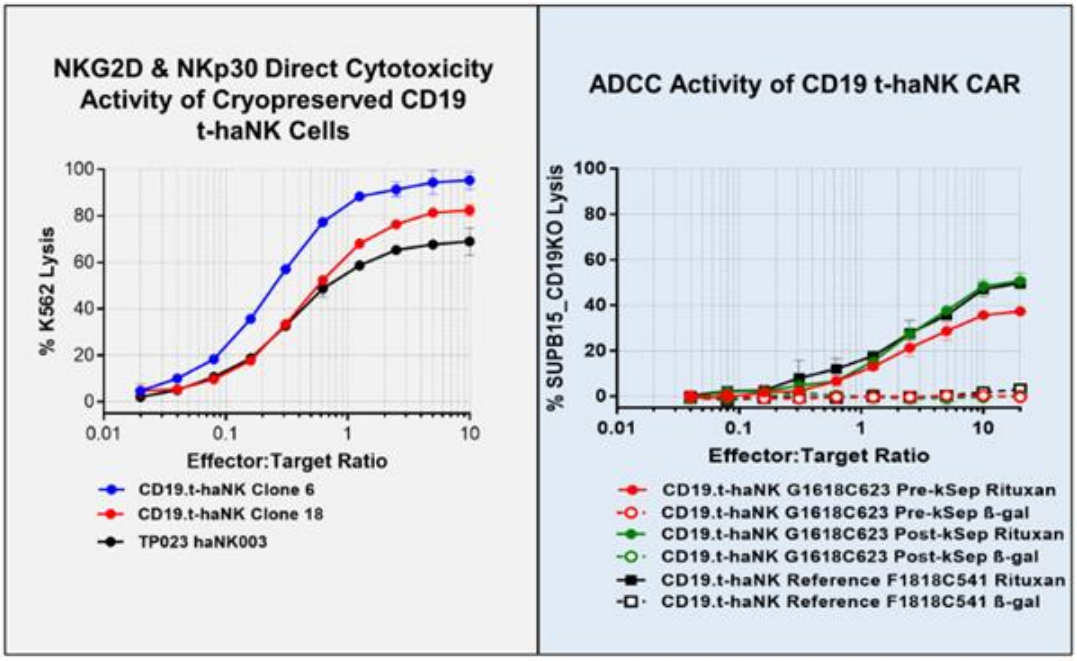
***In Vitro Research.*** Our CD19.t-haNK master cell bank is a uniform cell population that can be easily and stably expanded in continuous culture. It has demonstrated potent and specific *in vitro* and *in vivo* activity against CD19-expressing tumors via CAR-directed cytotoxicity. Likewise, it exhibited potent killing through innate mechanisms, including NKG2D and NKp30 receptors. Moreover, since CD19.t-haNK also expresses the high-affinity CD16 allele, the engineered enhancement of haNK cells, it can also mediate antitumor activity via ADCC when administered in combination with a monoclonal antibody. As such, a tri-targeting approach may be more effective at potentiating antitumor activity in all CD19 expressing liquid tumors, particularly when the appropriate IgG1-type antibody is added to the therapeutic regimen. The *in vitro* killing plots of our CD19.t-haNK cells against cancer cell lines utilizing CAR, innate and ADCC mechanisms are illustrated in the following slides.

# CD19.t-haNK™ CAR Specific Killing




# CD19.t-haNK™ Cells Maintain Both Innate Killing and ADCC Mediated Killing



***In Vivo Research.*** An array of *in vitro* and *in vivo* pharmacology proof-of-concept studies have been performed with CD19.t-haNK. The *in vivo* antitumor activity was investigated using a CD19-positive lymphoma cancer line in immunocompromised mouse models. Irradiated CD19.t-haNK cells were administered intravenously twice per week over a period of three weeks and resulted in statistically significant tumor growth inhibition on and after the first week compared to a control group. In addition, it was observed during necropsy that treatment with CD19.t-haNK cell treatments reduced liver metastasis, which was further corroborated by histological evaluation. Furthermore, treatment with CD19.t-haNK was able to reduce the number of animal death events, with 100% of the study subjects alive at the end of the study compared to only 50% of the subjects in the control group. Results from this study are indicative of the potential pharmacological effects of CD19.t-haNK for infusion in human lymphoma patients.

To investigate the *in vivo* biodistribution and persistence of CD19.t-haNK cells intravenously administered in CD19-positive Raji tumor-bearing mice, tissues were analyzed at six- and 48-hours after the final dose. CD19.t-haNK cells were detected at very low frequency in the liver and lungs at six-hours post-dosing, and none were detected at 48-hours post-dosing. The results of this study are consistent with previous biodistribution studies performed with haNK cells, indicating that the addition of the CD19 CAR does not affect the biodistribution pattern of the cells and that like haNK cells, CD19.t-haNK cells do not persist *in vivo*, a highly favorable feature that may underlie its excellent safety profile without adversely impacting potency.

In investigating *in vivo* toxicity and tumorigenicity of CD19.t-haNK cells after 28 days of repeat dosing in immunocompromised mice, results showed that all mice receiving product were overall as healthy as the control group throughout the study. There were no mortalities in either of the treatment groups and likewise, no adverse events were observed. Blood and serum samples collected at the end of the study revealed no significant differences between animals receiving drug product and those in the control group. In addition, gross necropsy and macroscopic morphologic examination revealed no tumor masses or organ abnormalities. Subsequent pathological evaluation of harvested tissues confirmed that there was no gross or microscopic evidence of toxicity or tumorigenicity associated with administration of irradiated CD19.t-haNK cells. We believe the results from this study provide strong support for the safety of cryopreserved, irradiated CD19.t-haNK cell therapy in human clinical trials.

***Diffuse Large B-Cell Lymphoma.*** Diffuse large B-cell lymphoma, or DLBCL, the most common subtype of non-Hodgkin's lymphoma, is a heterogeneous disease. The current standard for first-line therapy is a traditional chemotherapy regimen consisting of rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone. While approximately 50% to 60% of patients respond well to first-line therapy, approximately 15% to 25% of patients suffer from primary refractory disease, approximately 20% to 30% relapse after achieving a complete response, and 5% achieve only a partial response. Patients that relapse or are refractory to first-line therapy can be treated with one of an array of salvage chemotherapy regimens and if responsive, may subsequently proceed to undertake potentially curative stem cell transplantation. However, patients that are refractory or relapse after two or more lines of therapy, especially those that are not eligible for stem cell transplant or CAR-T cell therapy, have a very poor prognosis. New therapeutic options are critically needed to address this growing patient population.

We believe that the combined potential for our CD19.t-haNK cells to exhibit a robust CAR-directed and ADCC mediated anti-cancer effect against B-cell malignancies when combined with rituximab or avelumab, given the strong support from our preclinical programs, merits further evaluation in clinical trials to evaluate the safety and preliminary efficacy of CD19.t-haNK in subjects with relapsed or refractory DLBCL.

***Development Plan.***

***QUILT 3.061*** is an open-label phase I study that will assess the safety and preliminary efficacy of increasing doses of CD19.t-haNK monotherapy and determine the maximal feasible dose and designate the recommended phase II dose in subjects with diffuse large B-cell lymphoma who have progressed through two or more lines of therapy and are ineligible for transplant or CAR-T therapy. This first clinical trial for our CD19.t-haNK product candidate cleared FDA review last year for study initiation. The study will be conducted in two parts: the first being a standard dose escalation protocol using a 3 + 3 design, and the second, an expansion of the highest dose level with acceptable toxicity, to further characterize safety and efficacy.

Results from the trial will help us characterize the pharmacokinetic and pharmacologic profiles for CD19.t-haNK, generate preliminary estimates of efficacy in terms of objective response rate, progression-free survival, and overall survival, and help us assess tumor molecular profiles, as well as therapy-induced changes in immune responses and their correlations with subject outcomes. Additional study details have been posted to clinicaltrials.gov.

***Additional Potential t-haNK Product Candidates.***

Depending on the results obtained from our current clinical trial strategy, additional t-haNK product candidates currently advancing through pre-clinical development, including our EGFR and BCMA t-haNK programs, may be rapidly moved into first-in-human trials followed by disease and molecular marker specific studies.

***Registration Trials for haNK and PD-L1.t-haNK***

***Phase II 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 the checkpoint inhibitor avelumab, without chemotherapy in subjects that have progressed after treatment with a checkpoint inhibitor for Merkel cell carcinoma. This trial, which has already started enrolling, will be evaluating the objective response rate using Response Evaluation Criteria in Solid Tumors 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. Additional study details have been posted to clinicaltrials.gov.

This triple combination of immunotherapies has been safely studied in our NCV 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 is likewise observed in both *in vivo* and *in vitro* models.

***Merkel Cell Carcinoma.*** Merkel cell carcinoma, or MCC, 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.

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

***QUILT 88*** is a phase II/III open-label, randomized, two-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 two 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; and

B. Second or later-line therapy and within each cohort, enrolled subjects will be randomly assigned to receive 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.

Cohort A will serve as the phase II portion of the trial and will have three experimental arms, which allows for separate assessment of successively adding only aldoxorubicin, aldoxorubicin and N-803 and aldoxorubicin, N-803 and PD-L1.t-haNK. Cohort B would serve as the phase III potion of the trial. Safety and progression-free survival will be compared between the group using Response Evaluation Criteria in Solid Tumors Version 1.1 based on Blinded Independent Central Review. The IND has been filed and study details will be posted to clinicaltrials.gov upon FDA clearance.

***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 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 stage at diagnosis of 37% for localized, 12% for regional, 3% for distant, and 9% for all SEER stages combined.

***Phase IIb Second-Line or Greater Non-Small Cell Lung Cancer***

***QUILT 3.055*** is a phase IIb, open label study of PD-L1.t-haNK, N-803 and a checkpoint inhibitor in subjects with non-small cell lung cancer that have confirmed disease progression by investigator assessment per Immune-related Response Evaluation Criteria in Solid Tumors, or irRECIST, during treatment on-study with N-803 and a checkpoint inhibitor. This is part of a larger trial that initially utilizes N-803 and a checkpoint inhibitor for subjects who have progressed after an initial response to checkpoint inhibitor therapy. Safety and objective response rate defined as investigator-assessed complete response + partial response per Response Evaluation Criteria in Solid Tumors Version 1.1 based on Blinded Independent Central Review and secondarily per irRECIST will be determined. The IND amendment has been cleared by the FDA and study details will be posted to clinicaltrials.gov in due course.

***Phase III First and Second-Line Non-Small Cell Lung Cancer***

***QUILT 59*** is a phase III open-label, randomized, three-cohort study of standard-of-care therapy in combination with PD-L1.t-haNK, N-803 and a checkpoint antibody versus standard-of-care chemotherapy alone for first and second line treatment of subjects with locally advanced or metastatic squamous and non-squamous non-small cell lung cancer. The three-cohorts include:

A. Squamous first-line therapy;

B. Non-squamous first-line therapy; and

C. Squamous and non-squamous second-line therapy.

Within each cohort, enrolled subjects will be randomly assigned to receive PD-L1.t-haNK, N-803 and a checkpoint antibody with standard-of-care in the experimental arms or standard-of-care only in the control arms. Safety and progression-free survival will be compared between the group using Response Evaluation Criteria in Solid Tumors Version 1.1 based on Blinded Independent Central Review. Preparations are being made to file this IND and study details will be posted to clinicaltrials.gov shortly after FDA clearance.

***Non-Small Cell Lung Cancer.*** Lung cancer is the second most common cancer. About 222,500 new cases will be diagnosed this year. Non-small cell lung cancer, or NSCLC, is often insidious, producing no symptoms until the disease is well advanced. NSCLC makes up about 80% to 85% of all lung cancers. The three main types of NSCLC are squamous cell carcinoma, and non-squamous cell carcinoma, consisting of adenocarcinoma and large cell carcinoma. Adenocarcinoma is the most common form of lung cancer in the U.S, among both men and women. Squamous cell carcinoma, is the second most prevalent, accounting for 25% of all lung cancers. Large cell carcinoma is the smallest, accounting for approximately 10% of NSCLC tumors. Early recognition of symptoms may be beneficial to outcome. At initial diagnosis, 20% of patients have localized disease, 25% of patients have regional metastasis, and 55% of patients have distant spread of disease. Symptoms depend on the location of cancer.

The five-year survival rate for NSCLC is 24%. However, it is important to note that survival rates depend on several factors, including the subtype of lung cancer, and the stage of disease. For people with localized NSCLC, which means the cancer has not spread outside of the lung, the overall five-year survival rate is 61%. For regional NSCLC, which means the cancer has spread outside of the lung to nearby areas, the five-year survival rate is approximately 35%. If the cancer has spread to distant parts of the body, called metastatic lung cancer, the five-year survival rate is 6%. But because of new effective treatments, this number is changing, although better therapies are acutely needed.

***Phase II First and Second Line Locally Advanced or Metastatic Triple Negative Breast Cancer***

***QUILT 3.069*** is a phase II randomized, two-cohort study of PD-L1.t-haNK, N-803, aldoxorubicin and a checkpoint inhibitor in combination with standard-of-care therapy versus standard-of-care alone for first and second line treatment of subjects with locally advanced or metastatic triple-negative breast cancer, or TNBC. The two cohorts include:

A. First-line TNBC therapy; and

B. Second-line TNBC therapy.

Within each cohort, enrolled subjects will be randomly assigned to receive PD-L1.t-haNK, N-803 aldoxorubicin and a checkpoint antibody with standard-of-care in the experimental arms or standard-of-care only in the control arms. Safety and progression-free survival per Response Evaluation Criteria in Solid Tumors, or RECIST, Version 1.1, based on Blinded Independent Central Review, or BICR, will be compared across all treatment groups. Preparations are being made to file this IND and study details will be posted to clinicaltrials.gov shortly after FDA clearance.

***Triple Negative Breast Cancer.*** Breast cancer is the most common cancer among women in the U.S., the second most common cause of cancer death, and the main cause of death in women ages 45 to 55 years. In 2009, approximately 192,370 women in the U.S. were diagnosed with breast cancer, and an estimated 40,170 women died of the disease. TNBC accounts for approximately 15% of all breast cancers. Of these TNBC cases, about 75% are "basal-like." TNBC is a subtype of breast cancer that lacks expression of the estrogen receptor, or ER, and progesterone receptor, or PR, and does not overexpress the human epidermal growth factor 2 receptor, or HER2, protein. TNBC is an important area of research for both researchers and clinicians alike because:

i. TNBC is a poor prognostic factor for disease-free and overall survival;

ii. No effective specific targeted therapy is readily available for TNBC;

iii. There is a clustering of TNBC cases in premenopausal women and in women of African descent; and

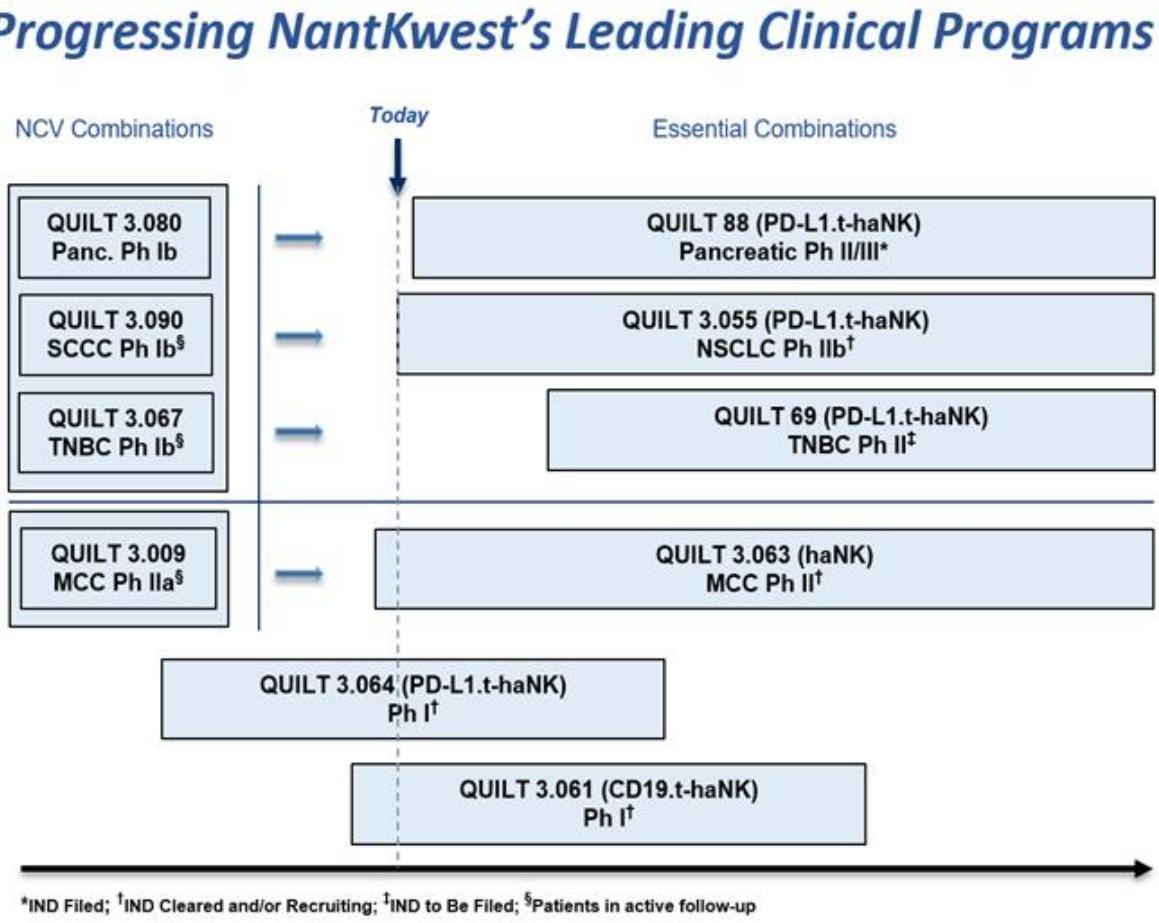
iv. The overlap of BRCA1-associated breast cancers with the TNBC phenotype is significant.

The prevalence of TNBC is highest in premenopausal African American women. A recent report notes that 39% of all African American premenopausal women diagnosed with breast cancer are diagnosed with TNBC. The prevalence of TNBC in this same age group in non-African American women is much lower, at approximately 15%. After adjusting for age and stage at diagnosis, African American women were almost three times more likely than white women to have triple-negative tumors. These ethnic or menopausal differences are not seen in either the ER+/HER2+ breast cancer subgroup or the ER+/HER2– subgroup. Five-year relative survival rates for triple-negative breast cancer by SEER stage at diagnosis are 91% for localized, 65% for regional, and 11% for distant.

Triple-negative breast cancer has fewer treatment options than other types of invasive breast cancer. This is because the cancer cells do not have the estrogen or progesterone receptors or enough of the HER2 protein to make hormone therapy or targeted drugs work. If the cancer has not spread to distant sites, surgery is an option. Chemotherapy might be given first to shrink a large tumor followed by surgery. It might also be given after surgery to reduce the chances of the cancer coming back. Radiation might also be an option depending on certain features of the tumor.

Because hormone therapy and HER2 drugs are not choices for women with TNBC, chemotherapy is often used. In cases where the cancer has spread to other parts of the body (i.e., stage IV) chemotherapy and other treatments that can be considered include PARP inhibitors, platinum chemotherapy, or immunotherapy.

***NantKwest's Ongoing Clinical Trials Activities:***




***Potential Development Catalysts for Driving Value:***

By virtue of parallel development of a range of products derived from our versatile NK cell platform in a variety of disease settings, numerous potential catalysts have emerged as value drivers for our business:

Early indicators of efficacy:

- Merkel cell cancer complete responses to aNK therapy;
- Lung cancer responses to aNK therapy;
- Triple negative breast cancer complete responses to haNK therapy;
- Pancreatic cancer complete response to PD-L1.t-haNK therapy.

Products:

- PD-L1.t-haNK in phase II and IIb trials for pancreatic cancer, non-small cell lung cancer and triple-negative breast cancer;
- haNK in phase II for Merkel cell cancer;
- CD19.t-haNK in phase I for diffuse large B-cell lymphoma;
- HER2.t-haNK IND-ready for HER2 expressing cancers;
- EGFR.t-haNK and BCMA.t-haNK in preclinical for EGFR and BCMA expressing cancers, respectively.

Exclusive Commercial License:

- We are an early investor and shareholder in Viracta Therapeutics, Inc., or Viracta, and an exclusive licensee of its novel class 1 histone deacetylase inhibitor, or HDACi, nanatinostat, which holds both Orphan Drug and Fast Track Designations from the FDA and is currently in a phase II clinical trial in combination with valganciclovir for patients with Epstein-Barr virus associated lymphomas. Being an HDACi, nanatinostat acts as an epigenetic activator, inducing cold tumors to express immunogenic proteins, thereby rendering them as immunologically recognizable by an activated immune system for elimination. As an easy to administer, short-acting oral agent, nanatinostat is potentially an ideal agent to use in combination with our NK therapies. Our worldwide exclusivity includes the conduct of research, development and commercial sale of nanatinostat in combination with NK cell therapies. We plan to explore therapeutic combinations of nanatinostat for patients with EBV, CMV and HPV associated malignancies, including nasopharyngeal, gastric, breast and cervical cancers and diffuse large B-cell lymphoma.

***Potential Regulatory Catalysts for Driving Value*:***

## Nantkwest Regulatory Forecast for Next Four Years

### Anticipated BLA Registration Filings 2021 - 2024

| Tumor Types & Indications | | Filing Date Forecast* | Agents | # of Sites | Status |
|---|---|---|---|---|---|
| Pancr. | **Metastatic Pancreatic Cancer:** Phase II/III, 2nd Line | 2024 | PD-L1.t-haNK | To Be Opened | IND Cleared |
| Lung | **Non-Small Cell Lung Cancer:** Phase IIb, 2nd Line | 2021 | PD-L1.t-haNK | Multiple Sites | IND Amendment Filed |
| MCC | **Merkel Cell Carcinoma:** Phase II, 2nd Line | 2023 | haNK + Anti-PD-L1 | 3 Active Sites | Recruiting |
| TNBC | **Triple Negative Breast Cancer:** Phase II, 1st & 2nd Line | 2022 | PD-L1.t-haNK | To Be Opened | IND Pending |

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

Additional information can be found in the corporate slide deck presented at the 38th annual J.P. Morgan Healthcare Conference on January 14, 2020 at https://ir.nantkwest.com/static-files/77614f06-5c1f-4c42-8761-b4d2f382425c.

***Coronavirus Related Activities:***

Global events relating to the spread of SARS-CoV-2 infections, which initially emerged late in 2019 and evolved rapidly into a widespread pandemic, has captured our attention as a unique opportunity to assist our state and country with developing therapies for patients with moderate to severe respiratory infections. Since February 2020, we have been formulating what we believe to be the best approach to study one or more of our clinical candidates, with the objective of hastening the resolution of symptoms, shortening the duration of viral shedding, lessening the burden of intensive care demand, advancing our understanding of this disease, and bridging the health care system to a time when we will have an adequate vaccine deployed around the world. As early clinical data on COVID-19 patients are being published, we are coming to a better understanding of the associated immunology for patients with moderate and severe disease as well as for convalescent patients.

A clearer patient narrative has only recently been forming, with clinical presentations of mild to severe disease associated with elevated neutrophil counts and markedly depressed NK and CD8+ T-lymphocyte counts that is in direct proportion with the severity of disease. Moreover, analysis of these NK and CD8+ T-lymphocytes reveal that they are functionally exhausted, meaning that they could no longer carry out target cell killing in a standardized assay. Interestingly, the natural killer cells also exhibited a high level of expression of the inhibitory receptor, NKG2A, and reduced expression of interferon-γ, or IFN-γ; interleukin-2, or IL-2; and granzyme B, or GzB; all of which are associated with exhaustion of chronic viral infection. Convalescent patients were found to have their NK and CD8+ T-lymphocyte numbers restored, reduced NKG2A expression and normalized expression of IFN-γ, IL-2 and GzB. Similar data was reported in patients with SARS-CoV viral infections during the 2003 outbreak.[13] These finding are indicative of a SARS-CoV-2 induced impairment of the innate immune antiviral response at an early stage of disease.[14]

Mechanistic research on both SARS-CoV, and MERS-CoV from the 2012 outbreak, paint the picture of a molecular arms race between host innate antiviral response and human coronavirus adaptations of evasion. MERS-CoV, for instance, induces repressive histone modifications to downregulate specific subsets of interferon-stimulated genes, or ISGs, which are responsible for establishing an 'antiviral state' in the cells that is effected through viral-RNA cleavage enzymes and IFN production. Both SARS and MERS CoVs have been reported to suppress IFN production and signaling pathways through these and other mechanisms, particularly in patients with severe diseases. When this was recreated in the laboratory setting and the deficiency in IFN-α production in CoV-infected cells was remedied by IFN-α treatment, CoV replication was inhibited.[15] This, together with other accumulated data, leads us to better understand the essential role of interferons in the anti-viral effect against CoV infection.

The administration of haNK cells following the infusion of IgG SARS-CoV-2-neutralizing antibodies obtained from the serum of convalescent patients could accomplish several things for patients with moderate to severe disease due to SARS-CoV-2 infection. Firstly, it could immediately supplement patients with ADCC-competent, 'non-exhausted' natural killer cells in numbers that approximate the body's otherwise normal natural killer cell levels. These natural killer cells are fully capable of expressing and potentially delivering IFN-γ, IL-2, and GzB to the site of infected organs to facilitate immune recruitment and adaptive responses. The neutralizing antibodies from convalescent serum could supplement the patient's humoral response, coat the CoV infected cells and mediate ADCC killing between it and the administered haNK cells. The overall objective is to shift the balance of the molecular arms race in favor of the patient's innate immune responses, thereby enabling more patients to recover. With our clinical supply of cryopreserved haNK dose forms in storage and available for on-demand clinical research use, we are well positioned to initiate trials rapidly.

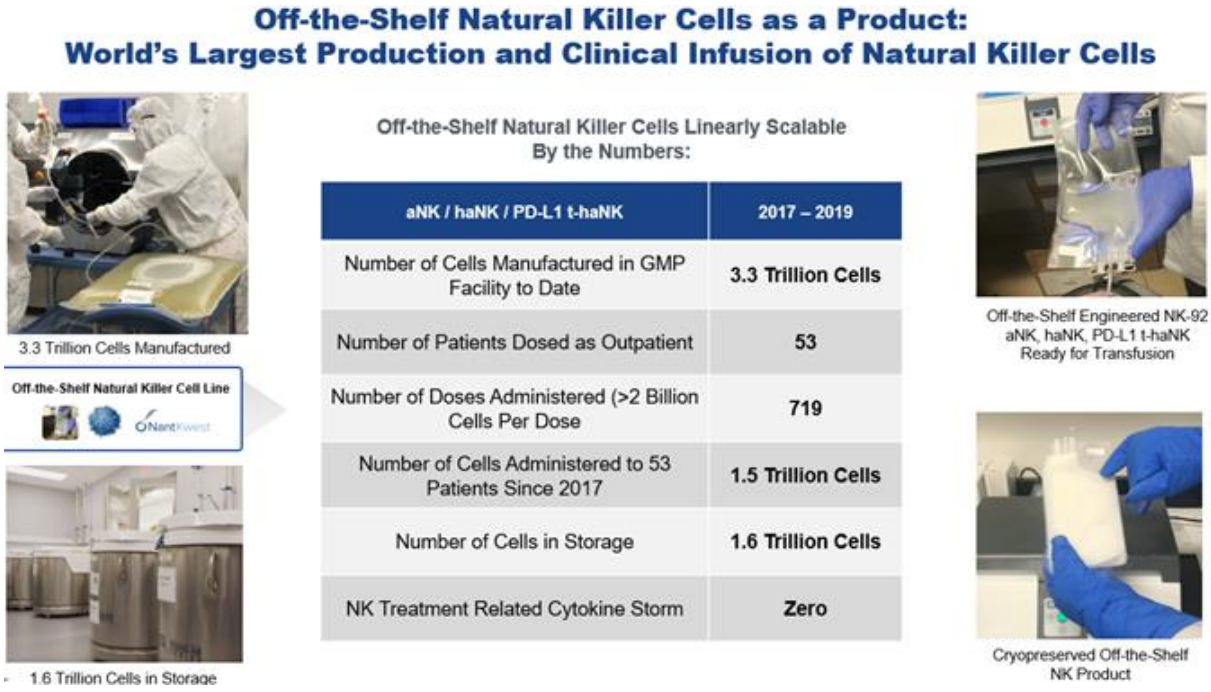
13 Zheng, M., et al. Cellular & Molecular Immunology, 2020

14 Am J Clin Pathol, 2004. 121(4): p. 507-11

15 Wong, L., et al. Virologica Sinica 2016. 31 (1): 12-23

**Achievements in Process Development, Scale-Up Manufacturing and Clinical Supply**

Manufacturing has continued to be one of our fastest growing functions in 2019. We made significant strides throughout the year in all of our core manufacturing and ancillary operational areas, including process development, scale-up manufacturing, materials sourcing, completion and certification of production facilities, pipeline buildup of cryopreserved and ready to infuse clinical product, all the way through and including clinical trial supply. An extensive patent portfolio of manufacturing methods applications has been filed to protect this body of pioneering work, which will serve as an added layer of protection to our existing patent estate.

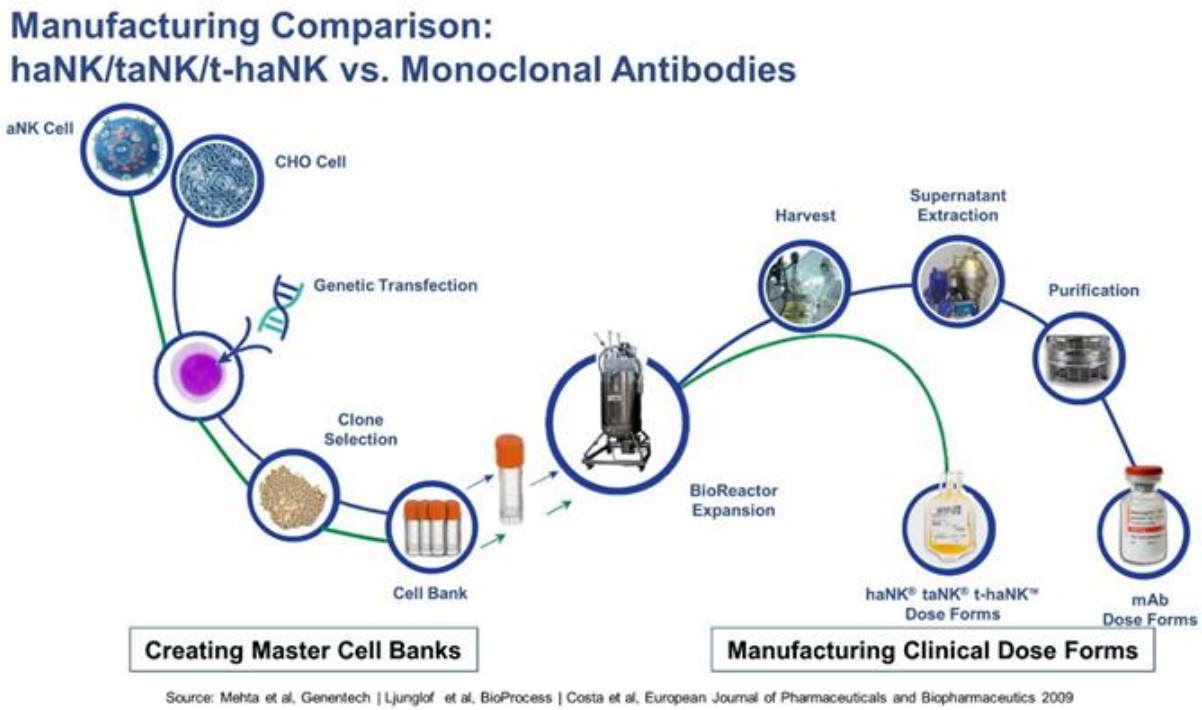



We have been qualifying, releasing and storing frozen clinical dose forms of haNK from the fourth quarter of 2017 through the fourth quarter of 2018 and PD-L1.t-haNK since the first quarter of 2019. Shelf-life stability for frozen haNK now exceeds two years, which has enabled us to accumulate an inventory of product large enough to satisfy in its entirety our QUILT 3.063 phase II Merkel cell carcinoma trial in an immediate, on-demand basis. Upon shipping receipt, clinical sites simply thaw the frozen product in a warming bath prior to infusion. We believe such simple clinical site requirements for product administration would expand patient accessibility well beyond select certified hospital centers into community outpatient practices and potentially into physician's offices. Developing the capability to freeze and thaw our cell therapy product while preserving optimal viability and potency was a key goal that we both achieved and continue to refine as we further scale our operations. Our therapeutic platform is flexible and thus our investments in developing manufacturing capabilities have been designed with the ability to introduce new variants of our cellular products quickly. Having developed core capabilities for the successful cryopreservation and recovery of our cellular products, we believe we are now well positioned to implement simpler and more cost effective storage and shipping procedures to supply clinical sites that are located thousands of miles from our production facility.

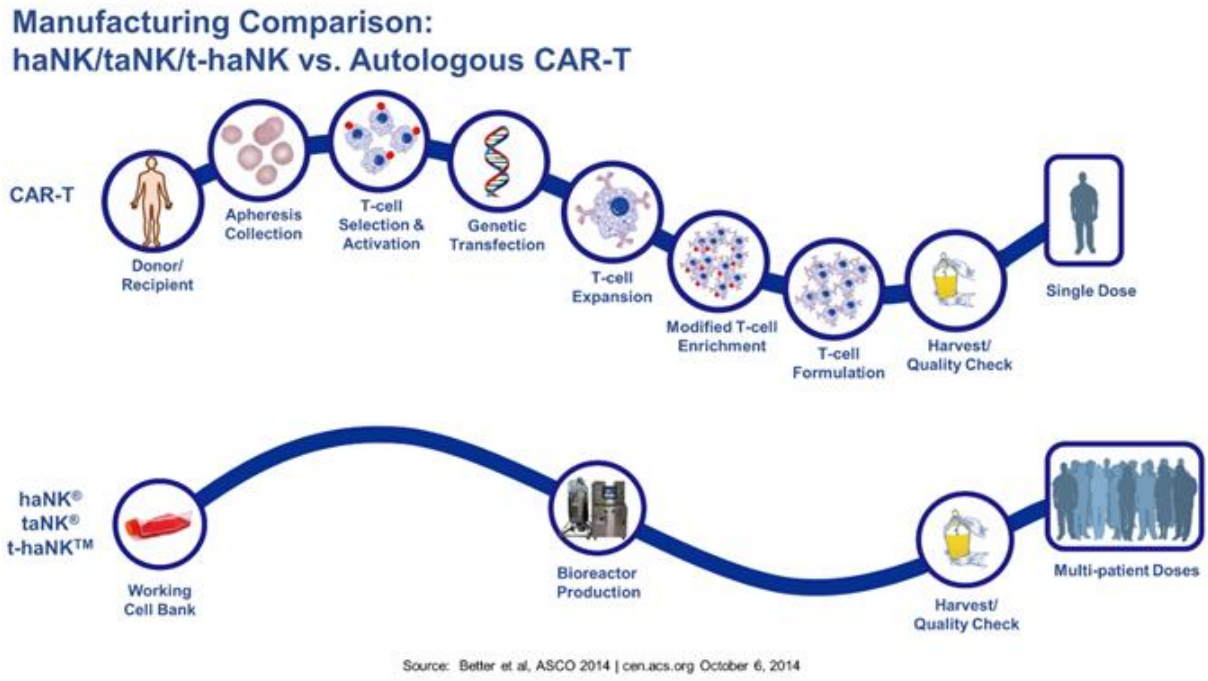

We believe we have unique processing and production capabilities that will enable us to leverage our investments in in-house operations to produce our cell therapy products at commercial scale. These capabilities will enable us to reduce our cost of goods sold and realize significant economies of scale. Further, the flexibility of these capabilities to apply to a wide range of new variants of our aNK cells will allow for more rapid scaling of our newly emerging t-haNK products from our pipeline and the initiation of a new series of clinical programs.

***The Production Process***

Our aNK platform production process largely resembles the widely used monoclonal antibody manufacturing process, without the laborious extraction and purification steps at the end, and bears the least resemblance to that of autologous CAR-T cell manufacturing. The figure below illustrates the key steps involved with master cell bank establishment, often starting with a Chinese hamster ovary, or CHO, cell line, in the case of antibody products and with an aNK cell line in the case of haNK, taNK and t-haNK products. Both utilize genetic engineering to achieve the desired clones, which after selection, are expanded to create master cell banks. From this point, a culture can be initiated from a single vial from the bank that will eventually be able to fill a bioreactor. In both cases, such a bioreactor can run for months with multiple harvests over the course of the culture. In the case of antibody products, it is the antibody-rich supernatant that must be separated from the cell culture and then purified before making the bulk product. In the case of haNK, taNK and t-haNK products, the cell culture is itself the product that simply requires centrifugation and washing before making the final dose forms. A single bioreactor can produce a significant number of doses that can be used to treat many patients.



The panel below compares the key steps in the manufacture of autologous CAR-T therapy with that of haNK, taNK and t-haNK. CAR-Ts have a high per-unit manufacturing cost due to a series of complex processes, including harvesting T-cells from patients in an invasive procedure called leukapheresis. Once the T-cells have been adequately collected, they are sent to the manufacturing facility for individualized processing that starts with genetic engineering and expansion in a dedicated cGMP clean room. Then, through an elaborate series of procedures, the cells are selected using bead removal before a single dose form is prepared and returned to the hospital for infusion back into the original patient. By contrast, the manufacture of our allogeneic "off-the-shelf" haNK, taNK and t-haNK cells involves a rapid, scalable and cost efficient process where cells from a master cell bank vial are grown in a bioreactor and, once ready to harvest, the cells are centrifuged and washed before placement into final dose forms. One vial from the master cell bank can potentially produce thousands of cryopreserved dose forms that would be available on-demand, without the typical two- to three week delay in orchestrating the logistics and preparation involved when using the CAR-T method.




***Building Out Our Manufacturing Capabilities***

Over the past year our process and manufacturing teams have worked diligently to further scale our operations to meet the anticipated commercial demand for our therapeutic products ahead of achieving regulatory approvals. The development of this capability has been key to ensure not just sufficient supply for our current and planned clinical trial operations, but also to ensure that we will be able to build an ample inventory of product to meet commercial demand, as well as to realize economies of scale for our pipeline of products being readied for the clinic.

While we initially relied upon external manufacturers, we found that to create a scalable product with a reliable and cost effective clinical supply capability, we needed to build a state of the art cGMP facility for the manufacture of all our cellular therapeutics. In order to ensure uninterrupted clinical supply, we implemented a dual-stage strategy. In the initial stage, we established a pilot cGMP manufacturing facility at our Culver City, California, site and for the second stage we simultaneously built out an approximately 24,250 square foot commercial cGMP facility in El Segundo, California. We completed the El Segundo facility buildout in May 2018 and subsequently outfitted and prepared the facility for commercial scale manufacturing and initiated clinical production of PD-L1.t-haNK at this facility starting in the first quarter of 2019.

Our initial production capabilities involved limited production of the cells in flasks and gas-permeable chambers. By 2016, our company possessed limited laboratory capabilities, as we were still dependent upon university partners and contract manufacturers for all of our cell production capabilities. While these did not yet involve bioreactors, they were sufficient to meet the limited clinical demands for our studies at the time. This foundational work was in part performed using the early production capabilities at Baylor University's Cell and Gene Therapy Center, in addition to Northwestern University, and a global contract manufacturing vendor. We recognized the serious limitations and inherent risks in relying on external manufacturing sources, including competition for timely slots for external production runs, exorbitant rising costs, reliance on untrained operators, the need to establish contract manufacturing redundancy in the event of a vendor failure and serious limitations in our ability to achieve consistent scale production. We therefore committed to a strategy of in-sourcing this core capability and have long since achieved this goal.

We commenced production operations at our pilot facility in Culver City, California in 2017. It was there that we initialized our in-house cGMP small-bioreactor program for our haNK product, as we progressed production from smaller bioreactor batches to larger ones. In tandem with this improvement in manufacturing capacity, we also established and refined a process to cryopreserve our cell product in ready-to-infuse bags and then integrated it with our main process into a single production line.

**2017 Pilot Manufacturing**

In 2018, we further increased the scale of our operations twice more by utilizing intermediate-sized bioreactor technologies and were able to outpace demand for clinical drug product while building an inventory of frozen product for future use. In anticipation of increased clinical trial enrollment for 2019, in the final months of 2018 we transferred clinical production operations from our pilot facility in Culver City to our new commercial facility in El Segundo. At present, we are operating fully independent of external manufacturing contractors and partners and have since realized significant improvements in quality, cost, time and reliability.

## 2018 Intermediate Phase Manufacturing

In 2019, we implemented our next larger-scale bioreactor technology in El Segundo, the procedures for which were developed and optimized at our process development facility in San Diego, California in 2018. This upgrade substantially improved our economies of scale, with higher production rates within the same footprint, while being less labor intensive, just as demand for clinical drug product increased. We now have the capability to continue to scale up ahead of increasing clinical demands through regulatory approval. We believe that developing even larger capacity bioreactors will allow us to scale well beyond regulatory approval from a central location, while meeting commercial drug product demands nationwide, as well as ultimately on a global scale.

***Manufacturing of Our t-haNK Product Candidates***

In 2018 and 2019, we developed manufacturing processes for our two lead products from our t-haNK platform, PD-L1.t-haNK and CD19.t-haNK, as well as for Her2.t-haNK and EGFR.t-haNK, at our approximately 44,700 square foot process development facility in San Diego. Adding to our already robust patent portfolio, we filed numerous patents protecting innovative methods and modifications to our bioreactor production procedures, media formulations, additives, special cryopreservation procedures and many other components that address the inherent challenges unique to large scale NK cell production. We believe this places NantKwest at a unique competitive advantage as a leader in commercial scale manufacturing of NK cell products.

***Present Day Manufacturing of Our NK Products***

This year, we have been in production of our PD-L1.t-haNK product, building a clinical supply of product ahead of anticipated demand from our mid- to late-stage clinical trials and Expanded Access Program. This will ensure that ready-to-infuse clinical dose forms are available on-demand at all our clinical testing centers.


**Competition**

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. We believe that our base proprietary aNK platform, differentiated haNK, taNK and t-haNK product candidates, strategic collaborations and cell-based immunotherapy expertise may provide us with competitive advantages. However, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions. The key competitive factors affecting the success of any approved product will include its efficacy, safety profile, pricing, and method of administration, as well as the level of promotional activity invested in it.

Our haNK, taNK and t-haNK product candidates will compete with other cell and molecule-based immunotherapy approaches using and/or targeting natural killer cells, T-cells and dendritic cells. Competitors focused on CAR-T related treatment approaches include AbbVie Inc., Atara Biotherapeutics, Inc., Intrexon Corporation, Allogene Therapeutics, Inc., Bristol-Myers Squibb Company, 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., CARsgen Therapeutics, Nanjing Legend Biotechnology Co., Ltd, Cartherics Pty Ltd, Novartis AG, Pfizer, Inc., Cellectis SA, Poseida Therapeutics, Inc., Celularity, Inc., Servier Laboratories, Celyad SA, Takeda/Shire, Fortress Biotech, Inc., TC BioPharm Ltd., Gilead Sciences, 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, GlaxoSmithKline plc., Green Cross LabCell Corp., 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., 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., Intrexon Corporation, Medigene AG, and Northwest Biotherapeutics, Inc.

Competitor companies focused on natural killer cell based approaches include 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., 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.

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.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, as well as significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective, or more effectively marketed and sold, than any treatment we may commercialize, and they may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our treatments.

Mergers and acquisitions in the biotechnology and pharmaceutical 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 study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or clinical-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new therapies enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have a better safety profile, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our therapeutic products, if approved, will be priced at a significant premium over competitive generic products and our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

**Intellectual Property**

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the U.S. and in jurisdictions outside of the U.S. related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. We seek to consistently file follow-on patent applications on further improvements and features of our NK cell-based products, thereby adding additional layers of protection and reducing reliance on our original patents that would be the earliest to expire and may be subject to challenge. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of natural killer cell-based immunotherapy. We expect to rely on data exclusivity, market exclusivity, patent term adjustments and patent term extensions when available, as well as on regulatory protection afforded through orphan drug designations. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

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. As of December 31, 2019, our owned and licensed patent portfolio consists of 39 patents and pending patent applications and provisional filings 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 141 licensed and owned patents and pending applications in 24 jurisdictions outside of the U.S., including 24 Patent Cooperation Treaty applications, that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. For example, these patents and patent applications include claims directed to:

- Natural Killer Cell Line Compositions and Methods-of-Use;
- Treatment of Cancer using Natural Killer Cell Lines;
- Treatment of Specific Diseases using Natural Killer Cell Lines;
- Combination Therapy using Natural Killer Cell Lines;
- CD16 Modified Natural Killer Cell Line Compositions and Methods-of-Use;
- CD16 Modified Natural Killer Cell Line with Monoclonal Antibodies for Treatment of Cancer;
- CAR-Expressing Natural Killer Cell Line Compositions and Methods-of-Use;
- CD16 Modified and CAR-Expressing Natural Killer Cell Line Compositions and Methods-of-Use;
- Homing and Cytokine Modified Natural Killer Cell Line Compositions and Methods-of-Use;
- Treatment of Viral and Bacterial Diseases using Natural Killer Cell Lines;
- Methods for Expansion, Cryopreservation and Commercial Manufacture; and
- Tumoricidal and Antimicrobial Compositions of Natural Killer Cell Line Derived Exosomes and Methods-of-Use.

As for the NK cell-based immunotherapy products and processes we develop and commercialize, in the normal course of business, we intend to pursue, when possible, composition, method of use, dosing and formulation patent protection. We may also pursue patent protection with respect to manufacturing and drug development processes and technology. The patents and patent applications outside of the U.S. in our portfolio are held primarily in Europe, Canada, Australia, China, Japan and Korea.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the U.S. are effective for 20 years from the earliest effective filing date. The patent term may be adjusted to compensate for delayed patent issuance, when such delays are caused by the patent office or successful appeals against patent office actions. There is no limit on this patent term adjustment. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the U.S. varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. Our issued patents are anticipated to expire at varying intervals through 2036. If patents are issued on our pending patent applications, the resulting patents are projected to expire at various dates through 2039. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunotherapy has emerged in the U.S. The patent situation outside of the U.S. is even more uncertain. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product

candidates and practicing our proprietary technology. Our issued patents and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

As of December 31, 2019, our worldwide trademark portfolio was comprised of (i) 12 U.S. trademark registrations; (ii) one pending U.S. trademark application; (iii) 35 foreign trademark registrations (five of which are Madrid Protocol International registrations); and (iv) five pending foreign trademark applications.

We may also rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For risks related to our proprietary technology, inventions, improvements and products, please see Part I, Item 1A, "*Risk Factors – Risks Related to Intellectual Property*" and "*Legal Proceedings*" of this Annual Report.

***Collaboration Agreements***

*ImmunityBio, Inc.* In January 2020, we entered into a Cost Allocation Agreement, or the Agreement, with ImmunityBio, Inc. and its subsidiaries, or ImmunityBio. The Agreement is effective as of October 1, 2019. ImmunityBio is a related party, as it is an affiliate of NantWorks. Simultaneously, we and ImmunityBio entered into Work Order Number One under the Agreement. Under the Agreement and Work Order Number One, the parties agreed to conduct a joint study, the clinical research trial being conducted pursuant to the protocol titled QUILT 3.063: *A phase 2 study of combination therapy with an IL-15 superagonist (N-803), off-the-shelf CD16-targeted natural killer cells (haNK), and avelumab without cytotoxic chemotherapy in subjects with Merkel Cell Carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor*. The ImmunityBio study drug included in the joint study is ImmunityBio's proprietary IL-15 superagonist known as N-803 and our study drug is our proprietary "off-the-shelf" CD16-targeted natural killer cell therapy known as haNK.

We will act as the sponsor of this joint study for purposes of regulatory matters, including submissions, correspondence, and communications. Additionally, we are designated as the contracting party to execute agreements with third and related parties relating to the joint study under Work Order Number One. We and ImmunityBio will split certain joint study costs equally related to Work Order Number One, in accordance with the terms of the Agreement. Shared joint study costs include cost related to conducting the joint study development activities, such as personnel related costs, as well as all costs associated to regulatory matters. Costs and expenses incurred in connection with the development, manufacturing, supply, delivery, and pre-patient administration dosing mechanism of each party's study drug, are excluded from the shared joint study costs. As of December 31, 2019, there was minimal joint research activity under the Agreement.

Under the agreement, each of ImmunityBio and the company will receive exclusive rights to any new intellectual property developed that relates solely to its respective study drug, and the parties will have joint co-equal rights in any other intellectual property. The Agreement expires upon the second anniversary of the effective date with the option to renew for additional successive one-year terms, but work orders for any joint studies still in process at the time of termination will continue until the applicable study is completed.

*Altor BioScience, LLC.* In August 2016, we entered into an exclusive Co-Development Agreement, or the Co-Development Agreement, with Altor BioScience, LLC, or Altor. Altor is a related party, as it is a wholly owned subsidiary of ImmunityBio. ImmunityBio is an affiliate of NantWorks. Under the Co-Development Agreement, the parties agreed to exclusively collaborate on the development of certain therapeutic applications combining our proprietary NK cells with Altor's N-801 and/or N-803 products with respect to certain technologies and intellectual property rights as may be agreed between the parties for the purpose of jointly developing therapeutic applications of certain effector cell lines.

We are the lead developer for each product developed by the parties pursuant to the Co-Development Agreement unless otherwise agreed to under a given project plan. Under the terms of the Co-Development Agreement, both parties granted a co-exclusive, royalty free, fully paid-up, worldwide license, with the right to sublicense (only to a third-party contractor assisting with research and development activities under this Co-Development Agreement and subject to prior consent, not to be unreasonably withheld), under the intellectual property, or IP, including the parties interest in the joint IP, solely to conduct any development activities agreed to by the steering committee as set forth in any development plan. Unless otherwise mutually agreed by the parties in the development plan for a project, we are responsible for all costs and expenses incurred by either party related to conducting clinical trials and other activities under each development program, including costs associated with patient enrollment, materials and supplies, third party staffing, and regulatory filings. Altor supplies free of charge, sufficient amounts of Altor products for all pre-clinical requirements and certain clinical requirements for up to 400 patients in phase I and/or phase II clinical trials, as required under the development plan for a project per the Co-Development Agreement.

Each company owns an undivided interest in and to all rights, title and interest in and to the joint product rights. The Co-Development Agreement expires upon the fifth anniversary of the effective date. We have dosed patients with N-803, an IL-15 superagonist, in several phase Ib/II trials.

***Licenses***

*Viracta Therapeutics, Inc.* In May 2017, we entered into an agreement with Viracta Therapeutics, Inc., or Viracta, to grant us exclusive worldwide rights to Viracta's phase II drug candidate, VRx-3996, for use in combination with our platform of NK cell therapies. In consideration for the license, we are obligated to pay to Viracta (i) mid-single digit percentage royalties of net sales of licensed products for therapeutic use, and (ii) milestone payments ranging from $10.0 million to $25.0 million for various regulatory approvals and cumulative net sales levels. We may terminate the agreement, in our sole discretion, in whole or on a product-by-product and/or country by country basis, at any time upon 90 days' prior written notice. In addition, either party may terminate the agreement in the event of a material breach or for bankruptcy of the other party.

*Hans G. Klingemann, M.D., Ph.D.* We hold the worldwide rights, title and interest to the NK-92 cell line and we believe that we control commercial use of our NK-92 cells in key territories. We also maintain and exclusively control the only clinical grade master cell bank for NK-92. The original NK-92 cell line was isolated by Hans G. Klingemann, M.D., Ph.D., our founder and Vice President of Research and Development, and all patents and patent applications pertaining to this cell line are now in the name of NantKwest, Inc. or ZelleRx Corporation, our former name. In February 2003, we obtained an exclusive, worldwide license from Dr. Klingemann to the NK-92 cell line, and related NK-92 patents and know-how, that had been assigned to him by the British Columbia Cancer Agency, to manufacture, use and sell products covered by the scope of any valid claim in any of the licensed patents. Dr. Klingemann subsequently assigned the cell line and those patents to us, but we are still obligated to pay a single-digit royalty on sales of licensed products to Dr. Klingemann, as well as to pay the British Columbia Cancer Agency a small percentage of our profits from the sale of the NK-92 cell line that Dr. Klingemann obtained from them.

*Fox Chase Cancer Center.* In July 2004, we entered into an exclusive license agreement with Fox Chase Cancer Center, or Fox Chase, pursuant to which we were granted an exclusive, worldwide, sublicensable license under certain patents and know-how pertaining to CD16 receptors-bearing NK-92 cell lines. We agreed to pay Fox Chase low single-digit royalties on sales of licensed products. We are also obligated to pay Fox Chase a percentage of the royalties and other compensation we receive from sublicensees of our rights from Fox Chase. Fox Chase is obligated to assign the licensed patents to us if we commence a phase III clinical trial of a licensed product and, if this does not occur, our license expires when the last of the licensed patents expires.

*Rush University Medical Center.* In March 2004, we entered into a license agreement with Rush University Medical Center, or Rush, pursuant to which Rush granted us an exclusive, worldwide, sublicensable license to certain intellectual property related to clinical use of NK-92 to develop and commercialize products and processes for the treatment of melanoma and renal cancer, or for the diagnosis or treatment of non-melanoma and non-renal cancer. In consideration for the license, we were obligated to pay to Rush single-digit royalties on sales of licensed products with a minimum royalty payment of $25,000 per year. The agreement also provided for payments upon completion of certain clinical, regulatory and commercialization milestones. We also agreed to pay to Rush a portion of certain payments that we receive under sublicensing arrangements. The license had a term of 12 years from 2006, the year in which royalty payments were first made, and included customary termination rights for both parties. Beginning in 2018, this license converted to a perpetual, irrevocable, fully paid royalty-free, exclusive license.

*University Health Network.* In May 2005, we entered into a license agreement with University Health Network, or UHN, pursuant to which we obtained from UHN an exclusive, worldwide, sublicensable license to certain intellectual property relating to NK-92 clinical trials data from UHN to develop and commercialize products and processes for the diagnosis and treatment of certain hematological malignancies. Our license from UHN will automatically expire if we have not filed for regulatory approval or launched a licensed product within specified periods of time, and also includes other customary termination rights for both parties.

***Joint Development and License Agreements***

*Intrexon Corporation.* In February 2010, we entered into a 17-year agreement with Intrexon Corporation, or Intrexon, pursuant to which we granted to Intrexon a worldwide, sublicensable license which may be exclusive with respect to certain indications designated by Intrexon, under certain patents relating to NK-92 cells to develop and commercialize modified NK-92 cells that express Intrexon's proprietary gene sequences for use as therapeutic and prophylactic agents in humans in specified therapeutic areas. Intrexon paid us a one-time license fee and is also obligated to pay non-material milestone payments with respect to specific indications, a royalty on net sales of the licensed products and a portion of the revenue Intrexon receives from third party sublicensees of its rights from us. Intrexon has the right to terminate the agreement upon 180 days' notice and both parties have the right to terminate the agreement for the other's uncured breach of the agreement.

We have licensed or sub-licensed our cell lines and intellectual property to numerous other pharmaceutical and biotechnology companies for non-clinical uses such as laboratory testing. Such licenses generally require the licensee to pay an upfront fee and annual research and commercial fees for products sold using our intellectual property and cell lines.

***Supply Agreements***

In 2018, we entered into various supply agreements with third parties to provide investigational agents to be used in our clinical trials.

***Anticipated Agreements and Considerations***

In addition to the collaboration and license agreements discussed above, we may enter into a commercial agreement relating to an IL-15 superagonist product developed by an affiliate, and we are also pursuing certain strategic research and/or license agreements with third parties to develop our candidate pipeline. These types of 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, if Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, any affiliated entities may be unwilling to continue their relationships with us on commercially reasonable terms, or at all, which in turn may impede our ability to control the supply chain for our combination therapies.

**Government Regulation**

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or cGLP, regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee for each clinical site before the clinical trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application, or BLA, after completion of all required clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigational sites to assess compliance with current Good Clinical Practices, or cGCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S., which must be updated annually and when significant changes are made.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

When a clinical trial using genetically engineered cells is conducted at, or sponsored by, institutions receiving National Institutes of Health, or NIH, funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the study is registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, and many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The NIH is responsible for convening the Recombinant DNA Advisory Committee, or RAC, a federal advisory committee that discusses protocols that raise novel or particularly important scientific, safety, or ethical considerations at one of its quarterly public meetings. The OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public. If the FDA allows the IND to proceed, but the RAC decides that full public review of the protocol is warranted, the FDA will request at the completion of its IND review that sponsors delay initiation of the protocol until after completion of the RAC review process.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, the initial human testing is often conducted in patients.
- *Phase II.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase III.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.
- *Phase IV.* In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called phase IV studies may be made a condition to approval of the BLA.

Phase I, phase II and phase III testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the Public Health Service Act, or PHSA, emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

***BLA Submission and Review by the FDA***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is subject to annual product and establishment user fees. These fees typically increase annually. A waiver of user fees may be obtained under certain limited circumstances.

Within 60 days following submission of the application, the FDA reviews a BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been filed, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter, a complete response letter, or a not approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or other restrictions to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more phase IV post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of ten months after the FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established breakthrough therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of, or any time after, the submission of an IND, but ideally before an end-of-phase II meeting with the FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller or more efficient clinical trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis. We may seek designation as a breakthrough therapy for some or all of our product candidates.

Fast track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

***Orphan Drugs***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the U.S., or a patient population greater than 200,000 individuals in the U.S. and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

***Post-Approval Requirements***

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, reporting of adverse experiences, periodic reporting, distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and any third-party manufacturers that we may decide to use. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us, and any third party manufacturers, that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA.

Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

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

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

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, and exclusion from participation in governmental health programs, like Medicare and Medicaid. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

***Other Healthcare Laws and Compliance Requirements***

Our sales, promotion, medical education, clinical research and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the U.S. in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs must comply with the federal Anti-Kickback Statute, the False Claims Act, physician payment transparency laws, privacy laws, security laws, and additional federal and state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the knowing and willing, direct or indirect offer, receipt, solicitation or payment of remuneration in exchange for or to induce the referral of patients, including the purchase, order or lease of any good, facility, item or service that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. The government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Many states have similar laws that apply to their state health care programs, as well as private payors.

Federal false claims and false statement laws, including the federal civil False Claims Act, or FCA, imposes liability on persons or entities that, among other things, knowingly present or cause to be presented claims that are false or fraudulent or not provided as claimed for payment or approval by a federal health care program. The FCA has been used to prosecute persons or entities that "cause" the submission of claims for payment that are inaccurate or fraudulent, by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, submitting claims for services not provided as claimed, or submitting claims for services that were provided but not medically necessary. Actions under the FCA may be brought by the Attorney General, or as a qui tam action by a private individual, in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, certain companies that were found to be in violation of the FCA have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors; knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; and willfully obstructing a criminal investigation of a healthcare offense. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. In addition, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our products, once commercialized, are sold in a foreign country, we may be subject to similar foreign laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on 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, for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers are required to collect and report detailed payment data and submit legal attestation to the accuracy of such data to the government each year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Additionally, entities that do not comply with mandatory reporting requirements may be subject to a corporate integrity agreement. Certain states also mandate implementation of commercial compliance programs, impose restrictions on covered manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, imposes specified requirements on certain health care providers, plans and clearinghouses (collectively, "covered entities") and their "business associates," relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain states have their own laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other and/or HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, imprisonment, contractual damages, reputational harm, and diminished profits and future earnings, any of which could adversely affect our ability to operate our business and our financial results.

In addition to the foregoing health care laws, we are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar worldwide anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to government officials or private-sector recipients for the purpose of obtaining or retaining business. We adopted an anti-corruption policy in connection with the initial public offering of our common stock in July 2015. The anti-corruption policy mandates compliance with the FCPA and similar anti-bribery laws applicable to our business throughout the world. However, we cannot assure you that such a policy or procedures implemented to enforce such a policy will protect us from intentional, reckless or negligent acts committed by our employees, distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

***Coverage and Reimbursement***

Sales of pharmaceutical products depend significantly on the extent to which coverage and adequate reimbursement are provided by third-party payors. Third-party payors include state and federal government health care programs, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidates, if approved, we cannot be certain of this. Third-party payors are increasingly challenging the price, examining the cost-effectiveness, and reducing reimbursement for medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective and thus may not be covered or sufficiently reimbursed. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payors, as each payor will make its own determination as to whether to cover a product and at what level of reimbursement. Thus, one payor's decision to provide coverage and adequate reimbursement for a product does not assure that another payor will provide coverage or that the reimbursement levels will be adequate. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

***Healthcare Reform***

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. 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. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the Affordable Care Act was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's 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 a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include, among others, the Budget Control Act of 2011, which mandates aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs. 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 modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the pharmaceutical and biotechnology industries as a whole is currently unknown. However, any changes to the Affordable Care Act are likely to have an impact on our results of operations and may have a material adverse effect on our results of operation. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect any future legislation or regulation in the U.S. may have on our business.

***Foreign Regulation***

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the U.S. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

**Employees**

As of December 31, 2019, we had 148 employees. Personnel of related companies who provide corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy and other administrative support services under our shared services agreement with NantWorks are not included in this number. For additional information, see Note 9 – *Related Party Agreements* of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of this Annual Report. Our ability to manage growth effectively will require us to continue to implement and improve our management systems, recruit and train new employees and select qualified independent contractors. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

**Corporate Information**

We were incorporated on October 7, 2002 in the state of Illinois under the name ZelleRx Corporation. On January 22, 2010, we changed our name to Conkwest, Inc. In March 2014, we formed Conkwest, Inc., our wholly owned subsidiary in the state of Delaware, or Conkwest Delaware, for the purposes of changing the state of our incorporation to the state of Delaware. In March 2014, we merged with and into Conkwest Delaware, with Conkwest Delaware surviving the merger. On July 10, 2015, we changed our name to NantKwest, Inc. Our website address is www.nantkwest.com. The contents of our website are not incorporated by reference into this Form 10-K. We provide free of charge through a link on our website access to our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as amendments to those reports, as soon as reasonably practical after the reports are electronically filed with, or furnished to, the Securities and Exchange Commission.

**Item 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as other information included in this Annual Report on Form 10-K, or Annual Report, including our financial statements and the related notes, and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," any of which may be relevant to decisions regarding an investment in or ownership of our stock. The occurrence of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth and ability to accomplish our strategic objectives. We have organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below.*

**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 December 31, 2019, we had an accumulated deficit of approximately $662.2 million. We incurred net losses of $65.8 million, $96.2 million, and $96.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. Our losses have resulted principally from costs incurred in ongoing preclinical studies, clinical trials and operations, research and development expenses, as well as general and administrative expenses.

A critical aspect of our strategy is to invest significantly in expanding our haNK, taNK and t-haNK 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 potential receipt of FDA approval, for our initial commercialization activities. Moreover, we do not expect to have any significant product sales or revenue for a number of 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' equity 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. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

***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 and t-haNK platforms and our product candidates;
- continuing to develop sustainable, scalable, reliable and cost-effective manufacturing and distribution processes for our product candidates, 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 technological and industry developments;

- identifying, assessing, acquiring and/or 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 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;
- identifying, assessing and developing new product candidates;
- 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;
- addressing any competing therapies and technological and market developments; 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' equity 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 December 31, 2019, we had cash and cash equivalents of $15.5 million and marketable debt securities of $37.6 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 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 than we presently anticipate.

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 product candidates;
- the costs of manufacturing, distributing and processing our product candidates and any products for which we receive regulatory approval;
- 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.

***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 and t-haNK 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 and t-haNK 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 and t-haNK 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 and t-haNK 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, gastric, pancreatic, lung, head and neck and colorectal cancers, as well as hematologic malignancies such as indolent B-cell lymphoma, acute lymphoblastic leukemia, or ALL, and diffuse large B-cell lymphoma, or DLBCL.

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. We believe that the data from previous preclinical studies will support the filing of additional INDs, to enable us to undertake additional clinical studies as we have planned. However, 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.

***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 and t-haNK product candidates will compete with other cell and molecule-based immunotherapy approaches using and/or targeting natural killer cells, T-cells and dendritic cells.

Competitors focused on CAR-T related treatment approaches include AbbVie Inc., Atara Biotherapeutics, Inc., Intrexon Corporation, Allogene Therapeutics, Inc., Bristol-Myers Squibb Company, 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., CARsgen Therapeutics, Nanjing Legend Biotechnology Co., Ltd, Cartherics Pty Ltd, Novartis AG, Pfizer, Inc., Cellectis SA, Poseida Therapeutics, Inc., Celularity, Inc., Servier Laboratories, Celyad SA, Takeda/Shire, Fortress Biotech, Inc., TC BioPharm Ltd., Gilead Sciences, 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, GlaxoSmithKline plc., Green Cross LabCell Corp., 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., 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., Intrexon Corporation, Medigene AG, and Northwest Biotherapeutics, Inc.

Competitor companies focused on natural killer cell based approaches include 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., 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.

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.

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 any product candidates we may develop against competitors.

***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.

***Our planned integrated ecosystem is to be comprised of multiple novel technologies that have never been tested in combination with our product candidates, and we do not know whether our attempts to use them in combination will be effective.***

Our business strategy includes using our integrated discovery engine to introduce new product candidates in combination with technologies that were developed by other companies with whom we have entered into strategic collaborations. Each technology and collaboration is unique and has its own risks, and the failure of any individual technology or the combination could materially impair our ability to successfully pursue our own aNK platform and related product candidates.

While we are free to pursue all antibodies, we are reliant on third parties and affiliates for such antibodies on which to base our taNK, haNK and t-haNK product candidates. We do not know if we can obtain such antibodies from third parties on commercially reasonable terms and such reliance on third parties may delay our development and increase the associated development costs.

We have also entered into collaborations with affiliates of NantWorks, LLC, or NantWorks, to provide us with access to their database of genomic, transcriptomic and proteomic information collected from a broad array of tumor cell and peripheral blood samples. Our rights to use the database are non-exclusive and are governed by agreements cancelable with 90 days' notice, and we therefore cannot guarantee that we would ultimately have any competitive advantage based on our use of this technology. The database also may not be able to identify novel tumor-associated antigens that are targetable with our technology and the genetic and proteomic analysis capability may not be effective as a companion diagnostic to guide therapeutic treatments.

Although we have agreements with these parties, we cannot control their actions and they may make mistakes, work with our competitors, or not devote sufficient time and attention to us. The arrangements may become cost-prohibitive for us, and their technologies may become obsolete or better options may be available that we are unable to utilize. We cannot assure you that using our technology in combination with theirs will be successful in producing product candidates in connection with these arrangements.

***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, taNK and t-haNK product candidates. To date, we have several INDs for our 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 institutional review board, or 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 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.

Adverse events observed in our phase I clinical trials of aNK conducted at third party centers included several grade 1 and 2 transient fevers and chills and individual occurrences of back pain, a transient grade 4 hypoglycemia and transient hypotension, all responsive to supportive care. 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 platform is uncertain and may never be realized.***

Our aNK platform is in the early stages of development. To date, aNK cells have only been evaluated in early clinical trials including four published phase I clinical safety trials in approximately 46 patients. These clinical trials were designed to evaluate safety and tolerability, and not designed to produce statistically significant results as to efficacy. Most of the data to date regarding aNK cells were derived from clinical trials not conducted by us, including physician-sponsored clinical trials, and utilizing product not manufactured by us but which we believe is comparable to aNK. The company currently has multiple ongoing clinical trials to evaluate cryopreserved 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.***

Three of our four completed phase I clinical trials with aNK have been investigator-initiated studies sponsored by the investigator's institution. 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. This relative lack of experience 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. In addition, our clinical trials must be conducted with material produced under GMP 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 and t-haNK 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 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. 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 December 31, 2019, we had 148 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 or t-haNK cells on a large scale or in a cost-effective manner.***

haNK, taNK and t-haNK 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 and t-haNK 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 and t-haNK 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 both haNK, taNK and t-haNK 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 and t-haNK 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 and t-haNK 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 Patrick 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 and t-haNK 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 and t-haNK cells.

***We are dependent on third parties to store our aNK, haNK, taNK and t-haNK 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 or t-haNK 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 or t-haNK 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 or t-haNK 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 or t-haNK 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 or t-haNK 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 or t-haNK 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 or t-haNK cells to clinical trial patients. If these medical personnel are not properly trained to administer, or do not properly administer, haNK, taNK or t-haNK cells, the therapeutic effect of haNK, taNK or t-haNK 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 or t-haNK cells will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that haNK, taNK or t-haNK cells are ineffective or harmful, the desire to use haNK, taNK or t-haNK 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;
- availability of alternative and competing treatments;

- cost effectiveness;
- 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 and t-haNK 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 and t-haNK 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 and t-haNK 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 and t-haNK cells are processed and administered may increase our exposure to liability. Medical personnel administer haNK, taNK and t-haNK 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 and t-haNK cells or components of our haNK, taNK and t-haNK cell therapy may cause unforeseen harmful side effects. For example, a patient receiving haNK, taNK and/or t-haNK cells could have a severe allergic reaction or could develop an autoimmune condition to materials infused with the haNK, taNK and/or t-haNK 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 and t-haNK cells. Similarly, we expect to use media in freezing our haNK, taNK and t-haNK 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 and t-haNK 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 and t-haNK 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 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 currently impacting China and elsewhere; 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 materially 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 and/or 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 is still evolving as of this time, 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 and/or negligent conduct that fails to:

- comply with the laws 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.

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 and civil monetary penalty laws, including the civil False Claims Act, 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 (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; 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.

***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.***

The Tax Cuts and Jobs Act of 2017 was approved by Congress on December 20, 2017. This legislation 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. Certain of these changes could have a negative impact on our business. In addition, adverse changes in financial outlook of our operations or changes in tax law 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.

**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 and t-haNK 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 and t-haNK 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 and t-haNK 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 or t-haNK 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 and t-haNK 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 and t-haNK 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 and t-haNK 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 and t-haNK 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 (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 agree to offer 50% 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 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 and legislative actions. 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, 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 and t-haNK 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 and t-haNK 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 its 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 important 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 may rely on our exclusive licenses from Rush University Medical Center and other licensors such as Fox Chase Cancer Research Center and the University Health Network. 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.

***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 December 31, 2019, our Chairman and CEO, Patrick Soon-Shiong, M.D., and entities affiliated with him, collectively own approximately 67.3% 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 67.6% 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 IPO 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;
- 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;
- general economic slowdowns;
- 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; 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 December 31, 2019 our chairman and CEO, Dr. Soon-Shiong, and his affiliates beneficially owned approximately 67.6% of our outstanding shares of common stock. Sales of stock by Dr. Soon-Shiong and his affiliates could have a material 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 a material 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 Securities and Exchange Commission or 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 approximately $291.8 million, $255.7 million and $0.2 million, respectively, 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 approximately $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. As a result of the analysis, the federal and state carryforwards associated with the NOLs were reduced by the amount of tax attributes estimated to expire during their respective carryforward periods.

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.

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 Tax Cuts and Jobs Act, as enacted on December 22, 2017, or TCJA, the amount of NOLs generated in taxable periods beginning after December 31, 2017, that we are permitted to deduct in any taxable year 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 generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely. Similar rules may apply under state tax laws.

Tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. The U.S. recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. In addition, governmental tax authorities are increasingly scrutinizing the tax positions of companies. If U.S. or other foreign tax authorities change applicable tax laws, our overall taxes could increase, and our business, financial condition or results of operations may be adversely impacted.

***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 67.3% of our common stock as of December 31, 2019) 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.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

The following table summarizes our principal properties leased as of December 31, 2019:

| Principal Properties Leased: | Approximate Square Feet | Operation | Lease Expiration Dates |
|---|---|---|---|
| San Diego, California | 44,681 | Laboratory - Research, Office | July 2023 |
| El Segundo, California* | 24,250 | Laboratory - Research & Manufacturing | July 2023 |
| Culver City, California* | 9,500 | Laboratory - Research & Manufacturing | December 2020 |
| Woburn, Massachusetts | 8,153 | Laboratory - Research, Office | May 2022 |
| Torrance, California** | 1,034 | Laboratory - Research | June 2027 |

* *Property leased from a related party.*

** *Represents square footage dedicated to us within the facility, however, the lease also permits our non-exclusive use of the third party's vivarium premises.*

The following table summarizes our principal property owned as of December 31, 2019:

| Principal Property Owned: | Approximate Square Feet | Operation |
|---|---|---|
| El Segundo, California | 36,434 | Distribution Warehouse |

For additional information, see Note 8 - *Commitments and Contingencies*, *Contractual Obligations – Leases* and Note 9 - *Related Party Agreements* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

**Item 3. Legal Proceedings.**

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### Market Information for Common Stock

Our common stock began trading on the Nasdaq Global Select Market under the symbol "NK" on July 28, 2015. Prior to that date, there was no public trading market for our common stock.

#### Holders of Record

As of March 23, 2020, we had 27 holders of record of our common stock. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

#### Dividend Policy

To date, we have not declared or paid any cash dividends. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

#### Securities Authorized for Issuance Under Our Equity Compensation Plans

Information regarding our equity compensation plans is incorporated by reference to Item 12, "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*" of Part III of this Annual Report.

#### Recent Sales of Unregistered Securities

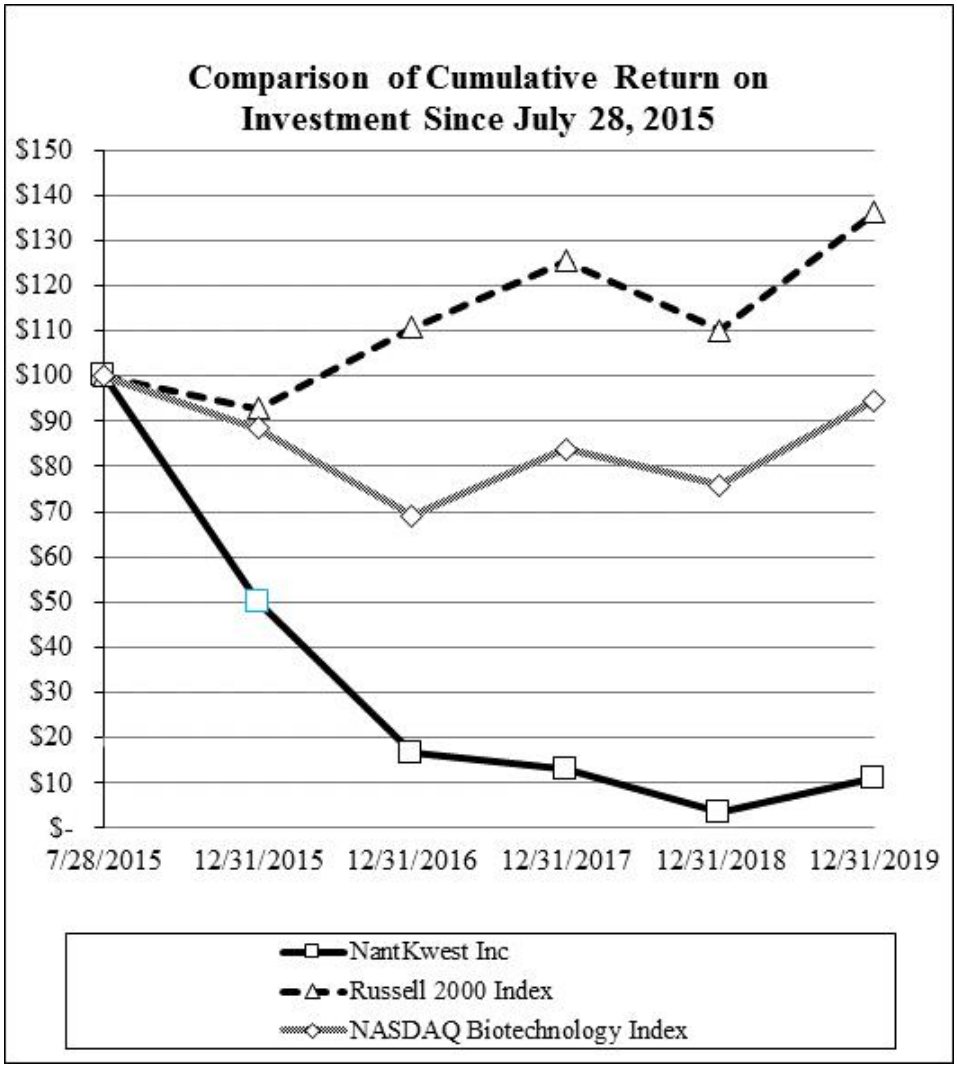
None.

#### Repurchases of Equity Securities by the Issuer

We did not repurchase any shares of our common stock during the three months ended December 31, 2019. At December 31, 2019, $18.3 million remained authorized for repurchase under our stock repurchase program. For additional information regarding our stock repurchase program, see Note 10 – *Stockholders Equity* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

**Stock Performance Graph**

The following graph compares the cumulative total return to stockholders on our common stock relative to the cumulative total returns of the Russell 2000 Index and the Nasdaq Biotechnology Index. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each index on July 28, 2015, the date our common stock began trading on the Nasdaq Global Select Market, and its relative performance is tracked through December 31, 2019. The returns shown are based on historical results and are not indicative of, or intended to forecast, future performance of our common stock or the index. This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or incorporated by reference into any filing of NantKwest, Inc. under the Securities Act of 1933, as amended, or the Securities Act.



**Item 6. Selected Financial Data.**

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," the consolidated financial statements and related notes, and other financial information included in this Annual Report on Form 10-K, or Annual Report.

The selected consolidated statements of operations data for the years ended December 31, 2019, 2018 and 2017 and the selected consolidated balance sheet data as of December 31, 2019 and 2018 are derived from our audited consolidated financial statements included elsewhere in this Annual Report. The following selected consolidated statements of operations data for the years ended December 31, 2016 and 2015 and the selected consolidated balance sheet data as of December 31, 2017, 2016 and 2015 are derived from our audited consolidated financial statements not included in this Annual Report.

| | For the Year Ended December 31, (In thousands, except per share data) | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| **Revenue** | $ 43 | $ 47 | $ 45 | $ 44 | $ 236 |
| Operating expenses: | | | | | |
| Research and development (including amounts with related parties) | 49,785 | 55,718 | 42,044 | 29,153 | 11,434 |
| Selling, general and administrative (including amounts with related parties) | 18,065 | 42,718 | 57,121 | 95,391 | 227,678 |
| Total operating expenses | 67,850 | 98,436 | 99,165 | 124,544 | 239,112 |
| **Loss from operations** | (67,807) | (98,389) | (99,120) | (124,500) | (238,876) |
| Other income (expense): | | | | | |
| Investment income, net | 1,642 | 1,857 | 2,665 | 3,097 | 2,988 |
| Change in fair value of warrant liability | — | — | — | — | (1,366) |
| Interest expense (including amounts with related parties) | (19) | (433) | (618) | (66) | — |
| Other income, net (including amounts with related parties) | 298 | 236 | 157 | 88 | 77 |
| Total other income | 1,921 | 1,660 | 2,204 | 3,119 | 1,699 |
| **Loss before income taxes** | (65,886) | (96,729) | (96,916) | (121,381) | (237,177) |
| Income tax benefit | 97 | 503 | 493 | 572 | 301 |
| **Net loss** | $ (65,789) | $ (96,226) | $ (96,423) | $ (120,809) | $ (236,876) |
| | | | | | |
| Net loss per share: | | | | | |
| Basic and diluted | $ (0.70) | $ (1.22) | $ (1.20) | $ (1.47) | $ (3.31) |
| | | | | | |
| Weighted average number of shares during the period: | | | | | |
| Basic and diluted | 94,210,087 | 79,132,220 | 80,583,910 | 81,979,005 | 71,519,609 |

| | As of December 31, (In thousands) | | | | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 15,508 | $ 16,821 | $ 23,872 | $ 8,083 | $ 175,908 |
| Working capital | 44,198 | 61,512 | 111,590 | 192,592 | 291,392 |
| Total assets | 143,123 | 181,950 | 250,440 | 317,496 | 366,849 |
| Total liabilities | 22,444 | 35,944 | 31,596 | 24,078 | 10,854 |
| Total stockholders' equity | 120,679 | 146,006 | 218,844 | 293,418 | 355,995 |

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

*The following discussion and analysis of our financial condition and results of operations should be read together with Item 6, "Selected Financial Data," the description of the business appearing in Item 1, "Business," of this report, and the Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K and the related notes included elsewhere in this report. This discussion contains forward-looking statements as a result of many factors, including those set forth under Item 1, "Business – Forward-Looking Statements" and Item 1A, "Risk Factors", and elsewhere in this Annual Report on Form 10-K. These statements are based on current expectations and assumptions that are subject to risks and uncertainties. Actual results could differ materially from those discussed in or implied by forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report, particularly in Item 1A, "Risk Factors".*

**Overview**

As a pioneering clinical-stage immunotherapy company, we are focused on harnessing the power of the innate immune system by using its natural killer cells, 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, 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 hold the exclusive right to commercialize aNK cells, a commercially viable NK cell line, and a wide range of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States, or U.S., and foreign composition and methods-of-use patents and applications covering the cells, improvements, methods of expansion and manufacture and use of aNK cells and their improvements as therapeutics to treat a spectrum of clinical conditions.

We also license exclusive commercial rights to a high-affinity CD16 receptor expressing enhancement of our aNK cell platform, covered in a portfolio of U.S. and foreign composition and methods-of-use patents and applications covering both the clinical use as a therapeutic to treat cancers in combination with antibody products, as well as the non-clinical use in laboratory testing of monoclonal antibodies.

We believe our proprietary NK cell platform, coupled with our integrated discovery ecosystem, positions us to implement precision cancer medicine by taking advantage of the advances that have evolved during the past decade and addressing newly discovered challenges of cancer. Cancer is only recently understood to be a complex of rare diseases, with hundreds of cancer specific proteins. We believe proteins, selectively expressed on the cancer cells and not on the essential normal tissue, represent large untapped targeting opportunities for immune effector cell products derived from our aNK cell platform.

**Our Approach**

***Multiple Modes of aNK Directed Tumor Cell Killing.*** Our NK platform has demonstrated the ability to induce cell death in cancers and virally infected cells through a variety of concurrent mechanisms including:

i. *Innate Killing*, whereby all of our NK platforms, aNK, haNK, taNK and t-haNK, recognize the abnormal proteins typically found on the surfaces of metabolically stressed cells, which upon binding, release toxic granules to immediately kill their targets;

ii. *Antibody-Mediated Killing* with our haNK and t-haNK platforms, which are aNK cells engineered to express antibody receptors that can bind to therapeutically administered antibody products or to antibodies naturally produced in the body, thereby enhancing the cancer cell killing effects of those antibodies through Antibody Dependent Cellular Cytotoxicity, or ADCC; and

iii. *CAR-Directed Killing* with our taNK and t-haNK platforms, which are aNK cells engineered to express chimeric antigen receptors, or CARs, that target tumor-specific proteins commonly found only on the surfaces of cancer cells and upon binding, induce cell death through the release of toxic granules directly into their targets and by the release of cytokines and chemokines, which recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells.

All three modes of killing; *Innate Killing, Antibody-Mediated Killing, and CAR-Directed Killing*, are employed by our proprietary t-haNK platform, which combines all the enhanced NK killing functions of aNK, haNK and taNK into a single product platform.

Our primary target therapeutic area is cancer, with a heavy emphasis on solid tumors. According to the National Cancer Institute, there was an estimated 1.7 million newly diagnosed cases of cancer in the U.S. in 2019, adding to the 16.9 million already living with cancer. In addition, we plan to advance therapies for hematologic malignancies and virally induced infectious diseases.

***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 typical 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 can also 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 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 ADCC. 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 commercialization going forward. We have optimized our haNK product manufacturing process partly through the successful development of a product that does 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 has been approved 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 and B7-H4;

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

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 demonstrates that taNK cell activation through the binding of its CAR receptors to these cancer specific proteins is 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 products under this platform avails itself to all three modes of killing: *innate*, *antibody-mediated* and *CAR-directed killing*. These products 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 products 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, authorized to commence phase I testing, a pipeline of prominent CARs for t-haNK, including HER2, which is nearing IND submission, and EGFR, which is advancing through human enabling studies, among others will enable us to address an even broader range of cancers as part of a chemotherapy-free combination regimen.

***The Nant Cancer Vaccine.*** The Nant Cancer Vaccine, or NCV, program is a personalized therapy regimen, which utilizes our "off-the-shelf" NK cell platform as the backbone of the regimen. NCV consists of an initial tumor-conditioning regimen followed by a molecularly-informed immunologic conditioning therapy. More specifically, NCV combines tumor and peripheral blood genomic and transcriptomic data derived from our affiliates NantOmics' and NantHealth Labs' sequencing and analytical services with the novel delivery of metronomic, albumin-bound low-dose chemotherapy in conjunction with certain other agents, followed by a sequenced administration of tumor-associated antigen vaccines and a unique IL-15 cytokine, all of which potentiate our NK cell therapy to potentially drive immunogenic cell death while avoiding the ravages of toxic high-dose chemotherapy. By inducing immunogenic cell death and enhancing a patient's innate and adaptive immune system, NCV is designed to attain a long-term, durable response in multiple cancer types with a potential for lower toxicity and improved efficacy and quality of life in comparison with current standards of care. We believe ultimately that employing our NK cell therapy in the context of NCV will be a highly effective combination for long term clinical success over available standards of care that employ maximum tolerated dose, tolerogenic cell death and immune system compromise.

***Our Integrated Discovery Ecosystem for Precision Medicine.*** In order to effectively target newly discovered neoepitopes, we plan to eventually integrate the following ecosystem to help drive the utility of our NK cell therapies against these unique cancer markers, including the use of our haNK platform in conjunction with cancer vaccines that induce *in vivo* antibody formation directed against these mutated proteins, as well as the development of t-haNK cells that directly target these mutated proteins:

i. a high-speed supercomputing infrastructure to help identify both known antigens on the surface of tumor cells and neoepitopes in clinical patients suffering from cancer, in a timely manner and at large scale;

ii. a next-generation genomic and transcriptomic sequencing infrastructure to verify the expression of the neoepitopes in the tumor cell, developed by our affiliate entity NantOmics;

iii. delivering the neoepitope via an adenoviral or yeast platform developed by an affiliate entity to induce production of IgG1-type antibodies in the body, which would in turn combine with our haNK cells to accelerate ADCC tumor killing;

iv. a diverse library of human antibodies from which to interrogate and extract an antibody to construct a CAR for genetic incorporation into our t-haNK platform; and

v. CAR-targeted t-haNK cells potentially capable of being produced as a scalable cell-based "off-the-shelf" therapy, without the need for patient compatibility matching.

We expect to regularly add newly discovered neoepitopes and novel antibody/CAR targets from our discovery engine and we believe the thousands of newly discovered antigens selectively expressed on the cancer cells and not on the essential normal tissue will provide us with the ability to create new libraries of cancer-specific antibodies and their corresponding CARs to be potentially delivered as living drugs for selective targeting of metastatic cancer cells and cancer stem cells.

We retain exclusive worldwide 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.

To date, we have generated minimal revenue related to the non-clinical use of our cell lines and intellectual property. We have not generated any revenue from product sales. We have incurred net losses in each year since our inception and, as of December 31, 2019, we had an accumulated deficit of approximately $662.2 million. Our net losses were approximately $65.8 million, $96.2 million and $96.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. Substantially all of our net losses resulted principally from stock-based compensation expense and costs incurred in connection with our ongoing clinical trials and operations, our research and development programs and from selling, general and administrative costs associated with our operations.

As of December 31, 2019, we had 148 employees. Personnel of related companies who provide corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy and other support services under our shared services agreement with NantWorks are not included in this number. For additional information, see Note 9 – *Related Party Agreements* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates' development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we do not expect to happen for at least the next several years, if ever. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. Failure to receive additional funding could cause us to cease operations, in part or in full.

**PD-L1.t-haNK Program**

Our novel GMP-grade, cryopreserved, "off-the-shelf" bi-specific PD-L1.t-haNK NK cell therapy, which received authorization from the FDA in June 2019 to proceed with a first-in-human trial, has completed enrollment in the second dose cohort of a phase I study in patients with locally advanced or metastatic solid cancers. We anticipate that this will prove to be safe to administer, based on past favorable safety profiles for other aNK cell products, and subsequently progress towards multiple phase II studies in patients with PD-L1 positive cancer indications. PD-L1.t-haNK is expected to serve 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 (see Note 7 – *Collaboration and License Agreements*, of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report). We believe that the addition of this selective IL-15 cytokine therapy will complement the efficacy of our bispecific NK cell therapy through its stimulation of the patient's own resident population of NK 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.

**Viracta Investment and Convertible Notes**

In March 2017, we participated in a Series B convertible preferred stock financing and invested $8.5 million in Viracta Therapeutics, Inc., or Viracta, a clinical stage drug development company. In May 2017, we executed an exclusive worldwide license with Viracta to develop and commercialize Viracta's proprietary histone deacetylase inhibitor drug candidate for use in combination with NK cell therapy and possibly additional therapies.

In June 2018, Viracta executed a 2018 Note and Warrant Purchase Agreement with existing and new investors, including us. The initial closing under the Purchase Agreement occurred in June 2018, at which point we purchased a convertible note, for $0.4 million, which under certain circumstances was convertible into preferred stock of Viracta, and a warrant to purchase Viracta's common shares. The convertible note accrued interest at 8% and had a one-year maturity date. In September 2018, a milestone closing under the Purchase Agreement occurred, at which point we purchased an additional convertible note for $0.4 million, which under certain circumstances was convertible into preferred stock of Viracta, and a warrant to purchase Viracta's common shares. The convertible note accrued interest at 8% and had a one-year maturity date. We classified these convertible notes as held-to-maturity notes receivable on the consolidated balance sheets. Effective January 31, 2019, the notes, together with accrued interest then outstanding, were converted to Series B preferred stock resulting in an increase to our investment in Viracta's Series B convertible preferred stock totaling $0.8 million. In May 2019, we exercised warrants to acquire 253,120 shares of Viracta common stock. At December 31, 2019, our investment in Viracta totaled $9.3 million.

For additional information, see Note 4 – *Viracta Investment and Convertible Notes* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

**Collaboration Agreements**

We anticipate that strategic collaborations will become an integral part of our operations, providing opportunities to leverage our partners' expertise and capabilities to further expand the potential of our technologies and product candidates. We believe we are well positioned to become a leader in cell-based immunotherapy due to our broad and vertically integrated platform and through complementary strategic partnerships.

In addition to the collaboration and license agreements discussed below, we may enter into a commercial agreement relating to an IL-15 superagonist product developed by an affiliate, and we are also pursuing supply arrangements for various investigational agents controlled by affiliates and third parties to be used in our clinical trials. These collaboration and supply 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, 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.

*ImmunityBio, Inc.* In January 2020, we entered into a Cost Allocation Agreement, or the Agreement, with ImmunityBio, Inc. and its subsidiaries, or ImmunityBio. The Agreement is effective as of October 1, 2019. ImmunityBio is a related party, as it is an affiliate of NantWorks. Simultaneously, we and ImmunityBio entered into Work Order Number One under the Agreement. Under the Agreement and Work Order Number One, the parties agreed to conduct a joint study, the clinical research trial being conducted pursuant to the protocol titled QUILT 3.063: *A phase 2 study of combination therapy with an IL-15 superagonist (N-803), off-the-shelf CD16-targeted natural killer cells (haNK), and avelumab without cytotoxic chemotherapy in subjects with Merkel Cell Carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor*. The ImmunityBio study drug included in the joint study is ImmunityBio's proprietary IL-15 superagonist known as N-803 and our study drug is our proprietary "off-the-shelf" CD16-targeted natural killer cell therapy known as haNK.

We will act as the sponsor of this joint study for purposes of regulatory matters, including submissions, correspondence, and communications. Additionally, we are designated as the contracting party to execute agreements with third and related parties relating to the joint study under Work Order Number One. We and ImmunityBio will split certain joint study costs equally related to Work Order Number One, in accordance with the terms of the Agreement. Shared joint study costs include cost related to conducting the joint study development activities, such as personnel related costs, as well as all costs associated to regulatory matters. Costs and expenses incurred in connection with the development, manufacturing, supply, delivery, and pre-patient administration dosing mechanism of each party's study drug, are excluded from the shared joint study costs. As of December 31, 2019, there was minimal joint research activity under the Agreement and we incurred approximately $0.1 million in costs related to the joint study that are subject to joint cost sharing under the Agreement.

Under the agreement, each of ImmunityBio and the company will receive exclusive rights to any new intellectual property developed that relates solely to its respective study drug, and the parties will have joint co-equal rights in any other intellectual property. The Agreement expires upon the second anniversary of the effective date with the option to renew for additional successive one-year terms, but work orders for any joint studies still in process at the time of termination will continue until the applicable study is completed.

*Altor BioScience, LLC.* In August 2016, we entered into an exclusive Co-Development Agreement, or the Co-Development Agreement, with Altor BioScience, LLC, or Altor. Altor is a related party, as it is a wholly owned subsidiary of ImmunityBio. ImmunityBio is an affiliate of NantWorks. Under the Co-Development Agreement, the parties agreed to exclusively collaborate on the development of certain therapeutic applications combining our proprietary NK cells with Altor's N-801 and/or N-803 products with respect to certain technologies and intellectual property rights as may be agreed between the parties for the purpose of jointly developing therapeutic applications of certain effector cell lines.

We are the lead developer for each product developed by the parties pursuant to the Co-Development Agreement unless otherwise agreed to under a given project plan. Under the terms of the Co-Development Agreement, both parties granted a co-exclusive, royalty free, fully paid-up, worldwide license, with the right to sublicense (only to a third-party contractor assisting with research and development activities under this Co-Development Agreement and subject to prior consent, not to be unreasonably withheld), under the intellectual property, or IP, including the parties interest in the joint IP, solely to conduct any development activities agreed to by the steering committee as set forth in any development plan. Unless otherwise mutually agreed by the parties in the development plan for a project, we are responsible for all costs and expenses incurred by either party related to conducting clinical trials and other activities under each development program, including costs associated with patient enrollment, materials and supplies, third party staffing, and regulatory filings. Altor supplies free of charge, sufficient amounts of Altor products for all pre-clinical requirements and certain clinical requirements for up to 400 patients in phase I and/or phase II clinical trials, as required under the development plan for a project per the Co-Development Agreement.

Each company owns an undivided interest in and to all rights, title and interest in and to the joint product rights. The Co-Development Agreement expires upon the fifth anniversary of the effective date. We have dosed patients with N-803, an IL-15 superagonist, in several phase Ib/II trials during the years ended December 31, 2019, 2018 and 2017. No charges for supplies by Altor were incurred in association with the above trials during the years ended December 31, 2019, 2018 and 2017.

**Licensing Agreements**

*Viracta Therapeutics, Inc.* In May 2017, we entered into an agreement with Viracta to grant 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. In consideration for the license, we are obligated to pay to Viracta (i) mid-single digit percentage royalties of net sales of licensed products for therapeutic use; and (ii) milestone payments ranging from $10.0 million to $25.0 million for various regulatory approvals and cumulative net sales levels. We may terminate the agreement, in our sole discretion, in whole or on a product-by-product and/or country by country basis, at any time upon 90 days' prior written notice. In addition, either party may terminate the agreement in the event of a material breach or for bankruptcy of the other party.

**Agreements with Related Parties**

Our Chairman and CEO, Dr. Soon-Shiong, founded and has a controlling interest in NantWorks, which is a collection of multiple companies in the healthcare and technology space. We have entered into arrangements with NantWorks, and certain affiliates of NantWorks that, taken together, we expect will facilitate the development of new genetically modified NK cells for our product pipeline.

*Share Repurchase*

In November 2018, we entered into a share repurchase agreement with an immediate family member of a director of the company, pursuant to which we repurchased 138,349 of our common shares for a total of $0.2 million under our existing share repurchase program.

*NantHealth Labs, Inc.*

In March 2018, we entered into an agreement with NantHealth Labs, Inc., or NantHealth Labs, to obtain blood-based tumor profiling services. NantHealth Labs is a related party, as it is a wholly owned subsidiary of NantHealth, Inc., a majority owned subsidiary of NantWorks. We are obligated to pay NantHealth Labs fixed, per-patient fees. The agreement has an initial term of five years and renews automatically for successive one-year periods, unless terminated earlier. During the years ended December 31, 2019 and 2018, $10,000 and $0.3 million, respectively, has been recognized in research and development expense on the consolidated statements of operations.

*Immuno-Oncology Clinic, Inc.*

Beginning in 2017, we entered into multiple agreements with Immuno-Oncology Clinic, Inc., or the Clinic, to conduct various clinical trials. The Clinic was formerly known as John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine, El Segundo, California. The Clinic is a related party as it is owned by one officer of NantKwest and NantWorks manages the administrative operations of the Clinic. Prior to June 30, 2019, one of the company's officers was an investigator or sub-investigator for all of the company's trials conducted at the Clinic.

In July 2019, we entered into a new agreement with the Clinic which superseded our existing agreements with the Clinic, effective as of July 1, 2019. The new agreement covers clinical trial and research related activities on a non-exclusive basis relating to our existing clinical trials, commenced prior to July 1, 2019, and prospective clinical trials and research projects. The new agreement also specifies certain services and related costs that are excluded from the new agreement. Prior to commencing any work under the new agreement, the parties have agreed to execute written work orders setting forth the terms and conditions related to specific services to be performed, including financial terms. For existing clinical trials, commenced prior to July 1, 2019, fees incurred for services performed after July 1, 2019 are covered under the new agreement and applied towards the below-mentioned prepayments. The initial term of the new agreement is for one year, but the agreement allows for an automatic renewal and additional extensions beyond the initial term. In July 2019, we executed a clinical trial work order under the new agreement with the Clinic for an open-label, phase I study of PD-L1.t-haNK for infusion in subjects with locally advanced or metastatic solid cancers.

In consideration of the services to be performed under the new agreement, we agreed to make payments of $7.5 million to the Clinic, of which $3.75 million and $1.875 million were paid in July 2019 and October 2019, respectively. The prepayments constitute a prepayment by us for services to be performed by the Clinic. We anticipate that the prepayment amount will be utilized in future periods as the Clinic provides additional services pursuant to the new agreement. Under the term of the new agreement, the outstanding balance of our prepayment shall be increased on a quarterly basis by an interest credit computed in accordance with terms specified in the new agreement.

To the extent any portion of the prepayments remain unearned by the Clinic on the third anniversary of the new agreement, we may elect at our sole discretion either to (i) not extend the term of the new agreement and have the Clinic reimburse us for the total amount of any remaining unused portion of the prepayments, or (ii) extend the term of the new agreement for up to three additional one year periods, at which time the Clinic will reimburse us for the total amount of any remaining unused portion of the prepayments plus interest if reimbursement is not made within 60 days of expiration. The Clinic may terminate this agreement upon each anniversary date upon sixty (60) days prior written notice and reimbursement in full to us of any outstanding unearned balance of the prepayments, provided that any such termination by the Clinic will not apply with respect to any work orders still in effect at the time of such termination.

During the years ended December 31, 2019, 2018 and 2017, expense of $1.1 million, $2.7 million and $0.8 million, respectively, has been recognized in research and development expense on the consolidated statements of operations for services performed by the Clinic.

*605 Doug St, LLC*

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, an entity owned by our Chairman and CEO, for approximately 24,250 square feet in El Segundo, California, which we converted to a research and development laboratory and a current Good Manufacturing Practices, or cGMP, manufacturing facility. The lease runs from July 2016 through July 2023. We have the option to extend the lease for an additional three-year term through July 2026. The monthly rent is $0.1 million with annual increases of 3% beginning in July 2017. For the years ended December 31, 2019, 2018 and 2017, we recorded rent expense of $0.9 million, $0.2 million and $0.2 million, respectively, which is reflected in research and development expense on the consolidated statements of operations.

*NantBio, Inc.*

In August 2018, NantBio, Inc., or NantBio, assigned an agreement to us for the use of a third-party research facility, which provides us with the exclusive right to use, and access to a portion of, the third party's laboratory and vivarium premises. NantBio is a related party as it is an affiliate of NantWorks. In conjunction with the assignment, we reimbursed NantBio for upfront payments which it had made to the third party of $0.9 million and paid $0.5 million directly to the third party for an aggregate value of $1.4 million. The assigned agreement is for a term of ten years and expires in June 2027. The agreement may be terminated by us at any time, with or without cause. In case of termination of the agreement, the third party will reimburse us for a pro-rata amount based upon the passage of time.

In January 2018, we entered into a laboratory services agreement with NantBio. The agreement, effective December 2017, included a sublease of approximately 1,965 square feet of laboratory and office space at our San Diego, California, research facility. This sublease was terminated effective December 31, 2019, pursuant to the terms of the agreement. For the years ended December 31, 2019, 2018 and 2017, we recognized $0.1 million, $0.1 million and $10,000, respectively, in other income on the consolidated statements of operations.

In March 2016, NantBio and the National Cancer Institute entered into a cooperative research and development agreement. The initial five year agreement covers NantBio and its affiliates, including us. Under the agreement, the parties are collaborating on the preclinical and clinical development of proprietary recombinant natural killer cells and monoclonal antibodies in monotherapy and in combination immunotherapies. We benefited from the preclinical and clinical research conducted during the first four years under this agreement. In each of April 2016, April 2017, August 2018, and May 2019, we paid $0.6 million to the National Cancer Institute as a prepayment for services under the agreement. We recognize expense associated with this agreement ratably over a 12-month period and recorded $0.6 million of research and development expense in each of the years ended December 31, 2019, 2018 and 2017.

*NantWorks*

In November 2015, we entered into a shared services agreement with NantWorks, which became effective in August 2015, under which NantWorks provides corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy, and other support services to us. We are charged for the services at cost plus reasonable allocations for indirect costs that relate to the employees providing the services. For the years ended December 31, 2019, 2018 and 2017, we recorded $2.1 million, $2.8 million and $3.6 million, respectively, to selling, general and administrative expense, and $1.5 million, $3.3 million and $3.2 million, respectively, in research and development expense under this arrangement on the consolidated statements of operations. These amounts exclude certain general and administrative expenses provided by third party vendors directly for our benefit, which have been reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

In June 2016, we entered into an amended shared services agreement with NantWorks to allow for the provision of such support services by us to NantWorks and/or any of its affiliates. For the years ended December 31, 2019, 2018 and 2017, we recorded expense reimbursements of $1.2 million, $0.6 million and $0.4 million, respectively, to selling, general and administrative expense, and $2.3 million, $2.6 million and $1.0 million, respectively, to research and development expense.

In November 2015, we entered into a facility license agreement with NantWorks, which became effective in May 2015, for approximately 9,500 square feet of office space in Culver City, California, which has been converted to a research and development laboratory and a cGMP laboratory. The term of the license extends through December 2020. The monthly rent is $47,000 with annual increases of 3% beginning in January 2017. For each of the years ended December 31, 2019, 2018 and 2017, we recorded rent expense of $0.6 million, $0.2 million and $0.2 million, respectively, which is included in research and development expense on the consolidated statements of operations.

*NantOmics, LLC*

In June 2015, we entered into an agreement, as amended in May 2018, with NantOmics, LLC, or NantOmics, which is a related party, as it is an affiliate of NantWorks. Pursuant to the agreement we obtain genomic sequencing and proteomic analysis services, as well as related data management and bioinformatics services, exclusively from NantOmics. We have rights to use the data and results generated from NantOmics' services in connection with the performance of the particular oncology trial with respect to which the services were performed, but NantOmics owns the data and results, as well as any other intellectual property it creates in performing these services on our behalf. We are obligated to pay NantOmics a fixed, per sample fee, determined based on the type of services being provided. The agreement has an initial term of five years and renews automatically for successive one-year periods, unless terminated. We have the right to terminate the agreement for convenience on 90 days prior written notice, and both parties may terminate if there is a material, uncured breach of the agreement by the other party. For the years ended December 31, 2019, 2018 and 2017, under this arrangement we recorded operating expense of $0.1 million, $0.1 million and $0.1 million, respectively, to research and development on the consolidated statements of operations.

*ImmunityBio*

ImmunityBio, Inc., or ImmunityBio, is a related party, as it is an affiliate of NantWorks. ImmunityBio was formerly known as NantCell, Inc.

In January 2020, we entered into a cost sharing agreement with ImmunityBio as further described above and in Note 15 - *Subsequent Events* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

In November 2018, we entered into an agreement with Etubics Corporation, or Etubics, a subsidiary of ImmunityBio. Pursuant to this agreement we sold used laboratory equipment to Etubics for $0.3 million. In conjunction with this sale, we recognized a loss on disposal of related laboratory equipment of $0.1 million, which was included in other income, net on the consolidated statements of operations.

In August 2016, we entered into a Co-Development Agreement with Altor as further described above and under *Collaborative Arrangements – Exclusive Co-Development Agreement* in Note 7 of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report. Altor is a related party, as it is a wholly owned subsidiary of ImmunityBio. No charges for supplies by Altor were incurred in association with the trials during the years ended December 31, 2019, 2018 and 2017.

In June 2015, we entered into a supply agreement with ImmunityBio pursuant to which we have the right to purchase ImmunityBio's proprietary bioreactors, made according to specifications mutually agreed to with ImmunityBio. We also have the right to purchase reagents and consumables associated with such equipment from ImmunityBio. When an upfront payment is made, it is included in prepaid expenses on the consolidated balance sheets until the product is received. The agreement has an initial term of five years and renews automatically for successive one-year periods unless terminated earlier.

As of December 31, 2019 and 2018, we had $1.8 million and $1.1 million, respectively, in capitalized equipment purchased from ImmunityBio, which is included in property, plant and equipment, net, on the consolidated balance sheets. During the years ended December 31, 2019, 2018 and 2017, we recorded research and development expense associated with reagents and consumables purchased from ImmunityBio of $0.1 million, $0.1 million and $0.3 million, respectively, on the consolidated statements of operations.

**Components of our Results of Operations**

**Revenue**

To date, we have derived substantially all of our revenue from non-exclusive license agreements with numerous pharmaceutical and biotechnology companies granting them the right to use our cell lines and intellectual property for non-clinical use. These agreements generally include upfront fees and annual research license fees for such use, as well as commercial license fees for sales of our licensee's products developed or manufactured using our intellectual property and cell lines. Our license agreements may also include milestone payments, although to date, we have not generated any revenue from milestone payments. To date, we have generated minimal revenue related to the non-clinical use of our cell lines and intellectual property. We have no products approved for commercial sale and have not generated any revenue from product sales. If we fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval for them, we may never be able to generate substantial future revenue.

**Operating Expenses**

We classify our operating expenses into research and development and selling, general and administrative expenses. Personnel costs, including salaries, benefits, bonuses, and stock-based compensation expense comprise a significant component of our research and development and selling, general and administrative expense categories. We allocate expenses associated with our facilities and information technology costs between these two categories based on the nature of each cost.

**Research and Development**

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consists of:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with investigative sites and consultants that conduct our clinical trials;
- manufacturing and testing costs and related supplies and materials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation; and
- facility expenses dedicated to research and development.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs.

Substantially all of our research and development expenses to date have been incurred in connection with our product candidates. We expect our research and development expenses to increase significantly for the foreseeable future as we advance our product candidates through clinical development, including the conduct of our ongoing and any future clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates as discussed in greater detail in Part I, Item 1A, "*Risk Factors*".

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses that patients receive;
- the cost of comparative agents used in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not expect any of our product candidates to be commercially available for at least the next several years, if ever.

**Selling, General and Administrative**

Selling, general and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in executive, finance, human resources and administrative support functions. Other selling, general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, advertising costs, expenses associated with obtaining and maintaining patents, consulting costs, royalties and licensing costs, and costs of our information systems.

Although our selling, general and administrative costs declined during the year ended December 31, 2019 as compared to the year ended December 31, 2018, we expect that our selling, general and administrative expenses during the year ended December 31, 2020 will increase. We have incurred and expect that we will continue to incur in the future, additional costs associated with operating as a public company, including costs to comply with stock exchange listing and SEC requirements, corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public companies. Additionally, if and when we believe that a regulatory approval of a product candidate appears likely, we expect to incur significant increases in our selling, general and administrative expenses relating to the sales and marketing of the approved product candidate.

**Other Income (Expense)**

Other income (expense) consists primarily of income from our investments in marketable debt securities, sublease rental income, interest expense from the accretion of our capital lease and financing obligations, foreign currency income (expense), and gains and losses on disposition of assets.

**Income Tax**

Income tax expense consists of U.S. federal and state income taxes. To date, we have not been required to pay U.S. federal income taxes because of our current and accumulated net operating losses. Our income tax expense to date primarily relates to minimum income taxes in the State of California. Our tax benefit relates to the amortization of deferred tax liabilities at our Korean subsidiary.

**Results of Operations**

***Comparison of the years ended December 31, 2019, 2018 and 2017 (in thousands)***

| | For the Year Ended December 31, | | | Change | |
|---|---|---|---|---|---|
| | 2019 | 2018 | 2017 | 2019 vs. 2018 | 2018 vs. 2017 |
| Revenue | $ 43 | $ 47 | $ 45 | $ (4) | $ 2 |
| Operating expenses: | | | | | |
| Research and development (including amounts with related parties) | 49,785 | 55,718 | 42,044 | (5,933) | 13,674 |
| Selling, general and administrative (including amounts with related parties) | 18,065 | 42,718 | 57,121 | (24,653) | (14,403) |
| Total operating expenses | 67,850 | 98,436 | 99,165 | (30,586) | (729) |
| Loss from operations | (67,807) | (98,389) | (99,120) | 30,582 | 731 |
| Other income (expense): | | | | | |
| Investment income, net | 1,642 | 1,857 | 2,665 | (215) | (808) |
| Interest expense (including amounts with related parties) | (19) | (433) | (618) | 414 | 185 |
| Other income, net (including amounts with related parties) | 298 | 236 | 157 | 62 | 79 |
| Total other income | 1,921 | 1,660 | 2,204 | 261 | (544) |
| Loss before income taxes | (65,886) | (96,729) | (96,916) | 30,843 | 187 |
| Income tax benefit | 97 | 503 | 493 | (406) | 10 |
| Net loss | $ (65,789) | $ (96,226) | $ (96,423) | $ 30,437 | $ 197 |

***Revenue***

The change in revenue was minimal during the comparative periods and consisted of license fees and royalties.

***Research and Development***

Research and development expense decreased $5.9 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The decrease in research and development expense was primarily attributable to decreases of $4.7 million in compensation and related expenses due to decreased staff and to fees for shared services rendered under our shared services agreement with NantWorks as a result of less clinical trial support activities, $2.0 million for pre-clinical and clinical trial costs mainly driven by decreased activity related to investigator sponsored trials and research agreements, and $1.7 million of intangible asset amortization expense due to the underlying asset being fully amortized as of March 2019. These decreases were partially offset by a net increase of $1.6 million for laboratory and manufacturing facility related expenses, including increases related to third-party facility and manufacturing process validation and qualification costs, depreciation expense, and lease expense, mainly driven and associated with our El Segundo cGMP facility, and decreases related to third party testing services and laboratory supplies. In addition, we recorded $0.9 million of expense related to impairment of laboratory equipment. We expect our research and development expenses to increase significantly for the foreseeable future as we advance our product candidates through clinical development and conduct our ongoing and planned clinical trials.

Research and development expense increased $13.7 million during the year ended December 31, 2018 as compared to the year ended December 31, 2017. The increase in research and development expense was attributable to increases of $7.8 million primarily due to the ramp-up of laboratory and GMP manufacturing activities driven in part by our El Segundo, California, facility where we completed construction in May 2018, $6.1 million in compensation and related expenses due to increased personnel and fees for services rendered under our shared services agreement with NantWorks, and $0.4 million in stock compensation expense primarily related to increased staff. The increase was partially offset by decreases of $0.7 million for clinical and regulatory consultant costs due to bringing these functions in-house.

***Selling, General and Administrative***

Selling, general and administrative expense decreased $24.7 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The decrease in selling, general and administrative expense was primarily attributable to a decrease of $20.8 million in stock-based compensation expense, which was primarily driven by a decrease due to vesting completed in July 2018 and March 2019 related to service-based equity awards issued to our Chairman and CEO in 2015. In addition, selling, general and administrative expense decreased by $2.3 million due to lower costs associated with litigation, $1.1 million due to decreased activity in shared services provided by NantWorks, and $0.6 million due to lower headcount related expenses. These decreases in selling, general and administrative expense were partially offset by a $0.2 million increase in other administrative costs. We expect our selling, general and administrative expenses to increase in the foreseeable future to support our ongoing operations, including accounting, audit, legal, and regulatory compliance, director and officer insurance costs, and other expenses associated with operating as a public company.

Selling, general and administrative expense decreased $14.4 million during the year ended December 31, 2018 as compared to the year ended December 31, 2017. The decrease in selling, general and administrative expense was primarily attributable to a decrease of $14.0 million in stock-based compensation expense mainly driven by a decrease of $13.8 million due to the completion of vesting in July 2018 related to service-based equity awards issued to our Chairman and CEO in 2015. In addition, selling, general and administrative expense decreased by $0.6 million due to decreased activity in shared services provided by NantWorks, $0.5 million for professional and consulting fees for accounting and compliance related services, and $0.4 million, primarily due to lower travel related expenses. These decreases in selling, general and administrative expense were partially offset by a $1.0 million increase mainly driven by litigation related expenses and other professional fees.

***Other Income (Expense)***

Other income increased by $0.3 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase in other income resulted primarily from lower interest expense of $0.4 million, offset in part by a decrease in investment income related to use of our investments for operations of $0.2 million.

Other income decreased by $0.5 million during the year ended December 31, 2018 as compared to the year ended December 31, 2017 due to a $0.8 million decrease in investment income related to use of our investments for operations, partially offset by a $0.2 million increase in interest expense related to our financing obligations.

***Income Tax Benefit***

The $0.4 million decrease in the income tax benefit during the year ended December 31, 2019 as compared to the year ended December 31, 2018, was due primarily to lower income tax benefits related to losses at our Korean subsidiary.

The change in income tax benefit was minimal during the year ended December 31, 2018 as compared to the year ended December 31, 2017.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Our principal sources of liquidity are our existing cash, cash equivalents, and marketable debt securities. We have historically invested our cash primarily in investment grade short- to intermediate-term corporate debt securities, commercial paper, government sponsored securities, U.S. treasury securities, and foreign government bonds and classify these investments as available-for-sale. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets. During the year ended December 31, 2019, our Chairman and CEO exercised warrants and options resulting in proceeds to us of $35.2 million and $4.1 million, respectively.

As of December 31, 2019, we had cash and cash equivalents, and restricted cash of $15.7 million compared to $17.0 million as of December 31, 2018. The decrease was attributable to cash used in operating activities of $61.4 million, offset in part by cash flows provided by financing and investing activities of $38.6 million and $21.5 million, respectively.

Investments in marketable debt securities were $37.6 million as of December 31, 2019, of which $36.1 million were short-term investments, as compared to $63.0 million as of December 31, 2018, of which $57.3 million were short-term investments.

***Cash Flows***

The following table sets forth our primary sources and uses of cash for the years ended December 31, 2019, 2018 and 2017 (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Cash provided by (used in): | | | |
| Operating activities | $ (61,362) | $ (63,381) | $ (48,780) |
| Investing activities | 21,456 | 57,101 | 99,552 |
| Financing activities | 38,593 | (771) | (34,983) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (1,313) | $ (7,051) | $ 15,789 |

***Operating Activities***

For the year ended December 31, 2019, our net cash used in operating activities of $61.4 million consisted of a net loss of $65.8 million, and $10.9 million of cash used by net working capital changes, partially offset by $15.4 million in adjustments for non-cash items. Adjustments for non-cash items primarily consisted of $9.0 million in depreciation and amortization, $2.6 million in stock compensation expense, $2.6 million of non-cash lease expense related to operating lease right-of-use assets, $0.9 million of impairment related to laboratory equipment, and $0.2 million in non-cash interest. The decrease in net working capital consisted primarily of decreases related to accrued expenses of $12.0 million, other long-term assets of $4.0 million, operating lease liabilities of $2.3 million, due to related parties of $1.1 million, and operating lease right-of-use assets of $0.8 million, partially offset by an increase related to prepaid expenses and other current assets of $9.3 million. The decrease in cash used in operating activities is primarily due to lower laboratory and manufacturing related costs and lower headcount and compensation costs including shared services, partially offset by higher clinical trial and related operational costs.

For the year ended December 31, 2018, our net cash used in operating activities of $63.4 million consisted of a net loss of $96.2 million, offset by $33.4 million in adjustments for non-cash items, primarily attributable to $23.4 million in stock-based compensation expense, as well as research and development and selling, general and administrative expenses, and a $0.6 million decrease of cash related to changes in working capital. Adjustments for non-cash items primarily consisted of the $23.4 million in stock-based compensation expense, $9.6 million in depreciation and amortization, $0.5 million in amortization of premiums on marketable debt securities, $0.3 million in non-cash interest related to our marketable debt securities, and $0.2 million related to loss on disposal of assets, reduced by $0.5 million of deferred income tax benefit. Changes in net working capital consisted primarily of increases related to prepaid and other current assets of $9.8 million, other assets of $1.2 million, accounts payable of $1.1 million, due to related parties of $0.7 million, and deferred rent of $0.5 million, partially offset by an increase in accrued expenses of $12.7 million. The increase in cash used in operating activities is primarily due to costs incurred in ongoing preclinical and clinical trials, the ramp-up of manufacturing activities, increased personnel, and research and development activities.

For the year ended December 31, 2017, our net cash used in operating activities of $48.8 million consisted of a net loss of $96.4 million, partially offset by $44.4 million in adjustments for non-cash items, primarily attributable to $37.0 million in stock compensation expense, as well as research and development and selling, general and administrative expenses, and $3.2 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of the $37.0 million in stock-based compensation expense, $5.6 million in depreciation and amortization, $1.6 million in amortization of premiums on marketable debt securities, $0.7 million in non-cash interest related to our marketable debt securities, and $0.1 million in loss on asset disposals, reduced by $0.5 million of deferred income tax benefit. Changes in net working capital consisted primarily of increases in due to related parties of $1.6 million, deferred rent of $1.2 million, other assets of $0.5 million, accounts payable of $0.2 million, and prepaid and other current assets of $0.2 million, partially offset by a decrease in accrued expenses of $0.3 million. The increase in cash used in operating activities is primarily due to costs incurred in ongoing preclinical and clinical trials, the ramp-up of manufacturing activities, increased personnel, and research and development activities.

***Investing Activities***

For the year ended December 31, 2019, net cash provided by investing activities was $21.5 million, which was primarily attributable to $112.3 million in sales and/or maturities of marketable debt securities, partially offset by $86.6 million in purchases of marketable debt securities, and $4.2 million in purchases of property, plant and equipment. During the year ended December 31, 2019 our purchases of marketable debt securities included our investment of $39.2 million of cash proceeds received in March 2019 from the exercise of stock options and warrants, together with reinvestment of excess cash related to maturing securities. Our investments in property, plant and equipment during the year ended December 31, 2019 mainly related to our El Segundo, California, facilities.

For the year ended December 31, 2018, net cash provided by investing activities was $57.1 million, which was primarily attributable to $165.3 million in sales and/or maturities of marketable debt securities and $0.4 million in proceeds from sales of laboratory equipment, partially offset by $94.8 million in purchases of marketable debt securities, driven by the reinvestment of excess cash resources, $13.1 million in purchases of property, plant and equipment, mainly related to our laboratory and cGMP build out in El Segundo, California, and $0.7 million in purchases of Viracta convertible notes.

For the year ended December 31, 2017, net cash provided by investing activities was $99.6 million, which was primarily attributable to $254.2 million in sales and maturities of marketable debt securities partially offset by $111.4 million in purchases of marketable debt securities driven by the reinvestment of excess cash resources, $34.8 million in purchases of property and equipment mainly related to our laboratory and cGMP build out in El Segundo, California, and equipment purchases for the El Segundo, California, research and cGMP facility, and $8.5 million in the purchase of an investment in equity securities.

***Financing Activities***

For the year ended December 31, 2019, net cash provided by financing activities was $38.6 million, which primarily consisted of cash proceeds of $35.2 million and $4.1 million resulting from the exercise of warrants and stock options, respectively, by our Chairman and CEO during March 2019, partially offset by $0.5 million used for stock repurchases, including commissions, and $0.1 million related to net share settlement of vested RSUs and option exercises for payment of employee payroll taxes.

For the year ended December 31, 2018, net cash used in financing activities was $0.8 million, which primarily related to $0.5 million of principal payments on our financing obligations, $0.2 million used for stock repurchases, and $0.1 million in net share settlement of exercised warrants and vesting of RSUs for payment of employee payroll taxes, partially offset by $0.1 million in proceeds from the exercise of warrants.

For the year ended December 31, 2017, net cash used in financing activities was $35.0 million, which consisted of $19.9 million in principal payments primarily related to our capital lease obligation, $15.2 million used for stock repurchases, and $1.0 million in net share settlement of exercised stock options and vesting of RSUs for payment of employee payroll taxes, partially offset by $1.2 million in proceeds from the exercise of stock options and warrants.

***Future Funding Requirements***

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 do not expect to generate significant revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates and we do not know when, or if, this will occur. In addition, we expect our expenses to significantly increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Moreover, since the completion of our IPO in July 2015, we have incurred and expect that we will continue to incur in the future additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. We expect that our expenses will increase substantially if and as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates' development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Based upon our current operating plan, we expect that our existing cash, cash equivalents, and marketable debt securities, and our ability to borrow from affiliated entities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months following the issuance date of the financial statements based on our Chairman and CEO's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required. We have based this estimate on assumptions that may prove to be incorrect, and we may use our available capital resources sooner than we currently expect. The successful development of any product candidate is highly uncertain. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our product candidates.

Our future capital requirements will depend on many factors, including:

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our product candidates;
- the costs of manufacturing, distributing and processing our product candidates;
- 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 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.

Because all of our product candidates are in the early stages of preclinical and clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of any of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. 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 your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures 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. 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 our product candidates that we would otherwise prefer to develop and market ourselves.

**Contractual Obligations, Commitments and Contingencies**

***Contractual Obligations and Commitments***

Our contractual obligations as of December 31, 2019 were as follows (in thousands):

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| **Contractual Obligations** | | | | | |
| Operating lease liabilities (1) | $ 17,053 | $ 4,271 | $ 7,424 | $ 3,629 | $ 1,729 |
| Total contractual obligations | $ 17,053 | $ 4,271 | $ 7,424 | $ 3,629 | $ 1,729 |

(1) Represents future minimum lease payments under all our leases as of December 31, 2019. The operating lease liability payments above do not include any related common area maintenance charges or real estate taxes.

For additional information, see Note 8 – *Commitments and Contingencies*, *Contractual Obligations – Leases and* Note 9 – *Related Party Agreements* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

***Contingencies***

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**Off-Balance Sheet Arrangements**

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

**Critical Accounting Policies, Significant Judgements and Use of Estimates**

Management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which are prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to valuation of equity-based awards, deferred income taxes and related valuation allowances, preclinical and clinical trial accruals, impairment assessments, useful lives of long-lived assets, loss contingencies, and fair value measurements. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

The following is not intended to be a comprehensive discussion of all of our significant accounting policies. See the notes accompanying our financial statements appearing in this Annual Report for a summary of all of our significant accounting policies and other disclosures required by U.S. GAAP.

***Preclinical and Clinical Trial Accruals***

As part of the process of preparing the financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, clinical research organizations and consultants. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

We estimate clinical trial and research agreement related expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. In accruing clinical and research related fees, we estimate the time period over which services will be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

***Research and Development Costs***

Major components of research and development costs include cash compensation and other personnel-related expenses, stock-based compensation, depreciation and amortization expense on research and development property and equipment and intangible assets, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on our behalf. Costs incurred in research and development are expensed as incurred.

Included in research and development costs are clinical trial and research expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. We record accruals for estimated costs under these contracts. When evaluating the adequacy of the accrued liabilities, we analyze the progress of the studies or clinical trials, including the phase or completion of events, invoices received, contracted costs and purchase orders. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period based on the facts and circumstances known at that time. Although we do not expect the estimates to be materially different from the amounts actually incurred, if the estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. Actual results could differ from our estimates.

***Cash, Cash Equivalents and Marketable Debt Securities***

We invest our excess funds in investment grade short- to intermediate-term corporate debt securities, commercial paper, government sponsored securities, and foreign government bonds and classify these investments as available-for-sale. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents and all investments purchased with original maturities of greater than three months as marketable debt securities. Marketable debt securities with remaining maturities of 12 months or less are classified as short-term and marketable debt securities with remaining maturities greater than 12 months are classified as long-term. All marketable debt securities are reported at fair value and any unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss), net of tax, on the consolidated statements of stockholders' equity, with the exception of unrealized losses believed to be other-than-temporary, which are recorded in investment income, net, on the consolidated statements of operations. Realized gains and losses are included in investment income, net, on the consolidated statements of operations. Realized gains and losses from sale of the securities and the amounts, net of tax, reclassified out of accumulated other comprehensive loss, if any, are determined on a specific identification basis.

We periodically evaluate whether declines in fair values of our investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss, as well as our ability and intent to hold the investment until a forecasted recovery occurs. Additionally, we assess whether we plan to sell the security or it is more likely than not we will be required to sell any investment before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of our investments, duration and severity of the decline in value, and our strategy and intentions for holding the investment. There were no other-than-temporary impairments recorded in years ended December 31, 2019, 2018 and 2017.

We minimize the credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of our primary financial institutions. While we maintain cash deposits in FDIC insured financial institutions in excess of federally insured limits, management believes we are not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. We have not experienced any losses on such accounts.

We have funded a certificate of deposit, or CD, as a substitute letter of credit for one of the leased properties. This CD is reported as long-term restricted cash and is included in other assets on the consolidated balance sheets as the landlord is the beneficiary of the account and we are not able to access the funds during the term of the lease.

***Contingencies***

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or of the range of potential losses disclosed. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances where our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

***Investment in Equity Securities***

We own non-marketable equity securities that are measured at cost, less impairment, adjusted for observable price changes in an orderly market for an identical or similar investment of the same issuer, because the preferred stock we hold is not considered in-substance common stock and such preferred stock does not have a readily determinable fair value. This investment is reviewed on a regular basis for possible impairment. If the fair value of the investment is determined to be less than its net carrying value, the investment will be written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an impairment indicator is present include: the investees' earning performance and clinical trial performance, change in the investees' industry and geographic area in which it operates, offers to purchase or sell the security for a price less than the cost of the investment, issues that raise concerns about the investee's ability to continue as a going concern, and any other information that we may be aware of related to the investment. Factors considered in determining whether an observable price change has occurred include: the price at which the investee issues equity instruments similar to those of our investment and the rights and preferences of those equity instruments compared ours. To date, we have not recorded any adjustments to the cost basis of this investment.

***Fair Value of Financial Instruments***

We record our available-for-sale investments at fair value. At December 31, 2019, our cash equivalents and investments in marketable debt securities totaled $37.6 million. Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, establishes three levels of inputs that may be used to measure fair value. Each level of input represents varying degrees of subjectivity and difficulty involved in determining fair value. Valuations using Level 1 and 2 inputs are generally based on price quotations and other observable inputs in active markets and do not require significant management judgment or estimation. We utilize a third-party pricing service to assist us in obtaining fair value pricing for these investments. While pricing for these securities is based on proprietary models, the inputs used are based on observable market information; therefore, we have classified our inputs as Level 1 and Level 2. For additional information, see Note 6 – *Fair Value Measurements* of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

***Long-Lived Assets***

Long-lived assets include property, plant and equipment and intangible assets. We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected undiscounted future cash flows arising from the assets using a discount rate determined by management to be commensurate with the risk inherent to our current business model. During the year ended December 31, 2019, we determined that certain bioreactor laboratory equipment could no longer be utilized in the production process. As a result, we recorded an impairment charge totaling approximately $0.9 million, which is included in research and development expense on the condensed consolidated statements of operations of the "Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report.

***Lease Obligations***

We adopted FASB ASC Topic 842, *Leases*, or ASC 842, effective January 1, 2019. For contracts entered into on or after the effective date, we determine if an arrangement is, or contains, a lease at lease inception. Our assessment is based on: (1) whether the contract involves the use of a distinct identified asset; (2) whether we obtain the right to substantially all of the economic benefit from the use of the asset throughout the period; and (3) whether we have the right to direct the use of the asset. At inception of a lease, we allocate the consideration in the contract to each lease component based on its relative stand-alone price to determine the lease payments. Leases entered into prior to January 1, 2019, which were accounted for under ASC 840, *Leases*, were not reassessed as we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification. We determine the lease term by assuming the exercise of renewal options that are reasonably assured. The exercise of lease renewal options is at our sole discretion. Several of our leases have renewal options, however, exercise of renewal is only assured for the El Segundo current Good Manufacturing Practices, or cGMP, facility, where we have made significant improvements.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. At lease commencement, leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: (1) the lease transfers ownership of the underlying asset by the end of the lease term; (2) the lease contains an option to purchase the underlying asset that is reasonably certain to be exercised; (3) the lease term is for a major part of the remaining economic life of the underlying asset; (4) the present value of the sum of the lease payments and any guaranteed residual value that is not already included in the lease payments equals or exceeds substantially all of the fair value of the underlying asset; or (5) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease is classified as an operating lease if it does not meet any one of these criteria.

We do not currently have any leases classified as finance leases. Our operating leases are included in operating lease right-of-use assets, net, other current liabilities, and operating lease liabilities on the consolidated balance sheets. At the commencement date, operating lease right-of-use assets and operating lease liabilities are determined based on the present value of lease payments to be made over the lease term. Operating lease right-of-use assets also include any rent paid prior to the commencement date, less any lease incentives received, and initial direct costs incurred. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. We have elected to combine our lease components (e.g., fixed payments including rent, real estate taxes and insurance costs) with non-lease components (e.g., common-area maintenance costs and equipment maintenance costs) and as such, we account for lease and non-lease components as a single component. Lease expense also includes amounts relating to variable lease payments. Variable lease payments include amounts relating to common area maintenance and real estate taxes.

We also elected not to recognize right-of-use assets and lease liabilities for qualifying short-term leases with an initial lease term of 12 months or less at lease inception. Such leases are expensed on a straight-line basis over the lease term.

The depreciable life of operating right-of-use-assets and leasehold improvements is limited by the expected lease term.

***Stock-based Compensation***

We account for stock-based compensation under the provisions of ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718, which applies to share-based payments issued to employees and nonemployees in exchange for goods or services. Under ASC 718, the fair value of an equity-classified award is estimated on the grant date without regard to service or performance conditions. The grant date fair values for options and warrants are estimated using the Black-Scholes-Merton option pricing model, and the grant date fair values for restricted stock units, or RSUs, are based upon the closing market price of our common stock on the date of grant.

We use the straight-line method to recognize stock-based compensation expense for our outstanding share awards that do not contain a performance condition. For awards subject to performance-based vesting conditions, we assess the probability of the individual milestones under the award being achieved and stock-based compensation expense is recognized over the service period commencing once management believes the performance criteria is probable of being met. For awards with service or performance conditions, we recognize the effect of forfeitures in compensation cost in the period that the award was forfeited.

***Stock Repurchases***

In November 2015, the board of directors approved a share repurchase program, or the 2015 Share Repurchase Program, allowing the CEO or CFO, on behalf of the company, to repurchase from time to time, in the open market or in privately negotiated transactions, up to $50.0 million of our outstanding shares of common stock, exclusive of any commissions, markups or expenses. The timing and amounts of any purchases were and will continue to be based on market conditions and other factors, including price, regulatory requirements and other corporate considerations. The 2015 Share Repurchase Program does not require the purchase of any minimum number of shares and may be suspended, modified or discontinued at any time without prior notice. We have financed, and expect to continue to finance, the purchases with existing cash balances. As it is the intent for the repurchased shares to be retired, we have elected to account for the shares repurchased under the constructive retirement method. For shares repurchased in excess of par, we allocate the purchase price in excess of par value to accumulated deficit.

***Utilization of Net Operating Loss Carryforwards, or NOLs, and Research and Development Credits***

As of December 31, 2019, we had federal, state and foreign income tax NOLs of approximately $291.8 million, $255.7 million and $0.2 million, respectively, which will begin to expire at various dates starting with 2022. 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, to offset future income taxes.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carry forwards and other pre-change tax attributes to offset its post-change income may be limited. We have completed a study to determine the impact of ownership changes on our NOLs and we have undergone significant ownership changes in previous years. Accordingly, some of our NOLs and research and development credits have been derecognized.

**Recent Accounting Pronouncements**

***Application of New or Revised Accounting Standards – Not Yet Adopted***

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The amendments in this update include removing the exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income, or a gain, from other items (e.g., discontinued operations or other comprehensive income), and the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. We are currently evaluating the impact that these amendments will have on our consolidated financial statements and we intend to early adopt these amendments on January 1, 2020. We do not expect that the adoption of these amendments will have a significant impact on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The new guidance supersedes existing U.S. GAAP for measuring and recording of credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, but may be adopted earlier. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*, which provides companies with an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis upon adoption of Topic 326. We are currently evaluating the impact that this new standard and its related amendments will have on our consolidated financial statements and we intend to adopt the standard on January 1, 2021. However, as the impact is dependent upon the investments held as of the adoption date, it is not possible for us to quantify the impact until the date of adoption.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the SEC during the three months ended December 31, 2019 did not, or are not expected to, have a material effect on our consolidated financial statements.

**JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933 for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain exemptions and reduced reporting requirements provided by the JOBS Act, including those relating to (i) providing an auditor's attestation report on our system of internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying 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, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC with at least $700 million of outstanding equity securities held by non-affiliates, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years, or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO, or December 31, 2020.

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

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our cash equivalents and investments. The primary objective of our investment activities is to preserve our capital to fund operations. A secondary objective is to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in low-risk, investment-grade debt instruments. As of December 31, 2019, we had $15.5 million in cash and cash equivalents and $37.6 million in our investment portfolio. Our cash equivalents are short-term investments with maturities of 90 days or less at the time of purchase. We maintain cash deposits in FDIC insured financial institutions in excess of federally insured limits. However, we believe that we are not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. As of December 31, 2019, we did not hold or issue financial instruments for trading purposes. To date, we have not realized any significant loss of principal on our investments.

***Interest rate risk – cash***

With the cash discussed above, our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S interest rates. However, we do not believe a sudden change in the interest rates would have a material impact on our financial condition or results of operations due to the short-term maturities on our cash equivalents. A hypothetical 100 basis point change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

***Interest rate risk – cash equivalents and investment portfolio***

We invest a portion of our cash in a number of diversified fixed and floating rate securities, consisting of marketable debt securities and debt funds that are subject to interest rate risk. Changes in the general level of interest rates can affect the fair value of our investment portfolio. If interest rates in the general economy were to rise, our holdings could lose value. At December 31, 2019, a hypothetical increase in interest rates of 100 basis points across the entire yield curve on our holdings would not have resulted in a material impact on the fair value of our portfolio.

***Foreign currency exchange risk***

We contract with clinical research organizations, investigational sites and suppliers in foreign countries and we have a bank account in Korea. We are, therefore, subject to fluctuations in foreign currency rates in connection with these agreements. We have not entered into any material foreign currency hedging contracts although we may do so in the future. To date we have not incurred any material effects from foreign currency changes on these contracts. The effect of a 10% adverse change in exchange rates on foreign currency denominated cash and payables as of December 31, 2019 would not have been material. However, fluctuations in currency exchange rates could harm our business in the future.

***Inflation risk***

Inflation may affect us by increasing our cost of labor, clinical trial, and other costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations for any period presented herein.

**Item 8. Financial Statements and Supplementary Data.**

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of NantKwest, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of NantKwest, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

**Adoption of ASU No. 2016-02**

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)*, and the related amendments.

**Basis for Opinion**

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2016.

Los Angeles, California
March 25, 2020

**NantKwest, Inc.**
**Consolidated Balance Sheets**
**(in thousands, except share and per share amounts)**

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 15,508 | $ 16,821 |
| Prepaid expenses and other current assets (including related parties) | 4,105 | 13,900 |
| Marketable debt securities, available-for-sale | 36,144 | 57,328 |
| Notes receivable, held-to-maturity | — | 723 |
| Total current assets | 55,757 | 88,772 |
| Marketable debt securities, noncurrent | 1,497 | 5,701 |
| Property, plant and equipment, net | 60,501 | 76,885 |
| Operating lease right-of-use assets, net (including related parties) | 11,729 | — |
| Equity investment | 9,253 | 8,500 |
| Intangible assets, net | — | 565 |
| Other assets (including related parties) | 4,386 | 1,527 |
| Total assets | $ 143,123 | $ 181,950 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,749 | $ 2,793 |
| Accrued expenses | 5,343 | 21,104 |
| Due to related parties | 486 | 1,696 |
| Other current liabilities (including related parties) | 3,981 | 1,667 |
| Total current liabilities | 11,559 | 27,260 |
| Operating lease liability, less current portion (including related parties) | 10,885 | — |
| Financing obligation, less current portion | — | 5,945 |
| Deferred rent | — | 2,739 |
| Total liabilities | 22,444 | 35,944 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value; 500,000,000 shares authorized; 98,460,404 and 79,087,734 issued and outstanding as of December 31, 2019 and December 31, 2018 | 10 | 8 |
| Additional paid-in capital | 782,965 | 741,246 |
| Accumulated other comprehensive loss | (105) | (267) |
| Accumulated deficit | (662,191) | (594,981) |
| Total stockholders' equity | 120,679 | 146,006 |
| Total liabilities and stockholders' equity | $ 143,123 | $ 181,950 |

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

**NantKwest, Inc.**
**Consolidated Statements of Operations**
**(in thousands, except share and per share amounts)**

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| **Revenue** | $ 43 | $ 47 | $ 45 |
| Operating expenses: | | | |
| Research and development (including amounts with related parties) | 49,785 | 55,718 | 42,044 |
| Selling, general and administrative (including amounts with related parties) | 18,065 | 42,718 | 57,121 |
| Total operating expenses | 67,850 | 98,436 | 99,165 |
| **Loss from operations** | (67,807) | (98,389) | (99,120) |
| Other income (expense): | | | |
| Investment income, net | 1,642 | 1,857 | 2,665 |
| Interest expense (including amounts with related parties) | (19) | (433) | (618) |
| Other income, net (including amounts with related parties) | 298 | 236 | 157 |
| Total other income | 1,921 | 1,660 | 2,204 |
| **Loss before income taxes** | (65,886) | (96,729) | (96,916) |
| Income tax benefit | 97 | 503 | 493 |
| **Net loss** | $ (65,789) | $ (96,226) | $ (96,423) |
| | | | |
| Net loss per share: | | | |
| Basic and diluted | $ (0.70) | $ (1.22) | $ (1.20) |
| | | | |
| Weighted-average number of shares during the period: | | | |
| Basic and diluted | 94,210,087 | 79,132,220 | 80,583,910 |

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

**NantKwest, Inc.**
**Consolidated Statements of Comprehensive Loss**
**(in thousands)**

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Net loss | $ (65,789) | $ (96,226) | $ (96,423) |
| Other comprehensive income (loss), net of income taxes: | | | |
| Net unrealized gains (losses) on available-for-sale securities | 158 | 114 | (65) |
| Reclassification of net realized gains (losses) on available-for-sale securities included in net loss | 4 | — | (32) |
| Total other comprehensive income (loss) | 162 | 114 | (97) |
| Comprehensive loss | $ (65,627) | $ (96,112) | $ (96,520) |

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

**NantKwest, Inc.**
**Consolidated Statements of Stockholders' Equity**
**(in thousands, except share and per share amounts)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Total |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2016** | **81,983,937** | **$ 8** | **$ 680,757** | **$ (284)** | **$ (387,063)** | **$ 293,418** |
| Stock-based compensation expense | — | — | 36,997 | — | — | 36,997 |
| Exercise of warrants | 47,226 | — | 61 | — | — | 61 |
| Exercise of stock options | 614,136 | — | 1,154 | — | — | 1,154 |
| Vesting of restricted stock units (RSUs) | 244,209 | — | — | — | — | — |
| Net share settlement for RSU vesting and option exercises | (234,020) | — | (1,039) | — | — | (1,039) |
| Repurchase of common stock | (3,633,610) | — | — | — | (15,227) | (15,227) |
| Other comprehensive loss | — | — | — | (97) | — | (97) |
| Net loss | — | — | — | — | (96,423) | (96,423) |
| **Balance at December 31, 2017** | **79,021,878** | **$ 8** | **$ 717,930** | **$ (381)** | **$ (498,713)** | **$ 218,844** |
| Stock-based compensation expense | — | — | 23,382 | — | — | 23,382 |
| Exercise of warrants | 93,254 | — | 57 | — | — | 57 |
| Vesting of RSUs | 172,330 | — | — | — | — | — |
| Net share settlement for RSU vesting and warrant exercises | (61,379) | — | (123) | — | — | (123) |
| Repurchase of common stock | (138,349) | — | — | — | (228) | (228) |
| Cumulative effect of the adoption of the new revenue standard | — | — | — | — | 186 | 186 |
| Other comprehensive income | — | — | — | 114 | — | 114 |
| Net loss | — | — | — | — | (96,226) | (96,226) |
| **Balance at December 31, 2018** | **79,087,734** | **$ 8** | **$ 741,246** | **$ (267)** | **$ (594,981)** | **$ 146,006** |
| Stock-based compensation expense | — | — | 2,627 | — | — | 2,627 |
| Exercise of warrants | 17,589,250 | 2 | 35,149 | — | — | 35,151 |
| Exercise of stock options | 1,986,300 | — | 4,070 | — | — | 4,070 |
| Vesting of RSUs | 395,051 | — | — | — | — | — |
| Net share settlement for RSU vesting and option exercises | (124,345) | — | (127) | — | — | (127) |
| Repurchase of common stock | (473,586) | — | — | — | (501) | (501) |
| Cumulative effect of the adoption of the new lease standard | — | — | — | — | (920) | (920) |
| Other comprehensive income | — | — | — | 162 | — | 162 |
| Net loss | — | — | — | — | (65,789) | (65,789) |
| **Balance at December 31, 2019** | **98,460,404** | **$ 10** | **$ 782,965** | **$ (105)** | **$ (662,191)** | **$ 120,679** |

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

**NantKwest, Inc.**
**Consolidated Statements of Cash Flows**
**(in thousands)**

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| **Operating activities:** | | | |
| Net loss | $ (65,789) | $ (96,226) | $ (96,423) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 9,012 | 9,555 | 5,566 |
| Stock-based compensation expense | 2,627 | 23,382 | 36,997 |
| Non-cash lease expense related to operating lease right-of-use assets | 2,604 | — | — |
| Amortization of net premiums and discounts on marketable debt securities | — | 463 | 1,597 |
| Non-cash interest items, net | 246 | 291 | 720 |
| Loss on impairment of assets | 869 | — | — |
| Loss on disposal of assets | — | 209 | 64 |
| Deferred income tax benefit | — | (498) | (497) |
| Gains (losses) on sales of marketable debt securities | 4 | (3) | (32) |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | 9,276 | (9,818) | 156 |
| Operating lease right-of-use assets, net | (800) | — | — |
| Other assets | (4,063) | (1,151) | 458 |
| Accounts payable | 41 | (1,100) | 150 |
| Accrued expenses and other liabilities | (12,020) | 12,708 | (299) |
| Due to related parties | (1,093) | (685) | 1,562 |
| Operating lease liabilities | (2,276) | — | — |
| Deferred rent and revenue | — | (508) | 1,201 |
| Net cash used in operating activities | (61,362) | (63,381) | (48,780) |
| | | | |
| **Investing activities:** | | | |
| Purchases of property, plant and equipment | (4,182) | (13,102) | (34,815) |
| Proceeds from sales of property, plant and equipment | — | 412 | — |
| Purchases of debt securities, held-to-maturity | — | (723) | — |
| Purchases of investments in equity securities | (3) | — | (8,500) |
| Purchases of marketable debt securities, available-for-sale | (86,618) | (94,770) | (111,355) |
| Sales/maturities of marketable debt securities | 112,259 | 165,284 | 254,222 |
| Net cash provided by investing activities | 21,456 | 57,101 | 99,552 |
| | | | |
| **Financing activities:** | | | |
| Principal payments of financing/capital lease obligations | — | (477) | (19,932) |
| Proceeds from exercises of stock options and warrants | 39,221 | 57 | 1,215 |
| Repurchases of common stock with commissions | (501) | (228) | (15,227) |
| Net share settlement for restricted stock unit vesting and warrant and option exercises | (127) | (123) | (1,039) |
| Net cash provided by (used in) financing activities | 38,593 | (771) | (34,983) |
| Net (decrease) increase in cash, cash equivalents, and restricted cash | (1,313) | (7,051) | 15,789 |
| Cash, cash equivalents and restricted cash, beginning of period | 17,000 | 24,051 | 8,262 |
| Cash, cash equivalents and restricted cash, end of period | $ 15,687 | $ 17,000 | $ 24,051 |

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

**NantKwest, Inc.**
**Consolidated Statements of Cash Flows (Continued)**
**(in thousands)**

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| **Reconciliation of cash, cash equivalents, and restricted cash at end of period:** | | | |
| Cash and cash equivalents | $ 15,508 | $ 16,821 | $ 23,872 |
| Restricted cash included in other assets | 179 | 179 | 179 |
| Cash, cash equivalents, and restricted cash, end of period | $ 15,687 | $ 17,000 | $ 24,051 |
| | | | |
| **Supplemental disclosure of cash flow information:** | | | |
| Cash paid during the period for: | | | |
| Interest | $ 19 | $ 475 | $ 668 |
| Income taxes | $ 3 | $ 4 | $ 3 |
| **Supplemental disclosure of non-cash investing and financing activities:** | | | |
| Property and equipment purchases acquired under capital lease | $ — | $ — | $ 19,448 |
| Property and equipment purchases included in accounts payable, accrued expenses, and other liabilities | $ 74 | $ 4,664 | $ 9,500 |
| Conversion of Viracta convertible notes and accrued interest into investment in equity securities of Viracta (Note 4) | $ 751 | $ — | $ — |
| Unrealized gains (losses) on marketable debt securities | $ 258 | $ 123 | $ (97) |
| Cashless exercises of stock options and warrants | $ 29 | $ 94 | $ 16 |

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

## 1. Description of Business

### *Organization*

NantKwest, Inc., or NantKwest, was incorporated in Illinois on October 7, 2002 under the name ZelleRx Corporation. On January 22, 2010, the company changed its name to Conkwest, Inc., and on July 10, 2015, the company changed its name to NantKwest, Inc. In March 2014, the company redomesticated from the State of Illinois to the State of Delaware and the Illinois company ceased to exist. We are a pioneering clinical-stage immunotherapy biotechnology company headquartered in San Diego, California with certain operations in Culver City and El Segundo, California and Woburn, Massachusetts. In these notes, the terms “we,” “our,” “the company” and “us” refer to NantKwest.

We are focused on harnessing the power of the innate immune system by using its natural killer cells, or NK cells, to treat cancer and viral infectious diseases. 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 hold the exclusive right to commercialize aNK cells, a commercially viable NK cell line, and a wide range of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States, or U.S., and foreign composition and methods-of-use patents and applications covering the cells, improvements, methods of expansion and manufacture and use of aNK cells and their improvements as therapeutics to treat a spectrum of clinical conditions.

We also license exclusive commercial rights to a high-affinity CD16 receptor expressing enhancement of our aNK cell platform, covered in a portfolio of U.S. and foreign composition and methods-of-use patents and applications covering both the clinical use as a therapeutic to treat cancers in combination with antibody products, as well as the non-clinical use in laboratory testing of monoclonal antibodies. We have non-exclusively licensed or sub-licensed our high-affinity CD16 bearing aNK cell platform and corresponding intellectual property to numerous pharmaceutical and biotechnology companies for such non-clinical uses.

### *Liquidity*

As of December 31, 2019, the company had an accumulated deficit of approximately $662.2 million. We also had negative cash flow from operations of approximately $61.4 million during the year ended December 31, 2019. The company expects that it will likely need additional capital to further fund development of, and seek regulatory approvals for, our product candidates, and to begin to commercialize any approved products.

We are currently focused primarily on the development of immunotherapeutic treatments for cancers and debilitating viral infections using targeted cancer and viral killing cell lines, and we believe such activities will result in the company’s continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of the company’s product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if the company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. We intend to cover our future operating expenses through cash and cash equivalents and marketable debt securities on hand and through a combination of equity offerings, debt financings, government or other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements. Additional financing may not be available to us when needed and, if available, financing may not be obtained on terms favorable to the company or its stockholders.

While we expect our existing cash, and cash equivalents and marketable debt securities, together with the ability to borrow from affiliated entities, will enable us to fund operations and capital expenditure requirements for at least the next 12 months, we may not have sufficient funds to reach commercialization. Failure to obtain adequate financing when needed may require us to delay, reduce, limit, or terminate some or all of our development programs or future commercialization efforts or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves, which could adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to existing stockholders may result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations, as well as covenants and specific financial ratios that may restrict our ability to operate our business.

## 2. Summary of Significant Accounting Policies

***Basis of Presentation***

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

The consolidated financial statements have been prepared assuming the company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of the uncertainty discussed in the Liquidity section of Note 1. We believe our existing cash, cash equivalents, and investments in marketable debt securities, and our ability to borrow from affiliated entities, will be sufficient to fund operations through 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 the company's operations with additional funds, including loans from affiliated entities, as required. We may also seek to sell additional equity, through one or more follow-on public offerings, or in separate financings, or obtain a credit facility. However, we may not be able to secure such financing in a timely manner or on favorable terms. Without additional funds, we may choose to delay or reduce our operating or investment expenditures. Further, because of the risk and uncertainties associated with the commercialization of the company's product candidates in development, we may need additional funds to meet our needs sooner than planned. To date, the company's primary sources of capital were its initial public offering and the concurrent private placement of common shares. In addition, during the year ended December 31, 2019, our Chairman and CEO exercised warrants and options resulting in aggregate cash proceeds of $39.2 million.

***Principles of Consolidation***

The consolidated financial statements include the accounts of NantKwest and its wholly owned subsidiaries. All intercompany amounts have been eliminated.

We apply the variable interest model under Accounting Standards Codification, or ASC Topic 810, *Consolidation*, to any entity in which we hold an equity investment or to which we have the power to direct the entity's most significant economic activities and the ability to participate in the entity's economics. If the entity is within the scope of the variable interest model and meets the definition of a variable interest entity, or VIE, we consider whether we must consolidate the VIE or provide additional disclosures regarding our involvement with the VIE. If we determine that we are the primary beneficiary of the VIE, we will consolidate the VIE. This analysis is performed at the initial investment in the entity or upon any reconsideration event.

For entities we hold as an equity investment that are not consolidated under the VIE Model, we consider whether our investment constitutes ownership of a majority of the voting interests in the entity and therefore should be considered for consolidation under the voting interest model.

Unconsolidated equity investments in the common stock or in-substance common stock of an entity under which we are able to exercise significant influence, but not control, are accounted for using the equity method. Our ability to exercise significant influence is generally indicated by ownership of 20 to 50 percent interest in the voting securities of the entity.

All other unconsolidated equity investments on which we are not able to exercise significant influence will be subsequently measured at fair value with unrealized holding gains and losses included in other income, net on the consolidated statements of operations. In the instance the equity investment does not have a readily determinable fair value and does not qualify for the practical expedient to estimate fair value in accordance with ASC 820, *Fair Value Measurement*, or ASC 820, we will apply the measurement alternative under ASC 321, *Investments—Equity Securities*, or ASC 321, pursuant to which we will measure the investment at its cost less impairment, adjusted for observable price changes in an orderly market for an identical or similar investment of the same issuer.

We own non-marketable equity securities that are accounted for using the measurement alternative under ASC 321 because the preferred stock held by us is not considered in-substance common stock and such preferred stock does not have a readily determinable fair value. All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an impairment indicator is present include: the investees' earnings performance and clinical trial performance, change in the investees' industry and geographic area in which it operates, offers to purchase or sell the security for a price less than the cost of the investment, issues that raise concerns about the investee's ability to continue as a going concern, and any other information that we may be aware of related to the investment. Factors considered in determining whether an observable price change has occurred include: the price at which the investee issues equity instruments similar to those of our investment and the rights and preferences of those equity instruments compared to ours.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to valuation of equity-based awards, deferred income taxes and related valuation allowances, preclinical and clinical trial accruals, impairment assessments, useful lives of long-lived assets, loss contingencies, and fair value measurements. We base our estimates on historical experience and on various other market-specific and relevant assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

***Risks and Uncertainties***

***Contingencies***

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or of the range of potential losses disclosed. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances when our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

***Concentration of Credit Risk and Other Risks and Uncertainties***

Financial instruments that potentially subject us to concentrations of risk consist principally of cash and cash equivalents and marketable debt securities.

Our cash and cash equivalents are held by one major financial institution in the U.S. and one in Korea.

Product candidates developed by us will require approvals or clearances from the U.S. Food and Drug Administration, or FDA, or international regulatory agencies prior to commercial sales. There can be no assurance that any of our product candidates will receive any of the required approvals or clearances. If we were to be denied approval or clearance or any such approval or clearance was to be delayed, it would have a material adverse impact on us.

***Cash, Cash Equivalents and Marketable Debt Securities***

We invest our excess funds in investment grade short- to intermediate-term corporate debt securities, commercial paper, government sponsored securities, and foreign government bonds. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents and all investments purchased with original maturities of greater than three months as marketable debt securities, classified as available-for-sale. Marketable debt securities with remaining maturities of 12 months or less are classified as short-term and marketable debt securities with remaining maturities greater than 12 months are classified as long-term. All marketable debt securities are reported at fair value and any unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss), net of tax, on the consolidated statements of stockholders' equity, with the exception of unrealized losses believed to be other-than-temporary, which are recorded in investment income, net, on the consolidated statements of operations. Realized gains and losses are included in investment income, net, on the consolidated statements of operations. Realized gains and losses from sale of the securities and the amounts, net of tax, reclassified out of accumulated other comprehensive loss, if any, are determined on a specific identification basis.

We periodically evaluate whether declines in fair values of our investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss, as well as our ability and intent to hold the investment until a forecasted recovery occurs. Additionally, we assess whether or not we have plans to sell the security or whether or not it is more likely than not we will be required to sell any investment before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of our investments, duration and severity of the decline in value, and our strategy and intentions for holding the investment. There were no other-than-temporary impairments recorded in the years ended December 31, 2019, 2018 and 2017.

We minimize credit risk associated with our cash and cash equivalents by periodically evaluating the credit quality of our primary financial institutions. While we maintain cash deposits in FDIC insured financial institutions in excess of federally insured limits, we do not believe that we are exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. We have not experienced any losses on such accounts.

We have funded a certificate of deposit (CD) as a substitute letter of credit for one of our leased properties. This CD is reported as long term restricted cash and is included in other assets on the consolidated balance sheets as the landlord is the beneficiary of the account and we are not able to access the funds during the term of the lease.

***Property, Plant and Equipment***

Property, plant and equipment is stated at historical cost less accumulated depreciation. Historical cost includes expenditures that are directly attributable to the acquisition of the items. All repairs and maintenance are charged to net loss during the financial period in which they are incurred. Depreciation of property, plant and equipment is calculated using the straight-line method over the estimated useful lives of the assets, as follows:

| | |
|---|---|
| Buildings | 39 years |
| Software | 3 years |
| Laboratory equipment | 5 years |
| Furniture & fixtures | 5 years |
| IT equipment | 3 years |
| Leasehold improvements | The lesser of the lease term or the life of the asset |

Upon disposal or impairment of property, plant and equipment, the cost and related accumulated depreciation is removed from the consolidated financial statements and the net amount, less any proceeds, is included in the consolidated statements of operations.

***Intangible Assets***

Intangible assets, which consisted of the cost of reacquiring a technology license during 2015, were amortized using the straight-line method over an estimated useful life of 4 years. As of December 31, 2019, our intangible assets were fully amortized.

***Patents***

Patent costs, including related legal costs, are expensed as incurred and recorded in selling, general and administrative expenses on the consolidated statements of operations.

***Impairments***

Long-lived assets include property, plant and equipment and intangible assets. We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected undiscounted future cash flows arising from the assets using a discount rate determined by management to be commensurate with the risk inherent to our current business model.

During the second quarter of 2019, we determined that certain bioreactor laboratory equipment could no longer be utilized in the production process. As a result, we recorded an impairment charge totaling $0.9 million, which is included in research and development expense on the consolidated statements of operations. There were no impairment losses recognized during the years ended December 31, 2018 and 2017.

***Fair Value of Financial Instruments***

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on our principal or, in absence of a principal, most advantageous market for the specific asset or liability.

We use a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires us to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value.

The three tiers are defined as follows:

- Level 1— Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets at the measurement date. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment. Our Level 1 assets consist of bank deposits and money market funds.
- Level 2— Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities. Our Level 2 assets consist of corporate debt securities including commercial paper, government sponsored securities and corporate bonds, as well as foreign municipal securities.
- Level 3— Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

During the years ended December 31, 2019, 2018 and 2017, no transfers were made into or out of the Level 1, 2 or 3 categories. We will continue to review the fair value inputs on a quarterly basis.

We utilize a third-party pricing service to assist in obtaining fair value pricing for our investments in marketable debt securities. Inputs are documented in accordance with the fair value disclosure hierarchy.

***Preclinical and Clinical Trial Accruals***

As part of the process of preparing the financial statements, we are required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations and consultants. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

We estimate clinical trial and research agreement related expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. In accruing clinical and research related fees, we estimate the time period over which services will be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

***Transactions with Related Parties***

As outlined in Note 9 – *Related Party Agreements*, we have various agreements with different related parties. Some are billed and settled in cash monthly. Others are billed quarterly and settled in cash the following month. Monthly accruals are made for all quarterly billing arrangements.

***Lease Obligations***

We adopted FASB ASC Topic 842, *Leases*, or ASC 842, effective January 1, 2019. For contracts entered into on or after the effective date, we determine if an arrangement is, or contains, a lease at lease inception. Our assessment is based on: (1) whether the contract involves the use of a distinct identified asset; (2) whether we obtain the right to substantially all of the economic benefit from the use of the asset throughout the period; and (3) whether we have the right to direct the use of the asset. At inception of a lease, we allocate the consideration in the contract to each lease component based on its relative stand-alone price to determine the lease payments. Leases entered into prior to January 1, 2019, which were accounted for under ASC 840, *Leases*, were not reassessed as we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification. We determine the lease term by assuming the exercise of renewal options that are reasonably assured. The exercise of lease renewal options is at our sole discretion. Several of our leases have renewal options, however, exercise of renewal is only assured for the El Segundo current Good Manufacturing Practices, or cGMP, facility, where we have made significant improvements.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. At lease commencement, leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: (1) the lease transfers ownership of the underlying asset by the end of the lease term; (2) the lease contains an option to purchase the underlying asset that is reasonably certain to be exercised; (3) the lease term is for a major part of the remaining economic life of the underlying asset; (4) the present value of the sum of the lease payments and any guaranteed residual value that is not already included in the lease payments equals or exceeds substantially all of the fair value of the underlying asset; or (5) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease is classified as an operating lease if it does not meet any one of these criteria.

We do not currently have any leases classified as finance leases. Our operating leases are included in operating lease right-of-use assets, net, other current liabilities, and operating lease liabilities on the consolidated balance sheets. At the commencement date, operating lease right-of-use assets and operating lease liabilities are determined based on the present value of lease payments to be made over the lease term. Operating lease right-of-use assets also include any rent paid prior to the commencement date, less any lease incentives received, and initial direct costs incurred. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. We have elected to combine our lease components (e.g., fixed payments including rent, real estate taxes and insurance costs) with non-lease components (e.g., common-area maintenance costs and equipment maintenance costs) and as such, we account for lease and non-lease components as a single component. Lease expense also includes amounts relating to variable lease payments. Variable lease payments include amounts relating to common area maintenance and real estate taxes.

We also elected not to recognize right-of-use assets and lease liabilities for qualifying short-term leases with an initial lease term of 12 months or less at lease inception. Such leases are expensed on a straight-line basis over the lease term.

The depreciable life of operating right-of-use-assets and leasehold improvements is limited by the expected lease term.

***Income Taxes***

We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis of assets and liabilities, as well as for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. We record valuation allowances to reduce deferred tax assets to the amount we believe is more likely than not to be realized.

We recognize uncertain tax positions when the position will be more likely than not upheld on examination by the taxing authorities based solely upon the technical merits of the positions. We recognize interest and penalties, if any, related to unrecognized income tax uncertainties in income tax expense. We did not have any accrued interest or penalties associated with uncertain tax positions as of December 31, 2019 and 2018.

We are subject to U.S. federal income tax, as well as income tax in Korea, California and other states. The federal returns for tax years 2016 through 2019 remain open to examination; the California returns remain subject to examination for tax years 2015 through 2019. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other respective tax authority. All other state jurisdictions remain open to examination. No income tax returns are currently under examination by taxing authorities.

***Stock Repurchases***

In November 2015, the board of directors approved the 2015 Share Repurchase Program (Note 10) allowing the CEO or CFO, on behalf of the company, to repurchase from time to time, in the open market or in privately negotiated transactions, up to $50.0 million of our outstanding shares of common stock, exclusive of any commissions, markups or expenses. The timing and amounts of any purchases were and will continue to be based on market conditions and other factors, including price, regulatory requirements and other corporate considerations. The 2015 Share Repurchase Program does not require the purchase of any minimum number of shares and may be suspended, modified or discontinued at any time without prior notice. We have financed, and expect to continue to finance, the purchases with existing cash balances. As it is the intent for the repurchased shares to be retired, we have elected to account for the shares repurchased under the constructive retirement method. For shares repurchased in excess of par, we allocate the purchase price in excess of par value to accumulated deficit.

***Revenue Recognition***

Beginning January 1, 2018, we adopted the provisions of FASB ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. This guidance requires that entities recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted ASC 606 on January 1, 2018 by recording the cumulative effect of the adoption to accumulated deficit. We applied the new guidance to contracts that were not complete as of January 1, 2018. Implementation of ASC 606 did not have a material impact on our consolidated financial statements.

We derive substantially all of our revenue from non-exclusive license agreements with a limited number of pharmaceutical and biotechnology companies granting them the right to use our cell lines and intellectual property for non-clinical use. These agreements generally include upfront fees and annual research license fees for such use, as well as commercial license fees for sales of the licensee products developed or manufactured using our intellectual property and cell lines.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

Under the company's license agreements with customers, the company typically promises to provide a license to use certain cell lines and related patents, the related know-how, and future research and development data that affect the license. We have concluded that these promises represent one performance obligation due to the highly interrelated nature of the promises. We provide the cell lines and know-how immediately upon entering into the contracts. The research and development data is provided throughout the term of the contract when and if available.

Our license agreement with Intrexon (Note 7) included a nonrefundable upfront payment of $0.4 million, received when we entered into the contract in 2010. In this instance, we determined that under ASC 606 it would be appropriate to recognize the initial milestone payment at a point in time, when we transferred the license. In this case, the intellectual property provided under the contract is functional intellectual property under ASC 606 and was determined to be a distinct performance obligation in the context of the arrangement. Prior to adoption, the upfront payment had been initially recorded as deferred revenue and was being recognized into revenue on a straight-line basis. As a result, upon adoption of ASC 606, we adjusted our accumulated deficit for the effects of recognizing revenue upfront for the initial milestone. The adjustment to accumulated deficit upon adoption was not material.

The license agreements may include nonrefundable upfront payments, event-based milestone payments, sales-based royalty payments, or some combination of these. The event-based milestone payments represent variable consideration and we use the most likely amount method to estimate this variable consideration. Given the high degree of uncertainly around achievement of these milestones, we do not recognize revenue from these milestone payments until the uncertainty associated with these payments is resolved. We currently estimate variable consideration related to milestone payments to be zero and, as such, no revenue has been recognized for milestone payments. We recognize revenue from sales-based royalty payments when or as the sales occur. On a quarterly basis, we re-evaluate our estimate of milestone variable consideration to determine whether any amount should be included in the transaction price and recorded in revenue prospectively.

Upon adoption, we changed our accounting policy from accounting for milestones payments under the milestone method to accounting for variable consideration as discussed above. The change in accounting policy did not change any amounts in the financial statements because of the significant uncertainty surrounding the estimate of variable consideration for milestone payments.

To date, we have generated minimal revenue related to the non-clinical use of our cells lines and intellectual property. We have no products approved for commercial sale and we have not generated any revenue from product sales. If we fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval for them, we may never be able to generate substantial future revenue.

***Research and Development Costs***

Major components of research and development costs include cash compensation and other personnel-related expenses, stock-based compensation, depreciation and amortization expense on research and development property and equipment and intangible assets, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on our behalf. Costs incurred in research and development are expensed as incurred.

Included in research and development costs are clinical trial and research expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. We record accruals for estimated costs under these contracts. When evaluating the adequacy of the accrued liabilities, we analyze the progress of the studies or clinical trials, including the phase or completion of events, invoices received, contracted costs and purchase orders. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period based on the facts and circumstances known at that time. Although we do not expect the estimates to be materially different from the amounts actually incurred, if the estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. Actual results could differ from our estimates.

***Stock-Based Compensation***

We account for stock-based compensation under the provisions of ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718, which applies to share-based payments issued to employees and nonemployees in exchange for goods or services. Under ASC 718, the fair value of an equity-classified award is estimated on the grant date without regard to service or performance conditions. The grant date fair values for options and warrants are estimated using the Black-Scholes-Merton option pricing model, and the grant date fair values for restricted stock units, or RSUs, are based upon the closing market price of our common stock on the date of grant.

We use the straight-line method to recognize stock-based compensation expense for our outstanding share awards that do not contain a performance condition. For awards subject to performance-based vesting conditions, we assess the probability of the individual milestones under the award being achieved and stock-based compensation expense is recognized over the service period commencing once management believes the performance criteria is probable of being met. For awards with service or performance conditions, we recognize the effect of forfeitures in compensation cost in the period that the award was forfeited.

***Litigation Costs***

We expense legal fees as they are incurred.

***Comprehensive Income (Loss)***

Comprehensive income or loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income or loss is composed of net income (loss) and other comprehensive income (loss). Our other comprehensive income or loss consists of unrealized gains and losses on marketable debt securities classified as available-for-sale, net of income taxes.

***Basic and Diluted Net Loss per Share of Common Stock***

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted loss per share is computed similarly to basic loss per share except that the denominator is increased to include the number of additional shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive. The following table details those securities that have been excluded from the computation of potentially dilutive securities:

| | As of December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Outstanding options | 4,506,950 | 6,493,250 | 5,693,250 |
| Outstanding RSUs | 1,139,428 | 867,911 | 888,189 |
| Outstanding warrants | — | 17,589,250 | 17,721,088 |
| Total | 5,646,378 | 24,950,411 | 24,302,527 |

Amounts in the table above reflect the common stock equivalents of the noted instruments.

***Segment and Geographic Information***

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. Our chief operating decision maker is the company's CEO. We view our operations and manage our business as a single operating and reporting segment. As of December 31, 2019 and 2018, the majority of our assets were held in the U.S. For the years ended December 31, 2019, 2018 and 2017, all of our revenue was derived in the U.S.

**Recent Accounting Pronouncements**

***Application of New or Revised Accounting Standards – Adopted***

We adopted ASC 842 on January 1, 2019, using the simplified transition approach which allowed us to not recast the comparative periods presented when transitioning to the new lease standard, while including required disclosures under ASC 840 for all periods presented under ASC 840. In addition, we elected the package of practical expedients permitted under the transition guidance, which among other things, allowed us to not reassess (1) whether a contract is or contains a lease, and (2) the classification of existing leases.

The adoption of ASC 842 had a substantial impact on our balance sheet. The most significant impacts were (i) the recognition of $13.5 million of operating lease right-of-use assets, net, and $16.4 million of operating lease liabilities, and (ii) the derecognition of assets and liabilities associated with the build-to-suit leases under ASC 840 (resulting in the derecognition of property, plant and equipment, net, of $6.6 million and net adjustments to related liabilities of $5.7 million). The build-to-suit leases were recorded as normal operating leases under ASC 842. The difference between the excess of build-to-suit related liabilities and assets of $0.9 million was recorded as an increase to our accumulated deficit. The cumulative-effect adjustment had no tax impact due to the valuation allowance against the gross deferred tax asset less reversing deferred tax liabilities. Adoption of this standard had no material impact on our results of operations and cash flows.

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (ASU 2018-15). This update aligns guidance for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Capitalized implementation costs will be amortized over the term of the hosting arrangement and expense related to the capitalized implementation costs will be presented in the same line item in the statements of operations as the fees associated with the service contract. As permitted by the standard, we elected to early adopt ASU 2018-15 on a prospective basis as of October 1, 2019. The adoption did not have a material effect on our consolidated financial statements.

***Application of New or Revised Accounting Standards – Not Yet Adopted***

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The amendments in this update include removing the exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income, or a gain, from other items (e.g., discontinued operations or other comprehensive income), and the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. We are currently evaluating the impact that these amendments will have on our consolidated financial statements and we intend to early adopt these amendments on January 1, 2020. We do not expect that the adoption of these amendments will have a significant impact on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The new guidance supersedes existing U.S. GAAP for measuring and recording of credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, but may be adopted earlier. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*, which provides companies with an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis upon adoption of Topic 326. We are currently evaluating the impact that this new standard and its related amendments will have on our consolidated financial statements and we intend to adopt the standard on January 1, 2021. However, as the impact is dependent upon the investments held as of the adoption date, it is not possible for us to quantify the impact until the date of adoption.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission during the three months ended December 31, 2019 did not, or are not expected to, have a material effect on our consolidated financial statements.

## 3. Financial Statement Details

***Prepaid expenses and other current assets***

As of December 31, 2019 and 2018, prepaid expenses and other current assets were made up of (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Prepaid preclinical and clinical trial services - with related party (Note 9) | $ 1,021 | $ — |
| Insurance premium financing asset | 757 | 339 |
| Prepaid supplies - with related party (Note 9) | 467 | 532 |
| Prepaid services | 440 | 230 |
| Prepaid rent | 392 | 536 |
| Prepaid insurance | 372 | 343 |
| Prepaid equipment maintenance | 251 | 329 |
| Interest receivable - marketable debt securities | 222 | 473 |
| Prepaid license fees | 78 | 104 |
| Insurance claim receivables | 34 | 10,882 |
| Due from related parties | 47 | 90 |
| Other | 24 | 42 |
| | $ 4,105 | $ 13,900 |

***Property, plant and equipment, net***

As of December 31, 2019 and 2018, property, plant and equipment, net, was made up of (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Construction in progress | $ — | $ 2,480 |
| Leasehold improvements | 33,406 | 4,087 |
| Buildings | 22,690 | 59,356 |
| Equipment | 21,434 | 20,878 |
| Software | 1,195 | 1,264 |
| Furniture & fixtures | 383 | 381 |
| | 79,108 | 88,446 |
| Accumulated depreciation | (18,607) | (11,561) |
| | $ 60,501 | $ 76,885 |

Depreciation expense related to property, plant and equipment was $8.4 million, $7.3 million and $3.3 million for the years ended December 31, 2019, 2018 and 2017, respectively.

As a result of adoption of ASC 842 (Note 2), we (i) reclassified $32.0 million of assets from buildings to leasehold improvements, and (ii) derecognized $6.6 million of assets associated with build-to-suit leases under ASC 840.

The impact of adoption of ASC 842 on property, plant, and equipment at December 31, 2018 was as follows (in thousands):

| | Balance December 31, 2018 | Adoption of ASC 842 Increase (Decrease) | Balance January 1, 2019 |
|---|---|---|---|
| Leasehold improvements | $ 4,087 | $ 32,014 | $ 36,101 |
| Buildings | 59,356 | (39,893) | 19,463 |
| Property, plant and equipment, gross | 88,446 | (7,879) | 80,567 |
| Accumulated depreciation | (11,561) | 1,293 | (10,268) |
| Property, plant and equipment, net | $ 76,885 | $ (6,586) | $ 70,299 |

***Intangible assets, net***

As of December 31, 2019 and 2018, intangible assets were made up of (in thousands):

| | As of December 31, 2019 | 2018 |
|---|---|---|
| Technology license | $ 9,042 | $ 9,042 |
| Less accumulated amortization | (9,042) | (8,477) |
| | $ — | $ 565 |

Our intangible assets were fully amortized as of March 31, 2019. Amortization expense was $0.6 million, $2.3 million and $2.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. Amortization for the company's technology license is included in research and development expense on the consolidated statements of operations.

***Other assets***

As of December 31, 2019 and 2018, other assets were made up of (in thousands):

| | As of December 31, 2019 | 2018 |
|---|---|---|
| Prepaid preclinical and clinical trial services - with related party (Note 9) | $ 4,075 | $ — |
| Restricted cash | 179 | 179 |
| Security deposit | 113 | 113 |
| Prepaid rent | — | 1,205 |
| Other | 19 | 30 |
| | $ 4,386 | $ 1,527 |

Restricted cash is comprised of a certificate of deposit that serves as collateral for a letter of credit required by our landlord as a security deposit related to our facility in San Diego, California.

***Accrued expenses***

As of December 31, 2019 and 2018, accrued expenses were made up of (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Accrued bonus | $ 2,002 | $ 2,079 |
| Accrued compensation | 1,064 | 943 |
| Accrued professional and service fees | 975 | 912 |
| Accrued laboratory equipment and supplies | 640 | 678 |
| Accrued preclinical and clinical trial costs | 281 | 704 |
| Accrued franchise, sales/use and property taxes | 200 | 250 |
| Litigation settlement accruals | — | 12,000 |
| Accrued construction costs | — | 3,341 |
| Other | 181 | 197 |
| | $ 5,343 | $ 21,104 |

***Other current liabilities***

As of December 31, 2019 and 2018, other current liabilities were made up of (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Operating lease liability - current portion (including amounts with related parties, Note 9) | $ 3,206 | $ — |
| Financing obligation - current portion | 757 | 965 |
| Deferred rent - current portion | — | 598 |
| Other | 18 | 104 |
| | $ 3,981 | $ 1,667 |

***Investment income, net***

Net investment income is as follows for the years ended December 31, 2019, 2018 and 2017 (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Interest income | $ 1,643 | $ 2,317 | $ 4,225 |
| Investment accretion income (amortization expense), net | 3 | (463) | (1,597) |
| Net realized (losses) gains on investments | (4) | 3 | 37 |
| | $ 1,642 | $ 1,857 | $ 2,665 |

Interest income includes interest from marketable debt securities, notes receivable, other assets, and interest from bank deposits. We did not recognize an impairment loss on any investments during the years ended December 31, 2019, 2018 and 2017.

## 4. Viracta Investment and Convertible Notes

In March 2017, we participated in a Series B convertible preferred stock financing and invested $8.5 million in Viracta Therapeutics, Inc., or Viracta, a clinical stage drug development company. In May 2017, we executed an exclusive worldwide license with Viracta to develop and commercialize Viracta's proprietary histone deacetylase inhibitor drug candidate for use in combination with natural killer cell therapy and possibly additional therapies. See Note 7 – *Collaboration and License Agreements – Royalties and In-licensing Agreements – Viracta License Agreement* for further information.

In June 2018, Viracta executed a 2018 Note and Warrant Purchase Agreement with existing and new investors, including us. The initial closing under the Purchase Agreement occurred in June 2018, at which point we purchased a convertible note for $0.4 million, which under certain circumstances was convertible into preferred stock of Viracta, and a warrant to purchase Viracta's common shares. The convertible note accrued interest at 8% and had a one-year maturity date. In September 2018, a milestone closing under the Purchase Agreement occurred, at which point we purchased an additional convertible note for $0.4 million, which under certain circumstances was convertible into preferred stock of Viracta, and a warrant to purchase Viracta's common shares. The convertible note accrued interest at 8% and had a one-year maturity date. We classified the convertible notes as held-to-maturity notes receivable on the consolidated balance sheets. Effective January 31, 2019, the notes, together with accrued interest then outstanding, were converted to Series B preferred stock resulting in an increase to our investment in Viracta's Series B convertible preferred stock of $0.8 million. In May 2019, we exercised warrants to acquire 253,120 shares of Viracta common stock. At December 31, 2019, our investment in Viracta totaled $9.3 million.

Based on the level of equity investment at risk, Viracta is not a VIE and therefore is not consolidated under the VIE Model. In addition, we do not hold a controlling financial interest in Viracta and therefore we do not consolidate Viracta under the voting interest model. As the preferred stock is not considered in-substance common stock, the investment is not within the scope of accounting for the investment under the equity method. As the preferred stock does not have a readily determinable fair value and does not qualify for the practical expedient to estimate fair value in accordance with ASC 820, we have elected to apply the measurement alternative under ASC 321, pursuant to which we measure our investment in Viracta at cost, less impairment, adjusted for observable price changes in an orderly market for an identical or similar investment of the same issuer.

As of December 31, 2019, our qualitative impairment assessment did not indicate there were events or changes in circumstances that may have had a significant adverse effect on the fair value of the investment. We have not recorded any impairments as of December 31, 2019, or on a cumulative basis. Further, we have not identified any downward or upward adjustments due to observable price changes in the investment as of December 31, 2019, or on a cumulative basis. Our investment in Viracta is reflected in equity investment on the consolidated balance sheets.

## 5. Financial Instruments – Investments in Debt Securities

At December 31, 2019, our investments in debt securities are detailed below (in thousands):

| | December 31, 2019 | | | | |
|---|---|---|---|---|---|
| | Weighted-Average Remaining Contractual Life (in years) | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| Current: | | | | | |
| Available-for-sale: | | | | | |
| Corporate debt securities | 0.2 | $ 32,382 | $ 10 | $ (3) | $ 32,389 |
| Foreign government bonds | 0.3 | 1,007 | — | — | 1,007 |
| Government sponsored securities | 0.5 | 2,752 | — | (4) | 2,748 |
| Current portion | 0.2 | 36,141 | 10 | (7) | 36,144 |
| Noncurrent: | | | | | |
| Available-for-sale: | | | | | |
| Corporate debt securities | 1.7 | 1,501 | — | (4) | 1,497 |
| Noncurrent portion | 1.7 | 1,501 | — | (4) | 1,497 |
| Total | 0.3 | $ 37,642 | $ 10 | $ (11) | $ 37,641 |

At December 31, 2018, our investments in debt securities are detailed below (in thousands):

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| Current: | | | | |
| Available-for-sale: | | | | |
| Corporate debt securities | $ 57,463 | $ 1 | $ (136) | $ 57,328 |
| Total available-for-sale | 57,463 | 1 | (136) | 57,328 |
| Held-to-maturity, notes receivable (Note 4) | 723 | — | — | 723 |
| Current portion | 58,186 | 1 | (136) | 58,051 |
| Noncurrent: | | | | |
| Available-for-sale: | | | | |
| Corporate debt securities | 3,067 | — | (76) | 2,991 |
| Government sponsored securities | 2,756 | — | (46) | 2,710 |
| Noncurrent portion | 5,823 | — | (122) | 5,701 |
| Total | $ 64,009 | $ 1 | $ (258) | $ 63,752 |

Accumulated unrealized losses on debt securities classified as available-for-sale that have been in a continuous loss position for less than 12 months and for more than 12 months at December 31, 2019 and 2018 were as follows (in thousands):

| | December 31, 2019 | | | |
|---|---|---|---|---|
| | Less than 12 months | | More than 12 months | |
| | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses |
| Corporate debt securities | $ 11,021 | $ (3) | $ 1,497 | $ (4) |
| Government sponsored securities | — | — | 2,748 | (4) |
| Total | $ 11,021 | $ (3) | $ 4,245 | $ (8) |

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Less than 12 months | | More than 12 months | |
| | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses |
| Corporate debt securities | $ 32,010 | $ (26) | $ 26,663 | $ (186) |
| Government sponsored securities | — | — | 2,710 | (46) |
| Total | $ 32,010 | $ (26) | $ 29,373 | $ (232) |

At December 31, 2019, 14 of the securities were in an unrealized loss position. We evaluated our securities for other-than-temporary impairment and concluded that the decline in value was primarily caused by current economic and market conditions. We do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases. Therefore, we did not recognize any other-than-temporary impairment loss during the years ended December 31, 2019, 2018 and 2017.

We recorded realized gains and losses on sales of available-for-sale debt securities as follows (in thousands):

| | Gross Realized Gains | Gross Realized Losses | Net Realized Gains (Losses) |
|---|---|---|---|
| 2019 | $ 4 | $ (8) | $ (4) |
| 2018 | $ 3 | $ — | $ 3 |
| 2017 | $ 52 | $ (15) | $ 37 |

## 6. Fair Value Measurements

Fair value is defined as an exit price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Authoritative guidance establishes a three-level hierarchy for disclosure that is based on the extent and level of judgment used to estimate the fair value of assets and liabilities.

***Recurring Valuations***

Financial assets and liabilities measured at fair value on a recurring basis are summarized below at December 31, 2019 and 2018 (in thousands):

| | Fair Value Measurements at December 31, 2019 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Current: | | | | |
| Cash and cash equivalents | $ 15,508 | $ 15,508 | $ — | $ — |
| Corporate debt securities | 32,389 | — | 32,389 | — |
| Foreign government bonds | 1,007 | — | 1,007 | — |
| Government sponsored securities | 2,748 | — | 2,748 | — |
| Noncurrent: | | | | |
| Corporate debt securities | 1,497 | — | 1,497 | — |
| Total assets measured at fair value | $ 53,149 | $ 15,508 | $ 37,641 | $ — |

| | Fair Value Measurements at December 31, 2018 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Current: | | | | |
| Cash and cash equivalents | $ 16,821 | $ 16,821 | $ — | $ — |
| Corporate debt securities | 57,328 | — | 57,328 | — |
| Noncurrent: | | | | |
| Corporate debt securities | 2,991 | — | 2,991 | — |
| Government sponsored securities | 2,710 | — | 2,710 | — |
| Total assets measured at fair value | $ 79,850 | $ 16,821 | $ 63,029 | $ — |

***Non-recurring Valuations***

Non-financial assets and liabilities are recognized at fair value subsequent to initial recognition when they are deemed to be other-than-temporarily impaired. There were no material non-financial assets and liabilities deemed to be other-than-temporarily impaired and measured at fair value on a non-recurring basis for the years ended December 31, 2019, 2018 and 2017.

## 7. Collaboration and License Agreements

***Collaborative Arrangements***

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two or more parties who are (i) active participants in the activity, and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

In January 2020, we entered into a Cost Sharing Agreement with ImmunityBio as further described in Note 15 – *Subsequent Events*.

*Exclusive Co-Development Agreement*

In August 2016, we entered into an exclusive Co-Development Agreement, or the Co-Development Agreement, with Altor BioScience, LLC, or Altor. Altor is a related party, as it is a wholly owned subsidiary of ImmunityBio (Note 9). Under the Co-Development Agreement, the parties agreed to exclusively collaborate on the development of certain therapeutic applications combining our proprietary NK cells with Altor's N-801 and/or N-803 products with respect to certain technologies and intellectual property rights as may be agreed between the parties for the purpose of jointly developing therapeutic applications of certain effector cell lines.

We are the lead developer for each product developed by the parties pursuant to the Co-Development Agreement unless otherwise agreed to under a given project plan. Under the terms of the Co-Development Agreement, both parties granted a co-exclusive, royalty free, fully paid-up, worldwide license, with the right to sublicense (only to a third-party contractor assisting with research and development activities under this Co-Development Agreement and subject to prior consent, not to be unreasonably withheld), under the intellectual property, or IP, including the parties interest in the joint IP, solely to conduct any development activities agreed to by the steering committee as set forth in any development plan. Unless otherwise mutually agreed by the parties in the development plan for a project, we are responsible for all costs and expenses incurred by either party related to conducting clinical trials and other activities under each development program, including costs associated with patient enrollment, materials and supplies, third-party staffing and regulatory filings. Altor supplies free of charge, sufficient amounts of Altor products for all pre-clinical requirements and certain clinical requirements for up to 400 patients in phase I and/or phase II clinical trials, as required under the development plan for a project per the Co-Development Agreement.

Each company owns an undivided interest in and to all rights, title and interest in and to the joint product rights. The Co-Development Agreement expires upon the fifth anniversary of the effective date. We have dosed patients with N-803, an IL-15 superagonist, in several phase Ib/II trials during the years ended December 31, 2019, 2018 and 2017. No charges for supplies by Altor were incurred in association with the above trials during the years ended December 31, 2019, 2018 and 2017.

***Royalties and In-licensing Agreements***

*Viracta License Agreement*

In May 2017, we entered into an agreement with Viracta under which we were granted exclusive worldwide rights to Viracta's phase II drug candidate, VRx-3996, for use in combination with our platform of NK cell therapies. In consideration for the license, we are obligated to pay to Viracta (i) mid-single digit percentage royalties of net sales of licensed products for therapeutic use; and (ii) milestone payments ranging from $10.0 million to $25.0 million for various regulatory approvals and cumulative net sales levels. We may terminate the agreement, in its sole discretion, in whole or on a product by product and/or country by country basis, at any time upon 90 days' prior written notice. In addition, either party may terminate the agreement in the event of a material breach or for bankruptcy of the other party.

*Chemotherapeutisches Forschungsinstitut Georg-Speyer-Haus, or GSH, and DRK-Blutspendedienst Baden-Wurttenberg-Hessen gGmbH, or BSD, License Agreement*

In August 2015, we entered into a license agreement with GSH and BSD under which we were granted an exclusive license to certain GSH-BSD patents, materials and know-how that specifically targets ErbB2 expressing cancers. In addition, GSH granted us an exclusive license to certain GSH only technology and materials. In consideration for the licenses, we agreed to pay initial and annual licensing fees, regulatory and commercial milestones and low single-digit percentage royalties on net sales of licensed products. We paid $1.1 million for the initial license fees, which was included in research and development expenses on the consolidated statements of operations for the year ended December 31, 2015. Annual license fees under the agreement began in 2018. In October 2018, we terminated this agreement in accordance with the terms of the agreement.

*Fox Chase Cancer Center License Agreement*

In 2004 and amended in 2008, we entered into an exclusive license agreement with Fox Chase Cancer Center, or Fox Chase, for the exclusive, worldwide right to certain patents and know-how pertaining to CD16 receptor bearing NK-92 cell lines. In consideration for this exclusive license, we agreed to pay Fox Chase (i) low single-digit percentage royalties on net sales of licensed products for therapeutic and diagnostic use; and (ii) mid-twenties percentage royalties on any compensation we receive from sublicensees.

*Rush University Medical Center License Agreement*

In 2004, we entered into a 12-year licensing agreement with Rush University Medical Center for the exclusive rights to license and grant sublicenses of certain intellectual property related to clinical use of NK-92. We are required to pay low to mid-single digit percentage royalties on net sales depending upon the various fields of studies and other factors. We were required to pay a minimum annual royalty of $25,000. The Rush University Medical Center License Agreement also provides for payments in the aggregate amount of $2.5 million upon the company achieving various milestones, including upon (i) the completion of phase II clinical trial associated with the licensed intellectual property; (ii) the approval by the FDA of a new drug application for a licensed product; and (iii) the first year that sales of the licensed product equals or exceeds $0.3 million. The license had a term of 12 years from 2006, the year in which royalty payments were first made, and included customary termination rights for both parties. Beginning in 2018, this license converted to a perpetual, irrevocable, fully paid, royalty-free, exclusive license.

During the years ended December 31, 2019, 2018 and 2017, we recorded royalty expense of $0, $4,200 and $25,000, respectively, related to the Rush University Medical Center License Agreement. Royalty expense is included in selling, general and administrative on the consolidated statements of operations. No milestones were met during the years ended December 31, 2019, 2018 and 2017.

***Out-Licensing Agreement***

*Intrexon License Agreement*

In February 2010, we entered into a 17-year license agreement with Intrexon Corporation, or Intrexon, pursuant to which we granted to Intrexon a non-exclusive, worldwide, sublicensable license to research and sell products under certain patents relating to modified NK-92 cells that express Intrexon's proprietary gene sequences for use as a therapeutic and prophylactic agent in humans in specified therapeutic areas. In consideration for the license agreement, Intrexon paid us a one-time fee of $0.4 million. Prior to adoption of ASC 606, this upfront payment had initially been recorded as deferred revenue and was being recognized into revenue on a straight-line basis. Upon adoption of ASC 606, we adjusted our accumulated deficit in an amount equal to the then remaining deferred revenue after concluding that under ASC 606 the upfront payment would have been recognized when the license was transferred in 2010. Intrexon will pay the following milestone payments: $0.1 million upon the first IND filing; $0.1 million upon the commencement of the first phase II clinical trial; $0.4 million upon the commencement of the first phase III clinical trial; and $0.5 million upon the first commercial sale relating to the licensed products. Intrexon is obligated to pay us a low single digit percentage royalty based on net sales of the licensed products by Intrexon and a mid-teen percentage royalty based on revenues received by Intrexon in connection with sublicenses of the licensed products. No milestone payments were due or received in the years ended December 31, 2019, 2018 and 2017, and, therefore, we recorded no milestone revenue for any of those years on the consolidated statements of operations.

**8. Commitments and Contingencies**

***Contingencies***

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or of the range of potential losses disclosed. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances where our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

*Securities Litigation*

In March 2016, a putative securities class action complaint captioned *Sudunagunta v. NantKwest, Inc., et al.*, No. 16-cv-01947 was filed in federal district court for the Central District of California related to the company's restatement of certain interim financial statements for the periods ended June 30, 2015 and September 30, 2015. A number of similar putative class actions were filed in federal and state court in California. The actions originally filed in state court were removed to federal court, and the various related actions were consolidated. Plaintiffs asserted causes of action for alleged violations of Sections 11 and 15 of the Securities Act of 1933 and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. Plaintiffs sought unspecified damages, costs and attorneys' fees, and equitable/injunctive or other relief on behalf of putative classes of persons who purchased or acquired the company's securities during various time periods from July 28, 2015 through March 11, 2016. In September 2017, the court denied defendants' motion to dismiss the third amended consolidated complaint. On August 13, 2018, the district court granted plaintiffs' motions for class certification and to strike plaintiffs' claims under the Securities Exchange Act of 1934 and Rule 10b-5. On August 24, 2018, at the district court's direction, plaintiffs filed a fourth amended consolidated complaint. On August 27, 2018, defendants petitioned the U.S. Court of Appeals for the Ninth Circuit to authorize interlocutory appeal of the class certification order. On September 7, 2018, defendants answered the fourth amended consolidated complaint. On September 21, 2018, the parties informed the Ninth Circuit that they had reached a settlement in principle, and the parties moved to stay appellate proceedings. On September 24, 2018, the parties notified the district court that they had reached a settlement in principle. On November 9, 2018, the plaintiffs filed an unopposed motion for preliminary approval of the settlement and notice to class members. On January 9, 2019, the district court granted the motion for preliminary approval. A final approval hearing was held on April 29, 2019, and the district court granted final approval and entered judgment on May 31, 2019.

Under the terms of the settlement, we paid $12.0 million to the plaintiffs as full and complete settlement of the litigation. We were responsible for $1.2 million of the settlement amount, which was recognized in selling, general and administrative expense during the third quarter of 2018, while the remaining $10.8 million was fully funded by our insurance carriers under our directors' and officers' insurance policy. We and the insurance carriers paid the settlement amount into a settlement fund in January 2019. Subsequent to receiving final approval of the settlement on May 13, 2019, the aforementioned settlement accrual, associated insurance claim receivable and restricted cash were released and are no longer reflected on our consolidated balance sheets as of December 31, 2019.

*Stipulation of Settlement*

In early April 2019, following board approval, which occurred in late March 2019, we entered into a settlement agreement, or the Stipulation of Settlement, with three stockholders of the company, each of whom had submitted a stockholder demand for the board to take action to remedy purported harm to the company resulting from certain alleged wrongful conduct concerning, among other things, disclosures about Dr. Soon-Shiong's compensation and a related-party lease agreement. The Stipulation of Settlement called for us to adopt certain governance changes, and for the three stockholders to file a stockholder derivative action in the Superior Court of the State of California, County of San Diego, followed by an application for court approval of the Stipulation of Settlement. On May 31, 2019, the court entered an order preliminarily approving the Stipulation of Settlement and scheduling the final settlement hearing for August 9, 2019. Pursuant to the Stipulation of Settlement, we have provided stockholders with notice of the settlement and the final settlement hearing.

Under the terms of the Stipulation of Settlement, which received final approval by the court on August 9, 2019, we paid an attorney's fee of $0.5 million to the plaintiffs as part of the settlement. Of that amount, we were responsible for half, which was recognized in selling, general and administrative expense on the consolidated statements of operations during the first quarter of 2019, while the other half was funded by our insurance carrier. We and the insurance carrier paid the settlement amount into a settlement fund in June 2019. Subsequent to receiving final approval of the settlement on August 9, 2019, the aforementioned settlement accrual, associated insurance claim receivable and restricted cash were released and are no longer reflected on our consolidated balance sheets as of December 31, 2019.

*Insurance Recoveries*

We have reflected our right to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and receipt is deemed probable. This includes instances where our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund. The amount of such receivable recorded at December 31, 2019 and 2018 was $34,000 and $10.9 million, respectively, and is included in prepaid expenses and other current assets on our consolidated balance sheets.

***Contractual Obligations - Leases***

We adopted ASC 842, as of January 1, 2019, using the simplified transition approach discussed in further detail in Note 2. As a result, prior periods were not recast. The following disclosures relate to our lease balances as of January 1, 2019 and December 31, 2019, under ASC 842 (in thousands):

| | Balance January 1, 2019 | Balance December 31, 2019 |
|---|---|---|
| Operating lease right-of-use assets, net | $ 13,532 | $ 11,729 |
| Other current liabilities | $ 2,960 | $ 3,206 |
| Operating lease liability, less current portion | $ 13,407 | $ 10,885 |

As a result of new agreements entered into subsequent to our adoption of ASC 842, we recognized an increase of $0.8 million in both operating lease right-of-use assets and operating lease liabilities during the year ended December 31, 2019.

Substantially all of our operating lease right-of-use assets and operating lease liabilities relate to facilities leases. We lease: (i) a research facility and office space in San Diego, California; (ii) a research and manufacturing space in Culver City, California, from a related party; (iii) a research and manufacturing facility in El Segundo, California, also from a related party; (iv) a research facility in Torrance, California, and (v) a research facility in Woburn, Massachusetts. See Note 9 – *Related Party Agreements* for further information.

Operating lease expense of $5.1 million, including variable lease costs of $1.2 million, was recorded in operating expenses on the consolidated statements of operations for year ended December 31, 2019. The weighted-average remaining lease term as of January 1, 2019 and December 31, 2019 was 5.4 years and 4.5 years, respectively. The weighted-average discount rate as of January 1, 2019 and December 31, 2019 was 9%. For the year ended December 31, 2019, cash outflows from operating leases, excluding variable lease costs, was $4.4 million.

Future minimum lease payments at December 31, 2019 are presented in the following table (in thousands). Common area maintenance costs and taxes are not included in these payments.

| Years ending December 31: | Operating Leases (a) |
|---|---|
| 2020 | $ 4,271 |
| 2021 | 3,753 |
| 2022 | 3,671 |
| 2023 | 2,546 |
| 2024 | 1,083 |
| Thereafter | 1,729 |
| Total future minimum lease payments | 17,053 |
| Less: Interest | 2,962 |
| Present value of operating lease liabilities | $ 14,091 |

(a) Operating lease payments include $3.3 million related to options to extend lease terms that are reasonably certain of being exercised.

In August 2018, NantBio, Inc., or NantBio, a related party (Note 9) assigned an agreement to us for the use of a third-party research facility, which provides us with the exclusive right to use and access to a portion of the third party's laboratory and vivarium premises. In conjunction with the assignment, we reimbursed NantBio for upfront payments, which it had made to the third party of $0.9 million, and paid $0.5 million directly to the third party for an aggregate value of $1.4 million. The assigned agreement is for a term of ten years and expires in June 2027. The agreement may be terminated by us at any time, with or without cause. In case of termination of the agreement, the third party will reimburse us for a pro-rata amount based upon the passage of time.

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, a related party (Note 9), for approximately 24,250 square feet in El Segundo, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. The lease runs from July 2016 through July 2023. We have the option to extend the lease for an additional three year term through July 2026. The monthly rent is $0.1 million with annual increases of 3% beginning in July 2017.

In March 2016, we entered into a lease agreement for an approximately 7,893 square foot facility in Woburn, Massachusetts, for a research and development laboratory, related office and other related uses. The initial lease term runs for 48 months from April 29, 2016 through May 31, 2020. In June 2016, the lease was amended to add 260 square feet, for a total of 8,153 square feet. Base rent for the initial term of the lease is $19,000 per month with a $1 per square foot annual increase on each anniversary date. In August 2019, we exercised our right pursuant to the lease agreement to extend the term of the lease for an additional two years through May 31, 2022. Consequently, we recognized an increase of $0.6 million in both operating lease right-of-use assets and operating lease liabilities on the consolidated balance sheets.

In November 2015, we entered into a facility license agreement with NantWorks LLC, or NantWorks, a related party (Note 9), for approximately 9,500 square feet of office space in Culver City, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. The license was effective in May 2015 and extends through December 2020. The monthly rent is $47,000, with annual increases of 3% beginning in January 2017.

In June 2015, we entered into a lease agreement for an approximately 44,700 square foot facility in San Diego, California, for a research and development laboratory, related office and other related uses. The term of the lease extends for seven years commencing on August 1, 2016. The base rent is $0.2 million per month with 3% annual increases on each anniversary date.

Prior to adopting ASC 842 on January 1, 2019, we recognized rent expense under operating leases on a straight-line basis. Fixed rent expense under ASC 840 for the years ended December 31, 2018 and 2017 was $2.8 million and $2.7 million, respectively.

## 9. Related Party Agreements

Our Chairman and CEO founded and has a controlling interest in NantWorks, which is a collection of multiple companies in the healthcare and technology space. As described below, we have entered into arrangements with NantWorks, and certain affiliates of NantWorks, to facilitate the development of new genetically modified NK cells for our product pipeline.

*Share Repurchase*

In November 2018, we entered into a share repurchase agreement with an immediate family member of a director of the company, pursuant to which we repurchased 138,349 of our common shares for a total of $0.2 million under our existing share repurchase program.

*NantHealth Labs, Inc.*

In March 2018, we entered into an agreement with NantHealth Labs, Inc., or NantHealth Labs, to obtain blood-based tumor profiling services. NantHealth Labs is a related party, as it is a wholly owned subsidiary of NantHealth, Inc., a majority owned subsidiary of NantWorks. We are obligated to pay NantHealth Labs fixed, per-patient fees. The agreement has an initial term of five years and renews automatically for successive one-year periods, unless terminated earlier. During the years ended December 31, 2019 and 2018, $10,000 and $0.3 million, respectively, has been recognized in research and development expense on the consolidated statements of operations. At December 31, 2018, we owed NantHealth Labs $49,300, which is included in due to related parties on the consolidated balance sheets. At December 31, 2019, no balances were due between the parties.

*Immuno-Oncology Clinic, Inc.*

Beginning in 2017, we entered into multiple agreements with Immuno-Oncology Clinic, Inc., or the Clinic, to conduct various clinical trials. The Clinic was formerly known as John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine, in El Segundo, California. The Clinic is a related party as it is owned by one officer of NantKwest and NantWorks manages the administrative operations of the Clinic. Prior to June 30, 2019, one of the company's officers was an investigator or sub-investigator for all of the company's trials conducted at the Clinic.

In July 2019, we entered into a new agreement with the Clinic which superseded our existing agreements with the Clinic, effective as of July 1, 2019. The new agreement covers clinical trial and research related activities on a non-exclusive basis relating to our existing clinical trials, commenced prior to July 1, 2019, and prospective clinical trials and research projects. The new agreement also specifies certain services and related costs that are excluded from the new agreement. Prior to commencing any work under the new agreement, the parties have agreed to execute written work orders setting forth the terms and conditions related to specific services to be performed, including financial terms. For existing clinical trials, commenced prior to July 1, 2019, fees incurred for services performed after July 1, 2019 are covered under the new agreement and applied towards the below-mentioned prepayments. The initial term of the new agreement is for one year, but the agreement allows for an automatic renewal and additional extensions beyond the initial term. In July 2019, we executed a clinical trial work order under the new agreement with the Clinic for an open-label, phase I study of PD-L1.t-haNK for infusion in subjects with locally advanced or metastatic solid cancers.

In consideration of the services to be performed under the new agreement, we agreed to make payments of $7.5 million to the Clinic, of which $3.75 million and $1.875 million were paid in July 2019 and October 2019, respectively. The prepayments constitute a prepayment by us for services to be performed by the Clinic. Under the term of the new agreement, the outstanding balance of our prepayment shall be increased on a quarterly basis by an interest credit computed in accordance with terms specified in the new agreement.

To the extent any portion of the prepayments remain unearned by the Clinic on the third anniversary of the new agreement, we may elect at our sole discretion either to (i) not extend the term of the new agreement and have the Clinic reimburse us for the total amount of any remaining unused portion of the prepayments, or (ii) extend the term of the new agreement for up to three additional one year periods, at which time the Clinic will reimburse us for the total amount of any remaining unused portion of the prepayments plus interest if reimbursement is not made within 60 days of expiration. The Clinic may terminate this agreement upon each anniversary date upon sixty (60) days prior written notice and reimbursement in full to us of any outstanding unearned balance of the prepayments, provided that any such termination by the Clinic will not apply with respect to any work orders still in effect at the time of such termination.

During the years ended December 31, 2019, 2018 and 2017, expense of $1.1 million, $2.7 million and $0.8 million, respectively, has been recognized in research and development expense on the consolidated statements of operations. At December 31, 2019 and 2018, we owed the Clinic $0.1 million and $0.6 million, respectively, for services excluded from the new agreement, which are included in due to related parties on the consolidated balance sheets, and as of December 31, 2019, we had a prepaid balance with the Clinic of $5.1 million, which is included in prepaid expenses and other currents assets, and other assets, on the consolidated balance sheets. We anticipate that the remaining prepayment amount as of December 31, 2019 will be utilized in future periods as the Clinic provides additional services pursuant to the new agreement.

*Tensorcom, LLC*

In April 2017, we entered into a sublease agreement with Tensorcom, LLC, or Tensorcom, for a portion of our San Diego, California, research and development laboratory and office space. The lease ran from May 1, 2017 through April 30, 2018. Tensorcom is a related party, as it is an affiliate of NantWorks. The sublease included a portion of the premises consisting of approximately 6,557 rentable square feet of space. The monthly base rent was $25,000 per month. For the years ended December 31, 2018 and 2017, $0.1 million and $0.2 million, respectively, was recognized in other income on the consolidated statements of operations under the sublease agreement. At December 31, 2019 and 2018, there were no balances due between the parties.

*605 Doug St, LLC*

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, an entity owned by our Chairman and CEO, for approximately 24,250 square feet in El Segundo, California, which has been converted to a research and development laboratory and a cGMP laboratory manufacturing facility. The lease runs from July 2016 through July 2023. We have the option to extend the lease for an additional three-year term through July 2026. The monthly rent is $0.1 million with annual increases of 3% beginning in July 2017. Lease expense for this facility is recorded in research and development expense on the consolidated statements of operations and was $0.9 million, $0.2 million and $0.2 million, respectively, for the years ended December 31, 2019, 2018 and 2017. At December 31, 2019 and 2018, no balances were due between the parties.

*NantBio, Inc.*

In August 2018, NantBio assigned an agreement to us for the use of a third-party research facility, which provides us with the exclusive right to use and access to a portion of the third party's laboratory and vivarium premises. NantBio is a related party as it is an affiliate of NantWorks. In conjunction with the assignment, we reimbursed NantBio for upfront payments which it had made to the third party of $0.9 million and paid $0.5 million directly to the third party for an aggregate value of $1.4 million. The assigned agreement is for a term of ten years and expires in June 2027. The agreement may be terminated by us at any time, with or without cause. In case of termination of the agreement, the third party will reimburse us for a pro-rata amount based upon the passage of time.

In January 2018, we entered into a laboratory services agreement with NantBio. The agreement, effective December 2017, included a sublease of approximately 1,965 square feet of laboratory and office space at our San Diego, California, research facility. This sublease was terminated effective December 31, 2019, pursuant to the terms of the agreement. We recognized $0.1 million, $0.1 million and $10,000, respectively, in other income on the consolidated statements of operations for the years ended December 31, 2019, 2018 and 2017. At December 31, 2019 and 2018, NantBio owed us $8,400 and $49,000, respectively, which is included in prepaid expenses and other current assets on the consolidated balance sheets.

In March 2016, NantBio and the National Cancer Institute entered into a cooperative research and development agreement. The initial five-year agreement covers NantBio and its affiliates, including us. Under the agreement, the parties are collaborating on the preclinical and clinical development of proprietary recombinant natural killer cells and monoclonal antibodies in monotherapy and in combination immunotherapies. We benefited from the preclinical and clinical research conducted during the first four years under this agreement. In each of April 2016, April 2017, August 2018, and May 2019, we paid $0.6 million to the National Cancer Institute as a prepayment for services under the agreement. We recognize research and development expense related to this agreement ratably over a 12-month period for each funding year and recorded $0.6 million, of expense associated with the agreement in each of the years ended December 31, 2019, 2018 and 2017. At December 31, 2019 and 2018, we had balances of $0.1 million and $0.1 million, respectively, included in prepaid expenses and other current assets related to this agreement, on the consolidated balance sheets.

*NantWorks*

In May 2018, we entered into an assignment agreement with NantWorks and a third-party construction firm. In connection with the agreement, we assigned our deposit of $0.4 million with the third-party firm to NantWorks for which NantWorks reimbursed us. This assignment represented unutilized deposits that NantKwest had previously made with the construction company, for which NantWorks can now utilize in applying such funds to future planned construction projects.

Under the NantWorks shared services agreement executed in November 2015, but effective August 2015, NantWorks provides corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy, and other support services. We are charged for the services at cost plus reasonable allocations for indirect costs that relate to the employees providing the services. For the years ended December 31, 2019, 2018 and 2017, we recorded $2.1 million, $2.8 million and $3.6 million, respectively, to selling, general and administrative expense, and $1.5 million, $3.3 million and $3.2 million, respectively, in research and development expense under this arrangement on the consolidated statements of operations. These amounts exclude certain general and administrative expenses provided by third party vendors directly for our benefit, which have been reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

In June 2016, we amended the existing shared services agreement with NantWorks whereby we can provide support services to NantWorks and/or any of its affiliates. For the years ended December 31, 2019, 2018 and 2017, we recorded expense reimbursements of $1.2 million, $0.6 million and $0.4 million, respectively, to selling, general and administrative expense and $2.3 million, $2.6 million and $1.0 million, respectively, to research and development expense.

At December 31, 2019 and 2018, we owed NantWorks a net amount of $0.4 million and $1.1 million, respectively, for all agreements between the two affiliates, which is included in due to related parties on the consolidated balance sheets.

In November 2015, we entered into a facility license agreement with NantWorks, which became effective May 2015, for approximately 9,500 square feet in Culver City, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. Lease expense for this facility is recorded in research and development expense on the consolidated statements of operations and was $0.6 million, $0.2 million, and $0.2 million for the years ended December 31, 2019, 2018 and 2017.

*NantOmics, LLC*

In June 2015, we entered into an agreement, as amended in May 2018, with NantOmics, LLC, or NantOmics, which is a related party, as it is an affiliate of NantWorks. Pursuant to this agreement we obtain genomic sequencing and proteomic analysis services, as well as related data management and bioinformatics services, exclusively from NantOmics. We will have rights to use the data and results generated from NantOmics' services in connection with the performance of the particular oncology trial with respect to which the services were performed, but NantOmics owns the data and results, as well as any other intellectual property it creates in performing these services on our behalf. We are obligated to pay NantOmics a fixed, per sample fee, determined based on the type of services being provided. The agreement has an initial term of five years and renews automatically for successive one-year periods, unless terminated earlier. For the years ended December 31, 2019, 2018 and 2017, we recorded operating expense of $0.1 million, $0.1 million and $0.1 million, respectively, to research and development under this arrangement on the consolidated statements of operations. At December 31, 2018, we owed NantOmics $24,000, which is included in due to related parties on the consolidated balance sheets. At December 31, 2019, no balances were due between the parties.

*ImmunityBio*

ImmunityBio, Inc., or ImmunityBio, is a related party, as it is an affiliate of NantWorks. ImmunityBio was formerly known as NantCell, Inc.

In January 2020, we entered into a cost sharing agreement with ImmunityBio as further described in Note 15 - *Subsequent Events*.

In November 2018, we entered into an agreement with Etubics Corporation, or Etubics, a subsidiary of ImmunityBio. Pursuant to this agreement we sold used laboratory equipment to Etubics for $0.3 million. In conjunction with this sale, we recognized a loss on disposal of related laboratory equipment of $0.1 million, which was included in other income, net on the consolidated statements of operations.

In February 2017, we entered into a research grant agreement with VivaBioCell S.p.A., or VBC, a subsidiary of ImmunityBio. VBC conducted research and development activities related to our NK cell lines using VBC's proprietary technology. For the years ended December 31, 2018 and 2017, $0.1 million and $0.6 million, respectively, was recognized in research and development expense on the consolidated statements of operations. No expense was incurred for the year ended December 31, 2019.

In August 2016, we entered into an exclusive Co-Development Agreement with Altor as described in Note 7 – *Collaboration and License Agreements*. Altor is a related party as it is a wholly owned subsidiary of ImmunityBio. No charges for supplies by Altor were incurred in association with the trials during the years ended December 31, 2019, 2018 and 2017.

In June 2015, we also entered into a supply agreement with ImmunityBio pursuant to which we have the right to purchase ImmunityBio's proprietary bioreactors, made according to specifications mutually agreed to with ImmunityBio. We also have the right to purchase reagents and consumables associated with such equipment from ImmunityBio. When an upfront payment is made, it is included in prepaid expenses on the consolidated balance sheets until the product is received. The agreement has an initial term of five years and renews automatically for successive one-year periods unless terminated earlier.

At December 31, 2019 and 2018, we had $1.8 million and $1.1 million, respectively, in capitalized equipment purchased from ImmunityBio, which is included in property, plant and equipment, net, on the consolidated balance sheets. During the years ended December 31, 2019, 2018 and 2017, we recorded research and development expense associated with reagents and consumables purchased from ImmunityBio of $0.1 million, $0.1 million and $0.3 million, respectively, on the consolidated statements of operations.

At December 31, 2019 and 2018, we had $0.5 million and $0.5 million, respectively, included in prepaid expenses and other current assets on the consolidated balance sheets related to consumables purchased from ImmunityBio. At December 31, 2019 and December 31, 2018, no balances were due between the parties.

## 10. Stockholders' Equity

*Stock Repurchase* – In November 2015, the board of directors approved a share repurchase program, or the 2015 Share Repurchase Program, allowing the CEO or CFO, on behalf of the company, to repurchase from time to time, in the open market or in privately negotiated transactions, up to $50.0 million of our outstanding shares of common stock, exclusive of any commissions, markups or expenses. The timing and amounts of any purchases were and will continue to be based on market conditions and other factors, including price, regulatory requirements and other corporate considerations. The 2015 Share Repurchase Program does not require the purchase of any minimum number of shares and may be suspended, modified, or discontinued at any time without prior notice. We have financed, and expect to continue to finance, the purchases with existing cash balances. The shares are formally retired through board approval upon repurchase.

To date, we have repurchased 6,403,489 shares of our common stock under the 2015 Share Repurchase Program at a total cost of $31.7 million. In addition, we have paid approximately $0.1 million of broker commissions on repurchases. We repurchased 473,586 shares, 138,349 shares (Note 9), and 3,633,610 shares during the years ended December 31, 2019, 2018 and 2017, respectively, for a total of $0.5 million, $0.2 million, and $15.2 million, respectively. At December 31, 2019, $18.3 million remained authorized for repurchase under the 2015 Share Repurchase Program.

*Common Stock Reserved for Future Issuance*

We are authorized to issue up to 500,000,000 shares of our common stock, par value $0.0001 per share at December 31, 2019. As of December 31, 2019, there were 98,460,404 shares of our common stock issued and outstanding.

The following table summarizes the common shares reserved for issuance on exercise or vesting of various awards at December 31, 2019:

| | |
|---|---|
| Outstanding stock options | 4,506,950 |
| Outstanding RSUs | 1,139,428 |
| Outstanding warrants | — |
| Total shares reserved for future issuance | 5,646,378 |

**11. Stock-Based Compensation**

*2014 Equity Incentive Plan* – In March 2014, the company's board of directors and stockholders approved the 2014 Equity Incentive Plan, or 2014 Plan, under which 11,109,000 shares of Class A common stock were reserved for the granting of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, or IRC, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and performance awards to employees, directors and consultants. Recipients of stock awards are eligible to purchase shares of our common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of awards granted under the 2014 Plan is ten years. Stock awards are generally not exercisable prior to the applicable vesting date, unless otherwise accelerated under the terms of the applicable stock plan agreement. Unvested shares of our common stock issued in connection with an early exercise allowed by the company may be repurchased by us upon termination of the optionee's service.

*2015 Equity Incentive Plan* – In July 2015, the company's board of directors adopted and the company's stockholders approved the 2015 Equity Incentive Plan, or 2015 Plan. In April 2019, the company's board of directors adopted, and in June 2019 the company's stockholders approved, an amendment to the 2015 Plan to reserve a further 3,000,000 shares of common stock for issuance pursuant to the 2015 Plan. The 2015 Plan, as amended, permits the grant of incentive stock options to the company's employees, and for the grant of non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to the company's employees, directors and consultants.

As of December 31, 2019 there were approximately 4.3 million shares of common stock reserved for future grants pursuant to the 2015 Plan. In addition, the shares reserved for future grants under the 2015 Plan include shares subject to stock options or similar awards granted under the 2014 Plan that expire or terminate without having been exercised in full and shares issued pursuant to awards granted under the 2014 Plan that are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2015 Plan pursuant to this provision is approximately 2.3 million shares as of December 31, 2019).

*Stock-Based Compensation*

The following table presents all stock-based compensation as included on the consolidated statements of operations (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Stock-based compensation expense: | | | |
| Warrants for common stock to an officer | $ — | $ 17,817 | $ 31,584 |
| Employee stock options | 1,309 | 4,057 | 4,267 |
| Employee RSUs | 938 | 1,193 | 894 |
| Non-employee RSUs | 380 | 315 | 252 |
| | $ 2,627 | $ 23,382 | $ 36,997 |
| Stock-based compensation expense in operating expenses: | | | |
| Research and development | $ 499 | $ 460 | $ 102 |
| Selling, general and administrative | 2,128 | 22,922 | 36,895 |
| | $ 2,627 | $ 23,382 | $ 36,997 |

*Stock Options*

The following table summarizes stock option activity under all equity incentive plans for the years ended December 31, 2019, 2018 and 2017:

| | Number of Shares | Weighted-Average Exercise Price | Aggregate Intrinsic Value (in thousands) | Weighted-Average Remaining Contractual Life (in years) |
|---|---|---|---|---|
| Outstanding at December 31, 2016 | 6,307,386 | $ 7.14 | $ 19,100 | 6.4 |
| Options exercised | (614,136) | $ 1.88 | | |
| Outstanding at December 31, 2017 | 5,693,250 | $ 7.71 | $ 11,920 | 5.3 |
| Options granted | 800,000 | $ 3.07 | | |
| Outstanding at December 31, 2018 | 6,493,250 | $ 7.14 | $ 563 | 4.8 |
| Options exercised | (1,986,300) | $ 2.06 | | |
| Outstanding at December 31, 2019 | 4,506,950 | $ 9.37 | $ 5,710 | 5.8 |
| Vested and Exercisable at December 31, 2019 | 3,973,614 | $ 10.22 | $ 5,326 | 5.5 |

The vested and exercisable shares at December 31, 2018 and 2017 were 5,577,531 and 5,114,656, respectively.

The following table provides a summary of options outstanding and vested as of December 31, 2019:

| Exercise Prices | Number Outstanding | Weighted-Average Remaining Contractual Life (in years) | Number Exercisable | Weighted-Average Remaining Contractual Life (in years) |
|---|---|---|---|---|
| $0.42 | 589,660 | 4.9 | 589,660 | 4.9 |
| $1.76 | 699,060 | 5.0 | 699,060 | 5.0 |
| $2.00 | 962,780 | 5.1 | 962,780 | 5.1 |
| $3.07 | 800,000 | 8.7 | 266,664 | 8.7 |
| $25.00 | 1,455,450 | 5.6 | 1,455,450 | 5.6 |
| | 4,506,950 | 5.8 | 3,973,614 | 5.5 |

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2019, 2018 and 2017 was $0.2 million, $0.6 million and $1.7 million, respectively. The cash received from exercised options was $4.1 million, $0 and $1.2 million, respectively, for the years ended December 31, 2019, 2018 and 2017.

During the year ended December 31, 2018, the company granted 800,000 stock options to key executives. These options have an exercise price of $3.07 per share, which was equal to the closing price of the company's common stock on the date of grant, and 25% vest on the one-year anniversary of the date of grant with the remaining options vesting ratably each month over the following three years. No stock options were granted to employees during the years ended December 31, 2019 and 2017. No stock options were granted to non-employees during the years ended December 31, 2019, 2018 and 2017.

The total unrecognized compensation cost related to non-vested stock options as of December 31, 2019 is $1.1 million, which is expected to be recognized over a weighted-average period of 2.7 years.

The company uses a Black-Scholes option-pricing model to determine the fair value of stock-based compensation under ASC Topic 718, *Stock Compensation*. The assumptions used for employee stock options granted during the year ended December 31, 2018, are presented in the table below:

| | |
|---|---|
| Expected term (years) | 6.0 - 6.1 |
| Risk-free interest rate | 2.8% |
| Expected volatility | 75.9% |
| Dividend yield | 0% |
| Weighted-average measurement date fair value | $2.09 |

The assumed dividend yield was based on the company's expectation of not paying dividends in the foreseeable future. The estimated volatility was based on a weighted-average calculation of the company's common stock together with a peer group of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The weighted-average expected life of options was estimated using the average of the contractual term and the weighted-average vesting term of the options.

*Restricted Stock Units*

The following table summarizes the restricted stock units, or RSUs, activity under the 2015 Plan:

| | Number of RSUs Outstanding | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested balance at December 31, 2016 | 814,456 | $ 13.98 |
| Granted | 615,983 | $ 4.50 |
| Vested | (244,209) | $ 15.82 |
| Forfeited/canceled | (298,041) | $ 10.28 |
| Unvested balance at December 31, 2017 | 888,189 | $ 8.14 |
| Granted | 487,472 | $ 3.57 |
| Vested | (172,330) | $ 6.16 |
| Forfeited/canceled | (335,420) | $ 6.27 |
| Unvested balance at December 31, 2018 | 867,911 | $ 6.69 |
| Granted | 749,793 | $ 1.12 |
| Vested | (395,051) | $ 8.83 |
| Forfeited/canceled | (83,225) | $ 7.29 |
| Unvested balance at December 31, 2019 | 1,139,428 | $ 2.23 |

We may grant RSUs to both employees and directors of the company and to employees of related parties that provide shared services to the company under the company's shared services agreement with NantWorks (Note 9). During the years ended December 31, 2018 and 2017, we granted 90,906 RSUs and 77,250 RSUs, respectively, to non-employees. All of the RSUs granted to non-employees during these periods were granted to employees of related companies under our shared services agreement with NantWorks (Note 9). There were no new grants made to non-employees during the year ended December 31, 2019.

As of December 31, 2019, there was $1.4 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 1.7 years. Of that amount, $1.3 million of unrecognized expense is related to employee grants with a remaining weighted-average period of 1.8 years and $0.1 million of unrecognized expense is related to non-employee grants with a remaining weighted-average period of 0.8 years.

*Warrants*

The following table summarizes the company's warrant activity:

| | |
|---|---|
| Outstanding at December 31, 2016 | 17,768,314 |
| Warrants exercised | (47,226) |
| Outstanding at December 31, 2017 | 17,721,088 |
| Warrants exercised | (93,254) |
| Warrants expired | (38,584) |
| Outstanding at December 31, 2018 | 17,589,250 |
| Warrants exercised | (17,589,250) |
| Outstanding at December 31, 2019 | — |
| Vested and exercisable at December 31, 2019 | — |

During the years ended December 31, 2019, 2018 and 2017, cash proceeds recognized from exercises of warrants were $35.2 million, $0.1 million and $0.1 million, respectively.

*Common Stock Reserved for Future Grants under the 2015 Equity Incentive Plan*

At December 31, 2019, there were approximately 4.3 million shares of common stock reserved for future grants of equity awards.

## 12. Income Taxes

The amount of loss before taxes is as follows (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| U.S. loss before taxes | $ (65,286) | $ (94,423) | $ (94,734) |
| Foreign loss before taxes | (600) | (2,306) | (2,182) |
| Loss before income taxes | $ (65,886) | $ (96,729) | $ (96,916) |

Income tax benefit for the years ended December 31, 2019, 2018 and 2017 consists of the following (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Current: | | | |
| Federal | $ — | $ — | $ — |
| State | 3 | 3 | 4 |
| Foreign | — | — | — |
| Total Current | 3 | 3 | 4 |
| Deferred: | | | |
| Federal | (79) | — | — |
| State | (21) | (8) | — |
| Foreign | — | (498) | (497) |
| Total Deferred | (100) | (506) | (497) |
| Income tax benefit | $ (97) | $ (503) | $ (493) |

The components that comprise the company's net deferred tax assets at December 31, 2019 and 2018 consist of the following (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 78,377 | $ 61,915 |
| Stock compensation | 8,536 | 79,281 |
| Operating lease liabilities | 3,884 | — |
| Depreciation and amortization | 2,042 | — |
| Tax credits | 898 | 845 |
| Accrued compensation | 775 | 795 |
| Leases and other accrued liabilities | 453 | 2,909 |
| Accrued legal expenses | — | 308 |
| Total deferred tax assets | 94,965 | 146,053 |
| Deferred tax liabilities: | | |
| Foreign intangibles | — | (1) |
| Operating lease right-of-use assets | (3,233) | — |
| Depreciation and amortization | — | (1,279) |
| Total deferred tax liabilities | (3,233) | (1,280) |
| Net deferred tax assets | 91,732 | 144,773 |
| Valuation allowance | (91,732) | (144,773) |
| Net deferred tax liability | $ — | $ — |

A reconciliation of the federal statutory income tax rate to the company's effective income tax rate is as follows:

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | 2019 | 2018 | 2017 |
| Tax computed at federal statutory rate | 21.0 % | 21.0 % | 34.0 % |
| State income taxes, net of federal tax benefit | (19.4) | 6.2 | 5.3 |
| Tax rate adjustment | 0.1 | (0.3) | 4.8 |
| Tax Cuts and Jobs Act | — | — | (53.4) |
| Research and development credits | 0.2 | 0.1 | 0.6 |
| Stock-based compensation | (82.5) | (0.1) | (0.3) |
| Other | (0.1) | 0.3 | 0.8 |
| Valuation allowance | 80.5 | (26.7) | 8.7 |
| Effective income tax rate | (0.2)% | 0.5 % | 0.5 % |

On December 22, 2017, the Tax Cuts and Jobs Act, or the TCJA, was enacted into law. The TCJA made significant changes to U.S. tax laws, including, but not limited to, the following: (a) reducing the federal corporate income tax rate from 35% to a flat 21%, effective January 1, 2018; (b) eliminating the federal corporate alternative minimum tax, or AMT, and changing how existing AMT credits can be realized; and (c) eliminating several business deductions and credits, including deductions for certain executive compensation in excess of $1.0 million.

As a result of the rate reduction, the company reduced the deferred tax asset balance as of December 31, 2017 by $51.7 million. Due to the company's full valuation allowance position, we also reduced the valuation allowance by the same amount.

In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118, or SAB 118, which provides guidance on accounting for the income tax effects of the TCJA. SAB 118 provides a measurement period that should not extend beyond one year from the TCJA enactment date for companies to complete the accounting related to the TCJA under ASC Topic 740, *Income Taxes*, or ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the TCJA for which the accounting under ASC 740 is complete. To the extent that a company's accounting for TCJA-related income tax effects is incomplete, but the company is able to determine a reasonable estimate, it must record a provisional estimate in its financial statements. If a company cannot determine a provisional estimate to be included in its financial statements, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before enactment of the TCJA. We completed our evaluation of the potential impacts of IRC Section 162(m) as amended by the TJCA on our December 31, 2018 consolidated financial statements, resulting in no adjustment for the years ended December 31, 2019, 2018 and 2017.

Pursuant to IRC Sections 382 and 383, annual use of the company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. We completed an IRC Section 382/383 analysis through March 2019 regarding the limitation of net operating loss and research and development credit carryforwards. As a result, we derecognized a portion of the deferred tax assets for net operating losses and federal and state research and development credits of $0.8 million from our deferred tax asset schedule as of December 31, 2019. There is no impact to tax expense for the derecognition of the net operating losses and federal and state research and development credits due to the valuation allowance recorded against the deferred tax assets. Additionally, we have not recognized the deferred tax asset for research and development credits carryforwards as of December 31, 2019 and 2018 because we are a part of a controlled group of affiliated companies with common ownership and cannot complete our calculation of the credit until the time that all members of the controlled group complete their analysis and calculation of qualified research expenditures. We do not expect that the unrecognized tax benefits will change within 12 months of this reporting date. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact the company's effective tax rate.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based on the level of historical operating results and the uncertainty of the economic conditions, we have recorded a full valuation allowance of $91.7 million at December 31, 2019. The change in the valuation allowance for the year ended December 31, 2019 was a decrease of $53.0 million which was mainly driven by the reversal of deferred tax assets related to stock compensation that will not be realized. The portion of the valuation allowance for deferred tax assets for which subsequently recognized tax benefits will be credited directly to contributed capital is $0.2 million.

We have not incurred any material interest or penalties as of the current reporting date with respect to income tax matters. We do not expect that there will be unrecognized tax benefits of a significant nature that will increase or decrease within 12 months of the reporting date. We are subject to U.S. federal income tax, as well as income tax in California and other states. The federal returns for tax years 2016 through 2019 remain open to examination and the California returns remain subject to examination for tax years 2015 through 2019. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other respective tax authority. All other state jurisdictions remain open to examination.

At December 31, 2019, the company has federal net operating losses, or NOLs, of approximately $291.8 million, state NOLs of $255.7 million, and foreign NOLs of $0.2 million. The federal NOL carryforwards begin to expire in 2024, the state NOL carryforwards begin to expire in 2030 and the foreign NOL carryforwards begin to expire in 2022. At December 31, 2019, the company also had federal research tax credit carryforwards of approximately $8.5 million and California research tax credits of $5.7 million. The federal research tax credit carryforwards begin to expire in 2034 and the state research tax credit carryforwards begin to expire in 2031.

The following table summarizes the changes to the amount of unrecognized tax benefits (in thousands):

| | |
|---|---|
| Unrecognized tax benefits at December 31, 2017 | $ 6,577 |
| Increase for prior year tax positions | 798 |
| Increase for current year tax positions | 4,608 |
| Unrecognized tax benefits at December 31, 2018 | 11,983 |
| Decrease for prior year tax positions | (7) |
| Increase for current year tax positions | 3,680 |
| Unrecognized tax benefits at December 31, 2019 | $ 15,656 |

Included in the balance of unrecognized tax benefits at December 31, 2019, is $14.1 million that, if recognized, would not impact our income tax benefit or effective tax rate as long as the deferred tax asset remains subject to a full valuation allowance. We do not expect any significant increases or decreases to our unrecognized tax benefits within the next 12 months.

## 13. Summarized Quarterly Data (Unaudited)

The following financial information reflects all normal recurring adjustments that are, in the opinion of management, necessary for a fair statement of the results of the interim periods.

The table below presents unaudited quarterly data for fiscal 2019 and 2018 (in thousands, except for share and per share amounts):

| | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter |
|---|---|---|---|---|
| **2019** | | | | |
| Revenue | $ 5 | $ 17 | $ 12 | $ 9 |
| Operating expenses | 18,340 | 17,313 | 16,077 | 16,120 |
| Operating loss | (18,335) | (17,296) | (16,065) | (16,111) |
| Net loss | (17,885) | (16,682) | (15,581) | (15,641) |
| Net loss per share - basic and diluted | $ (0.22) | $ (0.17) | $ (0.16) | $ (0.16) |
| Shares used in calculating net loss per share - basic and diluted | 81,261,302 | 98,594,355 | 98,331,695 | 98,419,166 |

| | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter |
|---|---|---|---|---|
| **2018** | | | | |
| Revenue | $ 5 | $ 4 | $ 31 | $ 7 |
| Operating expenses | 28,289 | 28,282 | 24,139 | 17,726 |
| Operating loss | (28,284) | (28,278) | (24,108) | (17,719) |
| Net loss | (27,519) | (27,732) | (23,635) | (17,340) |
| Net loss per share - basic and diluted | $ (0.35) | $ (0.35) | $ (0.30) | $ (0.22) |
| Shares used in calculating net loss per share - basic and diluted | 79,036,614 | 79,107,208 | 79,204,765 | 79,177,962 |

## 14. Employee Benefits

*Defined Contribution Benefit Plan* – In December 2015, the company adopted a 401(k) retirement and savings plan, or the 401(k) Plan, covering all employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. The company, at its discretion, may make certain contributions to the 401(k) Plan. We made contributions of $0.6 million, $0.5 million and $0.4 million during the years ended December 31, 2019, 2018 and 2017, respectively.

*Compensated Absences* – Under our vacation policy, salaried employees are provided unlimited vacation leave. Therefore, we do not record an accrual for paid leave related to these employees since we are unable to reasonably estimate the compensated absences that these employees will take.

## 15. Subsequent Events

***Collaborative Arrangement***

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two or more parties who are (i) active participants in the activity, and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

*Cost Allocation Agreement*— On January 29, 2020, we entered into a Cost Allocation Agreement, or the Agreement, with ImmunityBio, Inc. and its subsidiaries, or ImmunityBio. The Agreement is effective as of October 1, 2019. ImmunityBio is a related party, as it is an affiliate of NantWorks (Note 9). Simultaneously, we and ImmunityBio entered into Work Order Number One under the Agreement. Under the Agreement and Work Order Number One, the parties agreed to conduct a joint study, the clinical research trial being conducted pursuant to the protocol titled QUILT 3.063: *A phase 2 study of combination therapy with an IL-15 superagonist (N-803), off-the-shelf CD16-targeted natural killer cells (haNK), and avelumab without cytotoxic chemotherapy in subjects with Merkel Cell Carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor*. The ImmunityBio study drug included in the joint study is ImmunityBio's proprietary IL-15 superagonist known as N-803 and our study drug is our proprietary "off-the-shelf" CD16-targeted natural killer cell therapy known as haNK.

We will act as the sponsor of this joint study for purposes of regulatory matters, including submissions, correspondence, and communications. Additionally, we are designated as the contracting party to execute agreements with third and related parties relating to the joint study under Work Order Number One. We and ImmunityBio will split certain joint study costs equally related to Work Order Number One, in accordance with the terms of the Agreement. Shared joint study costs include cost related to conducting the joint study development activities, such as personnel related costs, as well as all costs associated to regulatory matters. Costs and expenses incurred in connection with the development, manufacturing, supply, delivery, and pre-patient administration dosing mechanism of each party's study drug, are excluded from the shared joint study costs. We expect that the joint study cost sharing component under the Agreement related to Work Order Number One will total approximately $2.1 million, subject to change dependent on clinical trial enrollments and progress. At December 31, 2019, there was minimal joint research activity under the Agreement and we incurred approximately $0.1 million in costs related to the joint study that are subject to joint cost sharing under the Agreement and are recorded in research in research and development expense on the consolidated statements of operations.

Under the agreement, each of ImmunityBio and the company will receive exclusive rights to any new intellectual property developed that relates solely to its respective study drug, and the parties will have joint co-equal rights in any other intellectual property. The Agreement expires upon the second anniversary of the effective date with the option to renew for additional successive one-year terms, but work orders for any joint studies still in process at the time of termination will continue until the applicable study is completed.

***Coronavirus Pandemic***

Due to the global viral outbreak caused by Coronavirus Disease 2019 (COVID-19) in 2020, there have been resulting effects which could negatively impact our financial condition or operations, including significant stock market exchange volatility, including various temporary volatility trading halts which commenced initially on March 9, 2020 due to market declines, various temporary business closures and event cancellations, and other effects including strains on hospitals and health provider resources which could result in clinical trial disruptions as the broader economic impact of COVID-19 develops. The ultimate impact of these matters to us and our financial condition and operations is presently unknown. The accompanying consolidated financial statements as of and for the year ended December 31, 2019 do not reflect the effects of these subsequent events.

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

None.

**Item 9A. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

Management, with the participation of its Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our CEO and CFO have concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

***Management's Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our CEO and CFO, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance (a) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, (b) our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (c) regarding the prevention or timely detection of the unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2019, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on this evaluation, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

***Changes in Internal Control over Financial Reporting***

There have been no changes in our internal control over financial reporting that occurred during the last fiscal quarter ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

***Inherent Limitations on Effectiveness of Controls***

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**Item 9B. Other Information.**

*2020 Goals and Objectives; Changes in Executive Compensation*

On March 20, 2020, the board of directors of NantKwest, Inc., or the company, reviewed and approved metrics with regard to the chief executive officer's, chief administrative officer's, and chief financial officer's target annual bonus relating to the company's goals for 2020 such as clinical trials, manufacturing, process development, research and development, and financial management. The board of directors also adopted and approved an increase to the base salary of Sonja Nelson, the company's chief financial officer, to $367,000 per year, with a potential cash bonus of up to 40% of her base salary for the year ending December 31, 2020.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2020 Annual Meeting of Stockholders, or the Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2019, and is incorporated herein by reference.

### Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement under the headings “Executive Compensation” and “Board of Directors and Corporate Governance – Director Compensation,” and is incorporated herein by reference.

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

The information required by this item will be contained in the Proxy Statement under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation – Equity Compensation Plan Information,” and is incorporated herein by reference.

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

The information required by this item will be contained in the Proxy Statement under the headings “Certain Relationships and Related Party Transactions” and “Board of Directors and Corporate Governance,” and is incorporated herein by reference.

### Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in the Proxy Statement under the heading “Ratification of Appointment of Independent Registered Public Accounting Firm – Fees Paid to the Independent Registered Public Accounting Firm” and is incorporated herein by reference.

## PART IV

**Item 15. Exhibits, Financial Statement Schedules.**

The consolidated financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K, or Annual Report, are as follows:

**(1) Consolidated financial statements**

Reference is made to the consolidated financial statements identified in the "Index to Financial Statements" under Part II, Item 8 of this Annual Report.

**(2) Financial Statement Schedules**

All other schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is otherwise on the consolidated financial statements or notes thereto.

**(3) Exhibits**

The documents listed in the Exhibit Index of this Annual Report are incorporated by reference or are filed with this Annual Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

**Exhibit Index**

| Exhibit Number | Description | Incorporated by Reference Herein | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation of NantKwest, Inc. | 8-K | 001-37507 | 3.1 | August 4, 2015 |
| 3.2 | Amended and Restated Bylaws of NantKwest, Inc., effective as of August 2, 2019. | 10-Q | 001-37507 | 3.1 | November 5, 2019 |
| 4.1 | Nominating Agreement by and between the Registrant and Cambridge Equities, LP, dated June 18, 2015. | S-1 | 333-205124 | 4.1 | June 19, 2015 |
| 4.2 | Form of Registration Rights Agreement by and between the Company and the Purchasers of Common Stock, dated June 2015. | S-1 | 333-205124 | 4.2 | June 19, 2015 |
| 4.3 | Registration Rights Agreement by and between the Company and Cambridge Equities LP, dated December 23, 2014. | S-1 | 333-205124 | 4.3 | June 19, 2015 |
| 4.4 | Registration Rights Agreement by and between the Company and Sorrento Therapeutics, Inc., dated December 13, 2014. | S-1 | 333-205124 | 4.4 | June 19, 2015 |
| 4.5 | Form of Subscription and Securities Purchase Agreement among the Company and the Subscribers of Series C Preferred Stock, dated as of April 1, 2014. | S-1 | 333-205124 | 4.5 | June 19, 2015 |
| 4.6 | Registration Rights Agreement, among the Company and the purchasers of Series B Preferred Stock, dated as of June 20, 2013. | S-1 | 333-205124 | 4.6 | June 19, 2015 |
| 4.7 | Specimen common stock certificate. | S-1/A | 333-205124 | 4.7 | July 15, 2015 |
| 4.8* | Description of the Registrant's Securities. | | | | |
| 10.1 | Form of Indemnification Agreement between the Company and each of its directors and executive officers. | S-1 | 333-205124 | 10.1 | June 19, 2015 |
| 10.2+ | 2014 Equity Incentive Plan and forms of agreements thereunder. | S-1 | 333-205124 | 10.2 | June 19, 2015 |
| 10.3+ | 2015 Equity Incentive Plan (As Amended and Restated June 6, 2019) and forms of agreements thereunder. | 10-Q | 001-37507 | 10.1 | August 6, 2019 |

| Exhibit Number | Description | Incorporated by Reference Herein | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | Filing Date |
| 10.4+ | Executive Incentive Compensation Plan. | S-1/A | 333-205124 | 10.4 | July 15, 2015 |
| 10.5+ | Amended and Restated Executive Employment Agreement between the Company and Patrick Soon-Shiong, effective March 24, 2015. | S-1/A | 333-205124 | 10.5 | July 15, 2015 |
| 10.6+ | Executive Employment Agreement between the Company and Barry J. Simon, M.D., dated January 1, 2015. | S-1 | 333-205124 | 10.6 | June 19, 2015 |
| 10.7 | License Agreement between the Company and Brink Biologics, Inc., dated June 9, 2015. | S-1 | 333-205124 | 10.7 | June 19, 2015 |
| 10.8 | License Agreement between the Company and Coneksis, Inc., dated June 9, 2015. | S-1 | 333-205124 | 10.8 | June 19, 2015 |
| 10.9 | License Agreement between the Company and Intrexon Corporation, dated February 23, 2010. | S-1 | 333-205124 | 10.10 | June 19, 2015 |
| 10.10 | UHN-ZelleRx License Agreement between University Health Network and the Company, dated May 9, 2005. | S-1 | 333-205124 | 10.11 | June 19, 2015 |
| 10.11 | License Agreement, as amended, between Fox Chase Cancer Center and the Company, dated as of July 10, 2004. | S-1 | 333-205124 | 10.12 | June 19, 2015 |
| 10.12 | Rush-ZelleRx License Agreement, between Rush University Medical Center and the Registrant, dated as of March 24, 2004. | S-1 | 333-205124 | 10.13 | June 19, 2015 |
| 10.13 | License Agreement, as amended, between Hans G. Klingemann and the Company, dated February 10, 2003. | S-1/A | 333-205124 | 10.14 | July 27, 2015 |
| 10.14 | Genomic and Proteomic Services Agreement by and between the Company and NantOmics, LLC, dated June 18, 2015. | S-1 | 333-205124 | 10.18 | June 19, 2015 |
| 10.15 | Lease Agreement by and between ARE - John Hopkins Court, LLC and the Company, dated June 19, 2015. | S-1/A | 333-205124 | 10.19 | July 27, 2015 |
| 10.16 | Shared Services Agreement by and between the Company and NantWorks, LLC, dated November 10, 2015. | 10-K | 001-37507 | 10.22 | March 30, 2016 |
| 10.17 | Facility License Agreement by and between the Company and NantWorks, LLC, dated November 10, 2015. | 10-K | 001-37507 | 10.23 | March 30, 2016 |
| 10.18+ | Offer Letter between Sonja Nelson and the Company, dated April 7, 2016. | 10-Q | 001-37507 | 10.1 | May 16, 2016 |
| 10.19 | Amended and Restated Shared Services Agreement by and between the Company and NantWorks LLC, dated June 28, 2016. | 10-Q | 001-37507 | 10.1 | August 15, 2016 |
| 10.20 | Lease agreement by and between the Company and 605 Doug Street, LLC, dated June 28, 2016. | 10-Q | 001-37507 | 10.1 | November 10, 2016 |
| 10.21+ | Letter Agreement with Barry Simon dated May 3, 2018. | 10-Q | 001-37507 | 10.1 | August 06, 2018 |
| 10.22+ | Offer of Employment Letter with Sonja Nelson dated June 11, 2018. | 10-Q | 001-37507 | 10.2 | August 06, 2018 |
| 10.23 | Notice of Pendency of Proposed Settlement of Stockholder Derivative Action dated May 31, 2019. | 8-K | 001-37507 | 99.1 | June 10, 2019 |
| 10.24 | Stipulation and Agreement of Settlement dated April 10, 2019. | 8-K | 001-37507 | 99.2 | June 10, 2019 |
| 10.25 | Letter Agreement between the Company and Immuno-Oncology Clinic, Inc., dated July 5, 2019. | 10-Q | 001-37507 | 10.4 | August 6, 2019 |

| Exhibit Number | Description | Incorporated by Reference Herein | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | Filing Date |
| 10.26* | Cost Allocation Agreement between the Company and ImmunityBio, Inc. and its subsidiaries, dated January 29, 2020. | | | | |
| 21.1* | Subsidiaries. | | | | |
| 23.1* | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. | | | | |
| 24.1* | Power of Attorney (Contained on Signature Page to this Annual Report on Form 10-K). | | | | |
| 31.1* | Rule 13a-14(a) / 15d-14(a) Certification of Principal Executive Officer. | | | | |
| 31.2* | Rule 13a-14(a) / 15d-14(a) Certification of Principal Financial Officer. | | | | |
| 32.1** | Section 1350 Certification of Chief Executive Officer. | | | | |
| 32.2** | Section 1350 Certification of Chief Financial Officer. | | | | |
| 101.INS | XBRL Instance Document | | | | |
| 101.SCH | XBRL Taxonomy Extension Schema Document | | | | |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | | | | |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document | | | | |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | | | | |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | | | | |

* Filed herewith.

** The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NantKwest, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

\+ Indicates a management contract or compensatory plan.

**Item 16. Form 10-K Summary.**

None.

## SIGNATURES

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

NantKwest, Inc.

Date: March 25, 2020

By: /s/ Patrick Soon-Shiong
**Patrick Soon-Shiong**
***Chairman and Chief Executive Officer***

## POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Patrick Soon-Shiong and Sonja Nelson, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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

| Signature | Title | Date |
|---|---|---|
| /s/ Patrick Soon-Shiong<br>**Patrick Soon-Shiong** | Chairman of the Board of Directors and Chief Executive Officer<br>*(Principal Executive Officer)* | March 25, 2020 |
| /s/ Barry J. Simon<br>**Barry J. Simon** | President, Chief Administrative Officer and Director | March 25, 2020 |
| /s/ Sonja Nelson<br>**Sonja Nelson** | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | March 25, 2020 |
| /s/ Steve Gorlin<br>**Steve Gorlin** | Director | March 25, 2020 |
| /s/ Michael D. Blaszyk<br>**Michael D. Blaszyk** | Director | March 25, 2020 |
| /s/ Frederick W. Driscoll<br>**Frederick W. Driscoll** | Director | March 25, 2020 |
| /s/ John C. Thomas, Jr.<br>**John C. Thomas, Jr.** | Director | March 25, 2020 |
| /s/ Cheryl L. Cohen<br>**Cheryl L. Cohen** | Director | March 25, 2020 |

# DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

NantKwest, Inc. has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our Common Stock.

## Description of Common Stock

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and our amended and restated Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.8 is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law, for additional information.

### Common Stock

We are authorized to issue up to a total of 500,000,000 shares of common stock, par value $0.0001 per share. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. Holders of our common stock have no cumulative voting rights. Further, holders of our common stock have no preemptive, conversion, redemption or subscription rights and there are no sinking fund provisions applicable to our common stock. Upon our liquidation, dissolution or winding-up, holders of our common stock are entitled to share ratably in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available.

As of December 31, 2019, there were 98,460,404 shares of common stock issued and outstanding and there were approximately 28 holders of record of our common stock. As of December 31, 2019, there were 4,506,950 shares of common stock underlying outstanding options and 1,139,428 shares of common stock underlying restricted stock units.

### Preferred Stock

Our board of directors is authorized, subject to certain limitations prescribed by law, to designate and issue up to a total of 20,000,000 shares of preferred stock, par value $0.0001 per share, without stockholder approval. The board may issue preferred stock from time to time in one or more series and fix the designations, preferences and rights of the shares of each such series and any qualifications, limitations or restrictions on the shares of each such series, including dividend rights and rates, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any such series.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could harm the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might harm the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### Registration Rights

On December 23, 2014, we entered into a Registration Rights Agreement with certain of our existing investors (the "Registration Rights Agreement") pursuant to which we provided such investors with a right to demand registration of their shares on Form S-3, if we are eligible to use Form S-3, otherwise, on Form S-1, exercisable at any time following the consummation of our initial public offering, provided that such demand is made at the request of the holders of at least 50.1% of such shares to be registered, subject to certain obligations set forth in the Registration Rights Agreement.

We have also granted certain of our existing investors "piggyback" registration rights, subject to certain other limitations that allow certain of our investors to include the shares of our common stock in any public offerings of equity securities initiated by us or any demand registration rights holder.

We will pay the registration expenses (other than underwriting discounts and applicable selling commissions incurred in connection with registration) of the holders of the shares registered pursuant to the registration rights described above. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include.

**Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

The provisions of Delaware law, our amended and restated Certificate of Incorporation and our Bylaws may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaw Provisions***

Our amended and restated certificate of incorporation and our amended and restated bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our management team, including the following:

- *Board of directors vacancies.* Our amended and restated certificate of incorporation and amended and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by our board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- *Advance notice requirements for stockholder proposals and director nominations*. Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our amended and restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.
- *No cumulative voting*. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation does not provide for cumulative voting.
- *Amendment of charter provisions*. Any amendment of the above provisions in our amended and restated certificate of incorporation requires approval by holders of at least two-thirds of our then outstanding voting securities.

- *Issuance of undesignated preferred stock*. Our board of directors has the authority, without further action by the stockholders, to issue up to 20,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.
- *Exclusive forum*. Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

**Listing**

Our common stock is listed on The Nasdaq Global Select Market under the symbol "NK."

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219. The transfer agent's telephone number is (800) 937-5449.

**Exhibit 10.26**

# COST ALLOCATION AGREEMENT

This Cost Allocation Agreement (this "Agreement"), entered into on January 29, 2020, but made effective as of October 1, 2019 (the "Effective Date"), documents the mutual understanding with respect to certain joint clinical research activities that NantKwest, Inc., a Delaware corporation ("NantKwest") and ImmunityBio, Inc., a Delaware corporation, and its subsidiaries ("IB") intend to conduct as development partners. In consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Joint Studies. The parties may from time to time agree to co-sponsor and conduct certain combination clinical studies (each a "Joint Study") pursuant to clinical trial protocols wherein at least one investigational agent is a proprietary therapeutic drug candidate owned or controlled by NantKwest (each, an "NK Study Drug") and at least one other investigational agent is a proprietary therapeutic drug candidate owned or controlled by IB (each, an "IB Study Drug"). Each NK Study Drug and IB Study Drug may be referred to individually or collectively herein as a "Study Drug" or "Study Drugs."

2. Work Orders. Prior to initiating any activities for a Joint Study, the parties shall agree in writing in a separate work order (each, a "Work Order") describing, amongst other things: (i) their respective development and management responsibilities (the "Development Activities"); (ii) the respective allocation of Joint Study costs and expenses in accordance with Section 3 below; (iii) regulatory responsibilities; and (iv) any other matters relating to the Joint Study.

3. Joint Study Costs and Payment Terms.

a. The parties agree to allocate the total costs (the "Total Cost") associated with each Joint Study (the "Cost Allocation") as set forth in the applicable Work Order. Unless expressly agreed otherwise in a Work Order, the following costs shall be included when calculating the Total Cost to be allocated between the parties in connection with each Joint Study: (i) all costs and expenses incurred by a party in connection with the Development Activities of the specific Joint Study including personnel related costs; (ii) all costs and expenses incurred by a party pursuant to third party and related party contracts relating to the Joint Study; (iii) all costs associated with regulatory matters associated with the Joint Study; and (iv) any other fees, charges and expenses incurred in connection with the Joint Study. Any costs, expenses, and fees incurred by each party in connection with each Joint Study that make up the Total Cost shall be charged at cost, without mark-up or profit, but including reasonable allocations of employee benefits and other direct and fairly allocated indirect costs that relate to the employees or consultants providing the applicable services.

b. Notwithstanding anything else in this Agreement to the contrary, each party shall bear its own costs and expenses incurred in connection with the development, manufacturing, supply, delivery, and pre-patient administration dosing mechnanics of its respective Study Drugs and such costs shall not be included in the Total Cost.

c. NantKwest and IB will jointly develop a mutually agreeable budget for each Joint Study (the "Budget"), which Budget may be updated from time to time upon mutual consent. Neither party may, without the prior written approval of the other party, incur any expenses in connection with a Joint Study except as expressly contemplated in the applicable Budget. For each Joint Study, the parties will also jointly prepare a quarterly, non-binding forecast (each, a "Forecast") in order to estimate the anticipated Joint Study expenses to be incurred in each calendar quarter. Notwithstanding the foregoing or anything else in this Agreement to the contrary, a variance between the actual amounts incurred and the amounts contemplated in each then-current Budget or Forecast shall neither excuse nor waive a party's obligations with respect to the sharing of Joint Study expenses in accordance with the cost allocation set forth in the applicable Work Order.

d. Within five (5) days of the end of each calendar month, each party shall provide the other with a good faith estimate of its itemized costs (internal and external) in the previous month relating to the applicable Joint Study, and a final, itemized report of the previous month's costs will be delivered to the other party within ten (10) days of the end of each month. The reports will be used to calculate the amount to be reimbursed by one party to the other by taking into account the over- or under-payment of each party relative to its share based on the Cost Allocation. When calculating the amount owed, one party may offset the amounts owed by the other party and pay the net amount to the other party. Payments of all undisputed amounts invoiced shall be payable within thirty (30) days of invoice receipt.

4. Regulatory Responsibilities. Each Work Order shall set forth the respective roles and responsibilities of the parties with respect to regulatory submissions and related activities for the applicable Joint Study, including without limitation the responsibility for preparing and filing the Investigational New Drug application (the "IND") filed with the United States Food and Drug Administration (the "FDA"). Such designated party shall be responsible for preparing, filing and maintaining all regulatory filings, including submissions and correspondence, and compliance with all requirements for the conduct of the applicable Joint Study.

a. Each party shall provide the other with a reasonable opportunity to review and comment upon all regulatory submissions no later than 15 days prior to the anticipated date of such submissions and will in good faith incorporate the comments from the other party.

b. Each party hereby grants to the other party a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference" (as defined in US FDA 21 CFR 314.3(b)), or similar "right of reference" as defined in applicable regulations in the relevant jurisdiction to its regulatory submissions, solely as necessary for the other party to prepare, submit and maintain regulatory submissions for its respective Study Drug(s). Further, each party shall provide to the other a cross-reference letter or similar communication to the applicable regulatory authority to effectuate such "right of reference" on a need-to-know basis with respect to the confidential part of the Drug Master Files of both parties. Where a "right of reference" is not possible, the parties will promptly discuss in good faith on how to make the required documentation available for regulatory submissions of Study Drug(s). Neither Party shall have the right to access the other party's Chemistry Manufacturing and Controls (CMC) data with respect to its Study Drug(s) without the express written consent of the other Party, except in the following circumstances: (i) to the extent required by applicable law or regulation; (ii) in the event the Parties elect to file joint regulatory submissions for one or more Joint Studies; or (iii) as expressly authorized in writing by the other Party.

5. Joint Study Contracts. For each Joint Study, the parties will designate either NantKwest or IB as the contracting party to enter into agreements with third or related parties, including without limitation, clinical trial agreements, relating to the conduct and management of the applicable Joint Study; provided, that the contracting party may not enter into any material agreement (including without limitation any clinical trial agreement) relating to a Joint Study without the express prior written consent of the other party and, provided further, that the other party shall also obtain the express prior written consent of the contracting party prior to entering into any agreements with third or related parties in connection with a Joint Study. Concurrently with the execution of each clinical trial agreement (CTA) relating to a Joint Study, the parties will execute a separate side letter to document their respective rights and obligations pursuant to such CTA. Further, to the extent of any other material agreements that may be required in connection with a particular Joint Study, the non-contracting party shall have the right to review and comment on the terms of such material agreement prior to execution.

6. Joint Decision-Making.

a. Steering Committee. Within 30 days after the effective date of each Work Order, the parties shall establish a steering committee (the "Steering Committee") to discuss Development Activity objectives for the applicable Joint Study and review the data and to monitor and to make certain decisions regarding such Joint Study. The Steering Committee will have reviewing, monitoring and approving responsibilities for the Joint Study and will attempt to facilitate the resolution of any disputes between the parties, as described in Section 6(c) below. The Steering Committee will also provide a forum for sharing advice, progress and results relating to such activities. Each party, through its representatives on the Steering Committee, will be permitted to provide advice and commentary with respect to the Joint Study. Each party will take such advice and commentary into good faith consideration when performing its duties hereunder. More specifically, the Steering Committee will:

i. Review and approve the Joint Study protocol and changes thereto;

ii. Discuss and oversee regulatory related activities to ensure regulatory compliance and timely management of responses to any regulatory authority queries during regulatory review processes;

iii. Approve publication strategies for Study Data;

iv. Facilitate the exchange of information in compliance with this Agreement in order to ensure that significant issues concerning adverse event information and safety issues are addressed consistently and in a timely manner; and

v. Review and approve all Joint Study reports.

For clarity, the Steering Committee will not have any power to amend, modify or waive the terms of this Agreement or any Work Order unless agreed to by both parties in writing.

b. Membership; Meetings. The Steering Committee will be composed of one (1) representative from each of IB and NantKwest, or such other number as the parties may agree, and will meet at least four (4) times per calendar year, or more or less often as the Steering Committee may determine. The Steering Committee will establish a schedule of times for meetings, taking into account, among other things, the planning needs of the Development Activities and the need of the Steering Committee to consult or render decisions. In addition, either party may schedule an additional meeting (not more than one additional meeting per calendar year) with at least 30 days' prior written notice to the other members of the Steering Committee. Meetings will take place in-person or by telephone or video conference as agreed to by members of the Steering Committee, except that at least one meeting per year will be in-person. In-person meetings will take place at NantKwest's or IB's offices whenever possible, unless otherwise agreed by the parties. Any member of the Steering Committee may designate a substitute to attend with prior written notice to the other Party. A quorum of the Steering Committee will exist whenever there is present at a meeting at least one representative from each party. Ad hoc guests may be invited to the Steering Committee meetings. Each party may replace its Steering Committee member with other representatives, at any time, upon written notice to the other party. Each party will bear its own costs, including travel costs, for personnel participating in the Steering Committee.

c. Decision-Making. Decisions of the Steering Committee will be made by consensus, with each party's representatives on the Steering Committee having collectively one vote in all decisions, unless otherwise specified in the Work Order. If the Steering Committee is unable to reach a consensus decision on a matter that is within its decision-making authority within 15 days after it has met and attempted to reach such decision, then such matter shall be resolved pursuant to Section 13(a) of this Agreement.

7. Joint Study Data. Each party agrees to promptly and regularly share with the other party, in such format as may be mutually agreed by the parties, all data, results, and other information generated pursuant to a Joint Study ("Study Data"). Study Data will be provided to the other party in a mutually agreeable format. Subject to any restrictions set forth in third party or related party contracts, the parties will jointly own the Study Data for each Joint Study and shall have equal rights of use for all lawful purposes.

8. Study Inventions. Any idea, concept, invention or discovery, whether or not patentable relating to a Joint Study or that is first conceived or reduced to practice in connection with the conduct of a Joint Study (any of the foregoing, a "Study Invention") as between themselves, and subject to the terms and conditions of any applicable third party or related party agreement, the parties hereby agree as follows: (a) if a Study Invention is solely an NK Platform Invention (defined below) then all rights in such Study Invention will vest in NantKwest; (b) if a Study Invention is solely an IB Platform Invention (defined below), then all rights in such Invention will vest in IB; (c) if a Study Invention is (x) both an NK Platform Invention and an IB Platform Invention or (y) neither an NK Platform Invention nor an IB Platform Invention, then the rights in such Study Invention will vest equally in both parties, and each party shall have an undivided co-equal right in such Study Invention.

"NK Platform Invention" means any Study Invention that relates to the applicable NK Study Drug or to any materials or Confidential Information of NantKwest provided hereunder, including without limitation the following: (i) improvements, modifications, derivatives, optimizations, or other compositions of matter; (ii) methods of use, discovery, processing, or manufacture; and (iii) properties or functionality of the drug discovery platform for any NK Study Drug.

"IB Platform Invention" means any Study Invention that relates to the applicable IB Study Drug or to any materials or Confidential Information of IB provided hereunder, including without limitation the following: (i) improvements, modifications, derivatives, optimizations, or other compositions of matter; (ii) methods of use, discovery, processing, or manufacture; and (iii) properties or functionality of the drug discovery platform for an IB Study Drug.

9. Altor-NK Co-Development Agreement. Both parties agree to negotiate in good faith to amend the Exclusive Co-Development Agreement dated as of August 16, 2016 (the "Co-Development Agreement"), made by and between NantKwest and IB's wholly-owned subsidiary Altor BioScience, LLC ("Altor"). The amendment shall amend certain terms of the Co-Development Agreement including, but not limited to, the fact that, from and after the Effective Date, no new clinical research activities shall be designated by the parties as Projects (as such term is defined in the Co-Development Agreement), and the Parties will document the specific Projects covered by the Co-Development Agreement, if any.

10. Term and Termination.

a. Term. Unless earlier terminated in accordance with its terms, the term of this Agreement shall continue for a period of two (2) years from the Effective Date, and may thereafter be renewed by the parties upon mutual agreement for additional successive one (1) year terms (the initial term and each renewal thereof, the "Term"). If any Joint Study has not been completed at the end of the initial or any renewal term, as applicable, or upon termination pursuant to Section 10(b)(i) below, then this Agreement will survive expiration of the Term until the completion or earlier termination of the Work Order for any such ongoing Joint Study. A Work Order may be terminated upon mutual agreement of both parties.

b. Termination Rights. Either party may terminate this Agreement or any Work Order (i) upon thirty days' written notice to the other party; or (ii) in the event of a material breach by the other party that is not cured within thirty (30) days of written notice provided by the non-breaching party. A party may also terminate this Agreement immediately if, at any time, the other party shall (iii) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that party or of its assets, (iv) propose a written agreement of composition or extension of its debts, (v) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition has not been dismissed within sixty (60) days after the filing thereof, (vi) propose or be a party to any dissolution or liquidation, (vii) make an assignment for the benefit of its creditors or (viii) admit in writing its inability generally to meet its obligations as they fall due in the general course.

c. In the event either party elects to terminate this Agreement or its development of any Study Drug for reasons other than safety, such party shall nevertheless continue to provide sufficient quantities of Study Drug to enable the completion of any ongoing Joint Study.

11. Confidentiality. Each of the parties agrees that any confidential information of the other party disclosed, received, developed or discovered in the course of performance under this Agreement, ("Confidential Information") shall be kept strictly confidential by the parties and may be used by the recipient only as necessary to perform its obligations or exercise or enforce its rights under this Agreement, except that either party may disclose such Confidential Information to the extent reasonably necessary in connection with the enforcement of this Agreement or as required by law or legal process, including any tax audit or litigation. The obligations set forth in this section shall not apply to (i) information that is already in the possession of the party receiving confidential information, provided that such information is not known by such party to be subject to another confidentiality agreement with or other obligation of secrecy to the other party or another party; (ii) information that becomes available to the public other than as a result of a disclosure, directly or indirectly, by the party receiving Confidential Information or its Affiliates; (iii) disclosures that are required by any legal requirement including any rule or regulation of the U.S. Securities and Exchange Commission (SEC) or of a stock exchange which may require such disclosure; or (iv) information that becomes available to the Party receiving Confidential Information on a non-confidential basis from a source other than the other party; provided that such source is not known by such party to be bound by a confidentiality agreement with or other obligation of secrecy to the other party. Notwithstanding any other provisions in this Agreement to the contrary, either party may disclose this Agreement and/or the existence thereof to investors, potential investors, acquirors, or potential acquirors for the limited purpose of entering into potential transactions; provided, that such potential or actual investors or acquirors are subject to written obligations to protect Confidential Information.

12. Indemnification; Limitation of Liability.

a. Indemnification. Each party will indemnify, defend, and hold the other party, its affiliates, and its and their respective employees, officers, directors, members, managers, and agents (any or all of the foregoing, the "Indemnitees") harmless from and against all damages, liabilities, losses, costs, and expenses (including, without limitation attorney fees) ("Damages") arising out of or relating to any suit, action or other legal proceeding to the extent brought as a result of the other party's (i) breach of its representations and warranties set forth in this Agreement, (ii) bad faith, (iii) gross negligence, or (iv) willful misconduct.

b. Limitation of Liability. EXCEPT WITH RESPECT TO INDEMNIFICATION FOR THIRD PARTY CLAIMS, GROSS NEGLIGENCE, WILFUL MISCONDUCT AND BREACHES OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH HEREUNDER, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES ARISING FROM ANY CLAIM OR ACTION HEREUNDER (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, REVENUE, ECONOMIC ADVANTAGE OR DATA) BASED ON CONTRACT, TORT OR OTHER LEGAL THEORY, AND WHETHER ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

13. Miscellaneous.

a. Dispute Resolution. In the event of any dispute or difference arising out of or relating to this Agreement or the breach thereof, the parties hereto shall use their best efforts to settle such disputes or differences in good faith negotiations, keeping in mind their mutual interests, in order to reach a just and equitable resolution of the dispute or difference satisfactory to both parties. Either party may make a written request to the other by sending notice thereof for a meeting of authorized senior managerial representatives to resolve the parties' differences. Such meeting shall take place within thirty (30) days of receipt of such notice at a time and location acceptable to both parties. If within sixty (60) days after a meeting of the senior representatives, the parties have not succeeded in negotiating a resolution of the dispute or difference, either party may pursue such legal and/or equitable remedies as may be available.

b. Assignment. Neither party will assign its rights or delegate any or all of its obligations under this Agreement without the express prior written consent of the other party; provided, that either party may assign all or any part of its rights to any affiliate or in connection with a merger, consolidation or sale or exclusive licensing of all or substantially all of the assets to which this Agreement relates. Any purported assignment or transfer in violation of this section shall be null and void and of no effect. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and permitted assigns.

c. Rights of Affiliates. Either party may in its sole discretion grant to one or more of its Affiliates the right to exercise the rights granted to such party, or undertake the obligations of such party, under this Agreement. For purposes of this Agreement, "Affiliate" means any person directly or indirectly controlled by, controlling, or under common control with a party, excluding (i) NantKwest, in the case of IB, and (ii) IB, in the case of NantKwest.

d. Governing Law. This Agreement is to be construed in accordance with and governed by the internal laws of the State of California without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of California to the rights and duties of the parties.

e. Equitable Remedies. Without limiting any other rights or remedies of a party, each party acknowledges that a breach of this Agreement by the other party may cause immediate and irreparable harm to the non-breaching party, for which an award of damages may not be adequate compensation and agrees that, in the event of such breach or threatened breach, the non-breaching party will be entitled to seek equitable relief, including in the form of orders for preliminary or permanent injunction, specific performance, interim or conservatory relief, and any other relief that may be available from any court, and each party hereby waives any requirement for the securing or posting of any bond in connection with such relief. Such remedies will not be deemed to be exclusive but will be in addition to all other remedies available to the parties at law or in equity.

f. Independent Contractors. The relationship between the parties is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

g. Third-Party Beneficiaries. This Agreement is for the sole benefit of the parties and their permitted successors and assigns, and nothing in this Agreement expressed or implied shall give or be construed to give to any person, other than the parties and their permitted successors and assigns, any legal or equitable rights hereunder, whether as third-party beneficiaries or otherwise.

h. Entire Agreement. This Agreement, together with all Work Orders, constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings and negotiations, both written and oral, between the parties with respect to the subject matter of this Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth in this Agreement has been made or relied upon by any party hereto.

i. Modification; Waivers. No modification, alteration or amendment to this Agreement shall be effective unless in writing and duly signed by authorized representatives of both parties. The waiver by either party of a breach of or a default under any provision of this Agreement shall not be effective unless in writing and shall not be construed as a waiver of any subsequent breach of or default under the same or any other provision of this Agreement, nor shall any delay or omission on the part of either party to exercise or avail itself of any right or remedy that it has or may have hereunder operate as a waiver of any such right or remedy. If there is a conflict between the terms of this Agreement and the Work Order, unless specifically stated otherwise in the fully executed Work Order, the terms of this Agreement shall prevail.

j. Severability. If any section, provision, or part of this Agreement is held to be illegal, invalid or unenforceable, such section, provision, or part shall be fully severable. The remainder of this Agreement shall remain in full force and effect.

k. Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same agreement, and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party.

[*Signature page follows.*]

**IN WITNESS WHEREOF**, the parties hereto have caused their duly authorized officers to execute this Cost Allocation Agreement as of the Effective Date.

**NANTKWEST, INC.**

By: /s/ Steven Yang
Name: Steven Yang
Title: General Counsel

**IMMUNITYBIO, INC.**

By: /s/ David Sachs
Name: David Sachs
Title: Acting CFO

**EXHIBIT 21.1**

**SUBSIDIARIES OF NANTKWEST, INC.**

| Name of Subsidiary | Jurisdiction of Organization |
|---|---|
| Inex Bio, Inc. | Republic of Korea |
| Infacell Therapeutics, Inc. | Delaware |
| 557 Doug St, LLC | California |

**EXHIBIT 23.1**

## Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-233082) and the Registration Statement (Form S-8 No. 333-205942), each pertaining to the 2015 Equity Incentive Plan and 2014 Equity Incentive Plan, and in the Registration Statement on Form S-3 (No. 333-233434) for the registration of common stock, preferred stock, warrants, debt securities and units of our report dated March 25, 2020, with respect to the consolidated financial statements of NantKwest, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Los Angeles, California
March 25, 2020

**EXHIBIT 31.1**

**Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Patrick Soon-Shiong, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 25, 2020

/s/ Patrick Soon-Shiong
Patrick Soon-Shiong
Chief Executive Officer
(Principal Executive Officer)

**EXHIBIT 31.2**

**Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Sonja Nelson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 25, 2020

/s/ Sonja Nelson
Sonja Nelson
Chief Financial Officer
(Principal Financial and Accounting Officer)

**EXHIBIT 32.1**

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

I, Patrick Soon-Shiong, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of NantKwest, Inc. for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of NantKwest, Inc.

Date: March 25, 2020

By: /s/ Patrick Soon-Shiong
Name: Patrick Soon-Shiong
Title: Chief Executive Officer

**EXHIBIT 32.2**

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

I, Sonja Nelson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of NantKwest, Inc. for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of NantKwest, Inc.

Date: March 25, 2020

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