NantKwest, Inc.
Form 10-K
March 13, 2019

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, 2018

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

(858) 633-0300

Registrant's telephone number, including area code

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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, 2018, was approximately $86.1 million. The number of shares of the Registrant's common stock outstanding as of March 8, 2019

was 79,087,734.

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 2019 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the Registrant's fiscal year ended December 31, 2018.

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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, 2018, 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 candidate and not infringe upon the intellectual property of others;
- regulatory developments in the United States (U.S.) and foreign countries;
- 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; and
- our use of proceeds from our initial public offering.

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

We are a pioneering clinical-stage immunotherapy company focused on harnessing the power of the innate immune system by using the natural killer cell 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 activated natural killer, or aNK, cell platform, as well as clinical testing and scale manufacturing of our leading product candidates. Natural killer, or 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 activation by other support molecules, typically required to activate adaptive immune cells such as T cells.

We hold the exclusive right to commercialize aNK cells, a commercially viable natural killer cell line, and a variety of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States (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 as a therapeutic to treat a spectrum of clinical conditions.

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

We believe that our proprietary NK cell line, coupled with our integrated discovery ecosystem, positions us to implement precision cancer medicine by leveraging 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 cells such as our activated NK cells.

Our Approach

Multiple Modes of 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 (1) Innate Killing, whereby all of our NK platforms recognize the abnormal proteins typically found on stressed cells, which upon binding, release toxic granules to immediately kill their targets; (2) Antibody Mediated Killing with our haNK and t-haNK platforms, which are NK 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 (3) Chimeric Antigen Receptor, or CAR, Directed Killing with our taNK and t-haNK platforms, which are NK cells engineered to express CARs that target tumor-specific proteins commonly found on the surface of cancer cells and, upon binding, induce cell death through the release of toxic granules directly into its 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 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, focusing on solid tumors and hematological malignancies. We eventually plan to advance therapies for 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 NK cells, our NK cells do not express the key inhibitory receptors that diseased cells often exploit to turn off the killing function of NK cells and escape elimination. We have developed a unique aNK cell, which omits many 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 (a) 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 (b) 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 its target by delivering a larger payload of lytic enzymes and cytokines responsible for both direct and indirect killing when compared to other NK cells isolated from healthy donors. We believe 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 clinical trials, we have further modified this 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 mediated antigen targeted killing, the t-haNK platform.

Antibody Mediated Killing - the haNK Platform. We have genetically engineered our aNK cells 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 NK 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 NK 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 NK 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 use in several phase Ib/II clinical trials.

CAR Mediated 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: (1) checkpoint ligands, such as PD-L1 and B7 H4; (2) widely-established tumor proteins such as HER2 and CD19; (3) novel surface antigens associated with cancer stem cells such as CD123 and IGF R1; and (4) newly discovered proteins from individual patient tumor samples, known as neoepitopes. 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 Mediated and Antibody Mediated Killing - the t haNK Platform. Our newest 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 mediated 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 lead t haNK product candidates, PD L1.t haNK and CD19.t haNK, both currently at the IND filing stage, a pipeline of prominent CARs for t haNK are advancing through human enabling studies, including BCMA, HER2 and EGFR, 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 cells as the backbone of the therapy. 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 IL 15, 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 in comparison with current standards of care. We believe ultimately that employing our NK cell therapy in the context of NCV would 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: (1) 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; (2) 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; (3) 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; (4) 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 (5) 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 NK 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 native 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.

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 (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 safety clinical trials to date, aNK 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 NK cells to kill virally infected cells. Preclinical studies in HIV, HCV, EBV and Ebola viruses demonstrate this capability.
- Well tolerated. aNK cells are hypo-immunogenic and have shown no dose limiting toxicities in over 46 patients who have received therapy to date, even when some patients received as many as 18 infusions of aNK cells over a six month period.
- 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 GMP compliant aNK cell bank, a proprietary asset of our Company.

5

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, the company recruited seasoned executives to lead manufacturing, clinical development, regulatory affairs, medical affairs, quality and other critical staff and continues to build the management and manufacturing infrastructure.

Company Vision

Our vision is to be the premier immunotherapy company, harnessing the power of the innate immune system with the NK cell at the core, to pioneer precision medicine in the treatment of 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 simple combination with a PD L1 checkpoint inhibitor and 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 into first-in-human clinical trials. We are making preparations to initiate phase I safety studies for the first two t haNK products to ever reach clinical testing. A CD19.t haNK IND has been submitted to the FDA and PD L1.t haNK is IND ready with a planned submission during the second quarter of 2019. We anticipate dosing patients in the second half of 2019. We intend to progress these programs to phase Ib/II trials in acute lymphoblastic leukemia, or ALL, and diffuse large B-cell lymphoma, or DLBCL, and in PD L1 high non-small cell lung cancers, respectively. We believe a pipeline of IND-ready t haNK product candidates will emerge in the second half of 2019 and may include HER2, EGFR and BCMA.t haNK products.
- 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 CD19.t haNK and PD L1.t haNK product candidates by designing trials that permit the enrollment of patients whose cancers demonstrate high levels of CD19 and PD L1, respectively, from a number of select cancer types. We believe this approach will enhance the development potential of our t haNK product pipeline.
- 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 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 and establish efficiencies across our pipeline products.
- Pursue opportunities with vaccine and cytokine combination partnerships that drive in vivo production of anti-cancer antibodies for ADCC killing with haNK and t haNK cells. We ultimately plan to enroll patients into a wide range of combination therapy studies that employ adenoviral and yeast vaccine platforms together with a novel IL 15 cytokine agonist to deliver tumor associated antigens that induce the natural production of IgG1-type antibodies in patients, and when combined with our haNK and t haNK cells, maximize both ADCC killing and adaptive immune responses.
- 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 inherent ability of NK cells to kill virally infected cells. Preclinical studies in HIV, HCV, EBV and Ebola viruses demonstrate this capability. Preliminary efforts are underway to evaluate the role of a unique CAR taNK product in clearing HIV reservoirs as part of a novel immunotherapy combination regimen.

Our Therapeutic Platforms

Leveraging Our Assets

In 2018, we developed a pre-clinical portfolio of t haNK products based on the combined attributes of our existing haNK and taNK platforms. We also advanced our haNK product into several clinical trials, which incorporated a comprehensively orchestrated tumor and immune-conditioning regimen known as the 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 Mediated 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 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) an optional CD28 co-stimulatory domain; and (4) one of several signaling domain segments which resides on the internal surface of the membrane where, upon external Fv 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 Mediated 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 NK cells, as well as independence from IL 2 supplementation for expansion and viability and a functional enhancer such as an activating cytokine or intensified trafficking ability. Based on this unique arrangement, t haNK cells can target two distinct cancer antigens at once: one via its CD16 receptor and an antibody such as rituximab (CD20), and the other through its CAR receptor (i.e. CD19), 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: (1) checkpoint ligands, such as PD L1 and B7 H4; (2) widely-established tumor proteins such as HER2 and CD19; (3) novel surface antigens associated with cancer stem cells such as CD123 and IGF R1; and (4) newly discovered proteins from individual patient tumor samples, known as neoepitopes.

The table below highlights some of our CAR taNK products and their intended targets using our aNK platform, as reported in the scientific and medical journals listed below.

Non-Clinical Validation of HER2.taNK, a Compelling Case for t haNK-based Therapies. We are preparing a novel lineup of virus-free t haNK product candidates that are IL 2 growth independent, cryopreserved, CAR expressing cell lines based on our haNK cell therapeutic, several of which are progressing towards phase I clinical trials. We previously licensed from Chemotherapeutisches Forschungsinstitut Georg-Speyer-Haus and DRK-Blutspendedienst Baden-Wurttenberg-Hessen GmbH a lentiviral based HER2 CAR expressing cell line that is based on our original aNK cell product, which lacks CD16 receptors for antibody mediated killing and is IL 2 growth dependent. Due to the rapid advancement and clinical readiness of our virus-free tri- and quad-cistronic t haNK platforms, we have decided to discontinue development of this licensed lentiviral-based product in favor of advancing an internally developed HER2 CAR expressing t haNK product. Such next-generation products avoid the safety concerns associated with the use of retro and lentiviral sequences, incorporate the high-affinity CD16 receptor for enhanced antibody mediated killing, as well as IL 2 and other functional components, which can potentially enhance clinical efficacy and reduce production costs. Additionally, data generated from the previously licensed HER2 CAR expressing cell line has provided significant non-clinical validation to continue to pursue our internally developed therapeutic targeting HER2.

Clinical Experience with our aNK 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 an activity and safety standpoint. We have demonstrated single-agent safety with dose escalations in both single and repeat dosing schedules to doses as high as 1×10^{10} cells/m^2 and as many as 18 infusions over a six-month period, corresponding to a cumulative dose of as much as 15×10^{10} cells. Infusion-related toxicities remained generally mild across all studies, with the exception of one grade 3 fever and one grade 4 hypoglycemic episode, neither of which resulted in dose reduction or study discontinuation. Some subjects that proceeded with additional testing were found to have developed anti-HLA antibodies, but none were required to withdraw from study and some continued to receive additional infusions uneventfully.

While many cell-based adaptive immunotherapy trials impose heavy pre-screening protocols, our subjects were not pre-selected based on the likelihood of response, but rather accepted all-comers 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 agents in order to enhance therapeutic effects.

Although aNK is not intended as a monotherapy, clinical activity was recorded in all studies conducted to date. Among the three Merkel cell cancer patients receiving aNK cells, one subject achieved a long-lasting partial response followed by a radiologic complete response at the time of occurrence of a new lesion, and one subject achieved a mixed response. Among the four lung cancer patients treated, three subjects had clinically significant responses including lymph node and mediastinal mass resolution and disease stabilization, respectively. Among 12 patients with advanced melanoma and renal cell carcinoma, one patient went on to have a mixed response, with some lesions resolving, while five other patients achieved disease stabilization after having breakthrough progression on their prior therapies. Among 12 subjects with advanced hematological malignancies, two subjects with Hodgkin's lymphoma and multiple myeloma, achieved a complete response, one subject achieved a partial response, another with a clinical-transient response, and one subject achieved a mixed-transient response. And lastly, 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:

Merkel Cell Carcinoma: QUILT 3.009 (NantKwest Sponsored)

This completed multi-center, nonrandomized, open-label phase II study was 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 used a Simon's two-stage optimal design where up to 12 patients would be enrolled in the first stage for treatment with aNK monotherapy, and if one or more patients from the initial group experienced progression-free survival for 16 weeks or more, then the second stage would initiate where the balance of the study could proceed to full enrollment. Shortly after achieving this progression-free survival rate metric, the protocol was amended so that patients enrolled in the second stage would receive aNK in combination with N 803, an IL 15 superagonist, developed by NantCell, Inc., an affiliated entity. Patients who were already receiving aNK as monotherapy received aNK in combination with N 803 in subsequent cycles. The aNK dose of 2×10^9 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 point 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.

The overall response rate in this initial group of patients was 29%, with two of seven patients experiencing a partial response or complete response. One patient receiving aNK monotherapy experienced an initial partial response for 62 days, followed by a complete response for 52 days, after which progressive disease was confirmed by biopsy. A second patient receiving aNK in combination with N 803 experienced a partial response for 58 days, followed by progressive disease. A third patient receiving aNK in combination with N 803 experienced stable disease for 184 days followed by progressive disease. 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. Moreover, treatment with both aNK monotherapy and aNK plus N 803 combination therapy were associated with anticancer activity. 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 a chemotherapy-free combination.

Advanced Solid Tumors (Investigator Sponsored)

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 therapy 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 1×10^9 cells/m^2, 3×10^9 cells/m^2, and 1×10^{10} cells/m^2 (1×10^{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 with stable blood cell counts 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.

Three patients with advanced lung cancer had clinically significant responses after two doses of aNK. One patient had a diagnosis of small cell lung cancer with a supraclavicular lymph node metastasis. After treatment with two infusions of 3×10^9 cells/m^2, the patient's lymph node metastasis could no longer be detected.

A second patient had small cell lung cancer with multiple metastases in the liver and a single metastasis in the lung just behind the sternum. After two infusions of 3×10^9 cells/m^2, there was significant regression in the lung metastasis. This was verified by x-ray analysis taken before and 14 days after aNK treatment. There was no remission of the liver metastasis.

A third patient had a diagnosis of non-small cell lung cancer with multiple lung metastases resistant to conventional chemotherapy. After treatment with two infusions of 1×10^{10} cells/m^2, the disease stabilized. Four months after receiving two initial infusions, the third patient received four additional infusions of aNK cells (5×10^9 to 1×10^{10} cells/m^2) over a period of six months, with no adverse events from either the initial or subsequent treatments.

Advanced Melanoma or Renal Cell Carcinoma (Investigator Sponsored)

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 multiple administrations of aNK in 12 patients 18 years and older with measureable refractory or relapsed advanced melanoma. The primary endpoints were the feasibility and safety of administration of multiple infusions of aNK. The four aNK dose levels were 1×10^8 cells/m^2, 3×10^8 cells/m^2, 1×10^9 cells/m^2, and 3×10^9 cells/m^2 administered intravenously on days one, three, and five.

Three patients developed grade 1 fever and one patient developed grade 3 fever, all possibly related to aNK infusions. One patient developed grade 4 hypoglycemia, considered related to aNK. 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.

One patient had a mixed response, five patients had stable disease, and six patients had progressive disease. All responses were transient in this heavily pretreated population. A single patient with renal cell carcinoma had a mixed response (progression in the mediastinum and reduction in lung masses) at four weeks post infusion. One patient with melanoma had a response of stable disease but had a minor response in a target lesion in the upper neck that was documented at two weeks post infusion.

Hematologic Malignancies (Investigator Sponsored)

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 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 1×10^9 cells/m^2, 3×10^9 cells/m^2, and 5×10^9 cells/m^2 administered intravenously on days one, three, and five of each cycle of treatment. Patients could receive up to six cycles, administered monthly.

A total of 12 patients were enrolled in the study. 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 anti-HLA antibodies, typically after the second cycle of aNK. 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 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, and this patient remains in remission more than ten years after aNK cell 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 DLBCL also showed a transient clinical improvement that was followed by progressive disease.

Acute Myeloid Leukemia: QUILT 3.018 (NantKwest Sponsored)

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 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: 1×10^9 cells/m^2 and 3×10^9 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 reduction of leukemia blasts were eligible to receive additional aNK infusions.

Seven patients were enrolled in the study and received treatment with aNK. None of the seven patients who received aNK cells 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 required hospitalization. These known aNK-related effects were reversible with supportive care. Hospitalizations that occurred during the observation period that were not related to aNK cell infusions were for line-related bacteremia, neutropenic fever, red blood cell and platelet transfusion, and pneumonia.

Six patients were evaluable for response. None of the patients achieved complete remission or partial response. One patient had reduction of the percentage of blasts after a course of therapy, and two patients had stable percentage of blasts.

Our Clinical Pipeline

haNK Product Candidate

Overview

Our haNK cell therapeutic is our molecularly engineered aNK cell platform which incorporates both the expression of (1) a natural, high-affinity antibody engager, Fc RIIIa/CD16 receptor, that binds to therapeutically administered cancer-targeting antibodies, resulting in destruction of the cancer targets through a mechanism widely referred to as ADCC, and (2) 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 our high affinity CD16 receptors are cleaved during ADCC-mediated killing of target cancer cells, thereby enabling our haNK cells 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, CD16 receptor expression rebounds and recovers rapidly in haNK cells after attacking its target when compared to other types of NK cells. This unique feature

distinguishes our haNK cell product as the true serial killer.

Our haNK cells also retain their innate killing mechanisms such as NKG2D receptors, 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 antibodies led to significantly enhanced tumor cell killing when compared to the use of the antibody as a single agent, thereby providing strong scientific support for this novel combination approach.

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 and in certain instances, 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. In the Delfia ADCC assay system it was determined that the concentration of Herceptin that gives half-maximum response (EC50) is 48% higher in the absence of haNK cells, thereby demonstrating how haNK assists Herceptin in achieving its peak killing capacity.

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

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.

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Addition of 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.

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

In the first graph above, 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.

In the second graph, 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.

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 either agent was alone.

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).

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).

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 exogenous antibody therapy than patients who were carriers of a 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.

Data from three clinical trials demonstrating this point are shown below. The rationale therefore is for combining haNK with Rituxan, Herceptin and Erbitux in patients with low affinity CD16 alleles (158F carriers or 158F/F or 158V/F) that it should enhance the killing effect of these antibodies and achieve the results for patients with 158V/V alleles.

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 Study

In 2018, we conducted a large part of our phase I first-in-human, open-label study to evaluate safety and preliminary activity and determine the maximum tolerated or feasible dose and the highest dose with acceptable toxicity for infusion in up to 16 subjects with metastatic or locally advanced solid tumors, QUILT 3.028. 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 efficacy. Formal assessment of the safety of haNK is in process by our Safety Review Committee. A preliminary look at the first five patients to receive repeat haNK infusions reported 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. As of the date of this filing, efficacy data is pending.

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 dendritic cell, T cell, and NK cell therapies, by testing novel combinations of vaccines, cell-based immunotherapy, metronomic chemotherapy, low dose radiotherapy and immunomodulators, including checkpoint inhibitors, in patients who have undergone next generation whole genome, transcriptome and quantitative proteomic analysis, with the goal of achieving durable, long-lasting remission for patients with cancer.

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 several successful IND submissions to the FDA for our phase Ib/II haNK combination trials, which we designated as NCV trials.

Building Towards Our First NCV Combination Trial

After demonstrating phase I safety and activity of aNK monotherapy in both single and repeat dosing, we evaluated haNK monotherapy in a similar fashion in our QUILT 3.028 study, where we studied haNK for infusion in subjects with metastatic or locally advanced solid tumors. We next demonstrated safety of the combination of aNK and NCV in pancreatic cancer patients in our QUILT 3.039 study. This was followed by the introduction of haNK to the NCV combination in our QUILT 3.060 study for patients with pancreatic cancer who have progressed on or after standard-of-care therapy. Lastly, 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. Should the data be supportive, upon completion of our QUILT 3.070 safety and activity study, we may have an opportunity to transition to a registration trial that would include a standard-of-care comparator arm.

Additionally, four phase Ib trials investigating haNK in combination with metronomic chemotherapy, an IL 15 superagonist, a checkpoint inhibitor, cancer vaccines, and stereotactic body radiation therapy in various solid tumor models including QUILT 3.067, QUILT 3.071, QUILT 3.080 and QUILT 3.090 have patients currently in active follow-up. Collectively referred to as the NCV studies, the primary endpoint is to determine safety of the combination treatment and, if safe, a phase II extension with a primary endpoint to determine objective response rate, is planned. By year-end 2018, over 250 doses of haNK (2×10^9 cells per dose) have been administered to subjects with squamous cell carcinomas, pancreatic cancer, triple-negative breast cancer and colorectal cancer. 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.

Throughout 2018, we initiated a total of seven NCV studies and have since safely dosed patients. Eligible patients generally include those who have recurrent or metastatic disease and have failed standard-of-care therapy. Cancer types addressed in studies opened in 2018 include triple negative breast, colorectal, pancreatic, and squamous cell carcinoma.

The following is a list of the phase Ib studies referenced above, that have patients in active follow-up:

The QUILT 3.067 Study. Nant Triple Negative Breast Cancer Vaccine: Molecularly informed integrated immunotherapy combining haNK cell therapy with adaptive T cell therapy in subjects with triple negative breast cancer who have progressed on or after standard-of-care therapy.

The QUILT 3.071 Study. Phase Ib/II trial of the Nant Colorectal Cancer Vaccine vs Regorafenib in subjects with metastatic colorectal cancer who have been previously treated with standard-of-care therapy.

The QUILT 3.080 Study. Phase Ib/II trial of the Nant Pancreatic Cancer Vaccine as treatment for subjects with pancreatic cancer who have progressed on or after standard-of-care therapy.

The QUILT 3.090 Study. Nant Squamous Cell Carcinoma Vaccine: Molecularly informed integrated immunotherapy combining innate haNK cell therapy with adaptive T cell therapy in subjects with squamous cell carcinoma who have progressed on or after platinum-based chemotherapy and PD 1/PD L1 therapy.

While this first generation of NCV studies demonstrated the initial safety of our approach and core strategies, we have now fully enrolled all intended patients for these phase Ib studies in early 2019. We expect to conclude treatment of these patients, analyze data and plan pivotal studies based on these results in select indications.

Quilt 3.063: Phase II Merkel Cell Carcinoma Trial Deploying Novel Triple Combination of "off-the-shelf" haNK Cell Therapy with Superagonist IL 15 Cytokine Therapy and PD L1 Checkpoint Inhibitor Therapy

In addition to the aforementioned NCV studies, we have opened a chemotherapy-free, pivotally-designed immunotherapy trial which builds upon our earlier phase II study that utilized our proprietary, "off-the-shelf" aNK cell therapy and N 803, which resulted in an objective response in three of seven patients. This new trial will evaluate a combination therapy using our "off-the-shelf" haNK cells as the backbone of the regimen, to which we will add N 803 and avelumab in subjects with Merkel cell carcinoma that have progressed on or after treatment with a checkpoint inhibitor. The combination of these three agents 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 NK 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.

We will determine the safety and efficacy of the triple combination treatment and objective response rate using response evaluation criteria in solid tumors version 1.1 based on blinded independent central review. We will also be obtaining progression-free survival, overall survival, disease-specific survival, duration of response, disease control rate, and quality of life by patient-reported outcomes. 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.

Merkel Cell Carcinoma. Merkel cell carcinoma is a rare and aggressive skin cancer that arises from uncontrolled growth of cells in the skin. Increasing in incidence, approximately 2,500 new cases are reported in the U.S. each year. Patients with metastatic or locally advanced Merkel cell carcinoma 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, Merkel cell carcinoma 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.

QUILT 3.063 will be one of our leading clinical development efforts in 2019, as we are currently engaged in study start-up activities at several clinical trial sites and plan to initially expand enrollment to approximately ten centers throughout the U.S. We believe that, if we are able to demonstrate a statistically measurable efficacy for Merkel cell carcinoma, we will be able to apply for marketing approval with the FDA.

Longer term, we plan to conduct a wide range of additional immunotherapy studies comprising haNK cell therapy in combination with commercially approved antibodies. Based on the preclinical and, eventually, clinical data generated through these studies, we believe we will be able to select additional promising pairings of our haNK product candidate with commercial antibody products for use as the core components in each targeted therapy regimen we develop.

t haNK Programs

Novel, First-in-Class PD L1.t haNK Product Candidate.

Introduction. PD L1.t haNK is a human, allogeneic, stable clonal NK cell line generated from our parental clinical-grade aNK master cell bank. By combining the potent cell killing mechanism mediated through PD L1 CAR targeting with the well-known and potent FcgRIIIa/CD16 mediated ADCC killing mechanism, when used in conjunction with therapeutic IgG1 monoclonal antibodies, we believe that such dual expression would not only be stable, but that each component would also contribute synergistically to constitute a highly potent and selectively active antitumor agent. Our PD L1.t haNK product stably expresses three primary proteins: (1) a human PD L1–targeted CAR; (2) the high-affinity variant of the human IgG1 Fc receptor, Fc RIIIa/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.

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 and in vivo activity against PD L1–expressing tumors via CAR-mediated cytotoxicity. Moreover, since PD L1.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 dual-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.

Pre-Clinical Experience. 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 a related CAR-expressing t haNK cell line, CD19.t haNK, following repeated administration in the presence of CD19 expressing tumors. CD19.t haNK cells were detected at very low frequency in the liver and lungs of CD19 tumor-bearing mice six-hours after dosing and were completely undetectable 48-hours after dosing. This study also indicated that the presence of the CD19-targeted CAR construct does not affect the biodistribution pattern of the CD19.t haNK cells. Likewise, the presence of a PD L1–targeted CAR is not expected to affect the biodistribution of the cells, and the cells are expected to circulate through the blood with accumulation likely 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.

As illustrated in the tables that follow, our clinical grade PD L1.t haNK cell product retains its CD16 expression and the innate killing, CAR mediated killing, and ADCC mediated killing mechanisms all remain fully intact after irradiation and thaw of our final dose form.

Development Plan. In 2019, we intend to open our first clinical trial for our PD L1.t haNK product candidate. We anticipate that this study will be an open label phase I study of PD L1.t haNK in subjects with locally advanced or metastatic relapsed/refractory solid cancers. 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 non-small cell lung cancer.

Our initial phase I, first-in-human, open-label study will evaluate safety and preliminary efficacy and determine the maximum tolerated or feasible dose and the highest dose with acceptable toxicity for infusion in subjects in subsequent trials. 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.

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 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.

CD19.t haNK Product Candidate.

Introduction. CD19.t haNK is a human, allogeneic, stable clonal NK cell line generated from our parental clinical-grade aNK master cell bank. By combining the potent cell killing mechanism mediated through CD19 CAR targeting the B-cell marker CD19 with the well-known and potent Fc RIIIa/CD16 mediated ADCC killing mechanism, when used in conjunction with therapeutic IgG1-type monoclonal antibodies, we believe that such a dual expression would not only be stable, but that each component would also contribute synergistically to constitute a highly potent and selectively active antitumor agent. Our CD19.t-haNK product stably expresses three primary proteins: (1) a CD19–targeted CAR; (2) the high-affinity variant of the human IgG1 Fc receptor, Fc RIIIa/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.

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-mediated 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 t haNK cells against cancer cell lines utilizing CAR, innate and ADCC mechanisms are illustrated in the following slides.

Pre-Clinical Experience. 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.

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 mediated 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. In 2019, we intend to open our first clinical trial for our CD19.t haNK product candidate. We anticipate that this study will be an open-label phase I study of CD19.t haNK in subjects with DLBCL who have received two or more lines of therapy and are ineligible for transplant or CAR T cell therapy. We will evaluate safety, preliminary efficacy and determine the maximum tolerated or feasible dose and the highest dose with acceptable toxicity for infusion in subjects in subsequent trials. 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.

Assuming the successful completion of the clinical trial, we believe we will have characterized the pharmacokinetic and pharmacologic profiles for CD19.t haNK, obtained preliminary estimates of efficacy 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.

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 HER2, EGFR and BCMA t haNK programs, may be rapidly moved into first-in-human trials followed by disease and molecular marker specific studies.

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

Manufacturing has continued to be one of our fastest growing functions in 2018. 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 and releasing frozen haNK since the fourth quarter of 2017. Shelf-life stability for frozen haNK continues to be extended, enabling the accumulation of product inventories for potential immediate on-demand availability. As a result, clinical trial sites will no longer be required to conduct final product formulation and release testing procedures in a special clean room prior to administration. Instead, clinical sites simply need to thaw the frozen product in a warming bath and infuse. These simplified clinical site requirements for product administration potentially expands patient accessibility well beyond select certified hospital centers and deep into the community at outpatient group practices and 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 cell therapies quickly. In 2018, we developed key capabilities for the successful cryopreservation and recovery of our cells, that we believe enables simpler and more cost effective storage and shipment of our cell therapies to patients in clinics that are located at a distance from our manufacturing site.

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 scale. These capabilities will help 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 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, 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 intermittent harvesting 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 scale our operations to meet the anticipated commercial demand for our therapeutic products upon achieving regulatory approvals. The development of this capability has been key to ensure not just sufficient supply for our current and planned clinical trials 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 GMP facility for the manufacture of all our cell therapeutics. In order to ensure uninterrupted clinical supply, we implemented a dual-stage strategy. In the initial stage, we established a pilot GMP manufacturing facility at our Culver City, California, site and for the second stage we simultaneously built out an approximately 24,250 square foot commercial GMP facility in El Segundo, California. We completed the El Segundo, California, facility buildout in May 2018 and subsequently outfitted and prepared the facility for commercial scale manufacturing, and we expect to initiate clinical production at this facility in early 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 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 GMP 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.

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 and time.

Looking forward, we are preparing to implement our latest third-generation bioreactor technology in 2019, which was developed at our San Diego, California, process development facility in 2018. This will once again improve our economies of scale, as demand for clinical drug product increases. We believe large capacity bioreactors will allow us to scale 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, we developed manufacturing processes for our two lead products from our t haNK platform, PD L1.t haNK and CD19.t haNK, at our approximately 44,700 square foot San Diego process development facility. 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 production challenges unique to large scale NK cell production. This places NantKwest at a unique competitive advantage as a leader in commercial scale manufacturing of NK cell products.

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 NK, T , and dendritic cells. Competitors focused on CAR T related treatment approaches include AbbVie Inc., Intrexon Corporation, Allogene Therapeutics, Inc., 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, Celgene Corporation, 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 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., and Takara Bio, Inc. Competitor companies focused on dendritic cell based approaches include Argos Therapeutics, Inc., Biovest International, Inc., ImmunoCellular Therapeutics, Ltd., Immune Design, Inc., Inovio Pharmaceuticals, Inc., Intrexon Corporation, Medigene AG, and Northwest Biotherapeutics, Inc. Competitor companies focused on NK cell based approaches include CytoSen Therapeutics, Inc., Dragonfly Therapeutics, Inc., Fate Therapeutics, Inc., Gamida Cell, Ltd., Nkarta Therapeutics, Inc., and Ziopharm Oncology, Inc. Large molecule focused immunotherapy competitors include Cytomx Therapeutics, Inc., Innate Pharma SA, and Sorrento Therapeutics, Inc. Other potential immunotherapy competitors include Glycostem Therapeutics BV 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 early-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 NK 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 NK cell-based immunotherapy product candidates, including related manufacturing processes and technology. As of December 31, 2018, 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. 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;
- Treating Viral Hemorrhagic Fever with 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 will expire at various dates through 2025. If patents are issued on our pending patent applications, the resulting patents are projected to expire at various dates through 2038. 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, 2018, our registered trademark portfolio contained 15 registered trademarks in the U.S., 32 registered trademarks in foreign jurisdictions (seven of which are Madrid Protocol trademarks), and ten pending trademark applications in foreign jurisdictions. 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

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, formerly known as Altor BioScience Corporation. Altor is a related party, as it is a wholly owned subsidiary of NantCell, which is an affiliate of NantWorks. Under the Co-Development Agreement, we agreed with Altor to exclusively collaborate on the development of therapeutic applications combining our proprietary natural killer 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 all 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 will own 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 in several phase Ib/II trials.

Licenses

Viracta. 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 natural killer cell therapies. Our Chairman and CEO is also the Vice Chairman of Viracta. 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 renal cancer, or for the diagnosis or treatment of non-melanoma and non-renal cancer. In consideration for the license, we are obligated to pay to Rush single-digit royalties on sales of licensed products with a minimum royalty payment of $25,000 per year, as well as non-material milestone 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 has a term of 12 years from 2006, the year in which royalty payments were first made, and includes customary termination rights for both parties. Beginning in 2019, 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

Sorrento Therapeutics, Inc. In December 2014, we entered into a Joint Development and License Agreement with Sorrento Therapeutics, Inc., or Sorrento. The agreement expired in December 2017. Since no joint product candidates were identified during the exclusive term, Sorrento has no rights to use the Company’s NK cells or other technologies or intellectual property rights or to begin related research, development or commercialization activities and the Company is free to pursue, and is actively pursuing, research, development and commercialization activities with antibodies that may bind to various targets.

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.

Chemotherapeutisches Forschungsinstitut Georg-Speyer-Haus, or GSH, and DRK-Blutspendedienst Baden-Wurttemberg-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. In October 2018, we terminated this agreement in accordance with the terms of the agreement largely due to the rapid advancement and clinical readiness of our virus-free tri- and quad-cistronic t haNK platforms. These next-generation products avoid the safety concerns associated with the use of retro and lentiviral sequences, include high-affinity CD16 for enhanced antibody mediated killing, as well as IL 2 and other functional components which can potentially enhance clinical efficacy and reduce production costs. IND-enabling studies for our internally developed HER2NEU.t haNK product is currently in preparation and will follow the regulatory development path previously forged by our CD19 and PD L1.t haNK programs.

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, 2018, we had 161 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, 2018, we had an accumulated deficit of approximately $595.0 million. We incurred net losses of $96.2 million, $96.4 million, and $120.8 million for the years ended December 31, 2018, 2017 and 2016, 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;
- addressing any competing technological and industry developments;

- identifying, assessing, acquiring and/or developing new technology platforms and product candidates across numerous therapeutic areas;
- obtaining regulatory approvals and marketing authorizations for product candidates;
- launching and commercializing any approved products, either directly or with a collaborator or distributor;
- obtaining market acceptance of and acceptable reimbursement for any approved products;
- completing collaborations, licenses and other strategic transactions on favorable terms, if at all;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; 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, 2018, we had cash and cash equivalents of $16.8 million and marketable debt securities of $63.0 million. We are using and expect to continue to use the net proceeds from our initial public offering, or IPO, and the concurrent private placement 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 Viracta and Altor;

- 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.

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We are involved in pending securities litigation and an adverse resolution of such litigation may adversely affect our business, financial condition, results of operations and cash flows.

Following our announcement that we have restated our interim financial statements for the quarters ended June 30, 2015 and September 30, 2015 to address errors related to certain stock-based awards to our Chairman and CEO and build-to-suit lease accounting related to one of our research and development and cGMP facilities, we became the subject of a lawsuit alleging securities law violations. This type of litigation can be expensive and disruptive to normal business operations, and the outcome can be difficult to predict regardless of the facts involved. An unfavorable outcome with respect to this type of lawsuit could have a material adverse effect on our business, financial condition, results of operations or cash flows. For additional information regarding this and other lawsuits in which we are involved, see Part I, Item 3, “Legal Proceedings” included in this Annual Report.

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 the early 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 mAbs 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 the net proceeds of our IPO and our existing cash and cash equivalents 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 NK, T , and dendritic cells. Competitors focused on CAR T related treatment approaches include AbbVie Inc., Intrexon Corporation, Allogene Therapeutics, Inc., 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, Celgene Corporation, 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 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., and Takara Bio, Inc. Competitor companies focused on dendritic cell based approaches include Argos Therapeutics, Inc., Biovest International, Inc., ImmunoCellular Therapeutics, Ltd., Immune Design, Inc., Inovio Pharmaceuticals, Inc., Intrexon Corporation, Medigene AG, and Northwest Biotherapeutics, Inc. Competitor companies focused on NK cell based approaches include CytoSen Therapeutics, Inc., Dragonfly Therapeutics, Inc., Fate Therapeutics, Inc., Gamida Cell, Ltd., Nkarta Therapeutics, Inc., and Ziopharm Oncology, Inc. Large molecule focused immunotherapy competitors include Cytomx Therapeutics, Inc., Innate Pharma SA, and Sorrento Therapeutics, Inc. Other potential immunotherapy competitors include Glycostem Therapeutics BV 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 early-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.

Our Joint Development and License Agreement with Sorrento Therapeutics, Inc., or Sorrento, expired in December 2017. During our exclusive term, no joint taNK product candidates were identified for development. Although we have been free to independently pursue HER2Neu, CSPG4, CD33, CD123, GD2 and other specified antibodies during the Sorrento exclusive term and are now free to independently pursue all antibodies, we are reliant on third parties 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.

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 and 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 clinical investigators observe clinical trial protocol or continue to participate in a clinical trial;
- 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.

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; 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 on third parties to conduct many of our preclinical studies and clinical trials. Any failure by a third 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. 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 and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs 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 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, 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 an entity controlled by 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 and 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 could harm our business.

If we lose members of our senior management, 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 will primarily focus 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 NantWorks, a collection of multiple companies in the healthcare and technology space, which he founded in 2011. 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, 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 vest upon the achievement of certain performance milestones to Dr. Soon-Shiong. These performance warrants provided to Dr. Soon-Shiong have fully vested. 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 NantOmics, LLC ("NantOmics"), NanoCav, LLC ("NanoCav"), NantCell, Inc. ("NantCell"), NantBio, Inc. ("NantBio"), VivaBioCell S.p.A. ("VivaBioCell"), NantHealth Labs, Inc. ("NantHealth Labs"), which was formally known as Liquid Genomics, Inc., and Altor BioScience, LLC ("Altor") to 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. As a result, they or 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 the other therapeutic fields in which we may target in the future). In addition, we are 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 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.

In January 2018, we entered into a sublease agreement with NantBio related to our San Diego, California, facility. This agreement for space and services was effective as of December 1, 2017 for a term of 24 months. Our Chairman and CEO has a controlling interest in NantBio. As a result, 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. 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. Given that we changed our corporate name to NantKwest in 2015, this is particularly true of the various NantWorks companies.

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, 2018, we had 161 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 will 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 small-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. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 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; 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 natural killer 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 or other business interruption. 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.

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;

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- 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 NK 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:

- 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;

- a decision by us or regulators to suspend or terminate our clinical trials if the participating patients 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 investigators 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 re-approvals. This may cause our reputation in the market place to suffer or subject us to lawsuits, including class action suits.

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 products 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.

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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.

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 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 EU 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. has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings 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.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It remains unclear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA 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.

An important change introduced by the AIA is that, as of March 16, 2013, the U.S. transitioned to a "first-inventor-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 in the USPTO after that date but 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. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing 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.

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. Recently, the AIA introduced new 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 terminates on the 12th anniversary of our first payment of royalties, at which point the license is deemed perpetual, irrevocable, fully paid royalty-free, exclusive license, and may be terminated earlier by either party for material breach.

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 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. 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.

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. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former 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.

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. 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 laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. 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. 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.

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, 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.

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, 2018, our Chairman and CEO, Patrick Soon-Shiong, M.D., and entities affiliated with him, collectively own approximately 59.2% of the outstanding shares of our common stock. Additionally, Dr. Soon-Shiong holds options and a warrant to purchase an aggregate of 20.3 million additional shares of our common stock, which would give him and his affiliates ownership of approximately 67.5% of our outstanding shares of common stock if they were fully vested and 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; 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, such as the securities litigation described in Note 8 – Commitments and Contingencies – Securities Litigation of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report, 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 and the warrant held by our Chairman and CEO, 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 particular, the options and warrant to purchase common stock held by our Chairman and CEO at December 31, 2018, may entitle him to acquire up to an aggregate of 20.3 million additional shares of our common stock, or approximately 25.7% of our outstanding common stock. Sales of stock by these stockholders 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, including shares issuable upon the exercise of outstanding options and warrants, 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, 2018, or for any other period. Accordingly, no such opinion was expressed.

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.

We have made restatements of our financial statements in the past, and if this were to occur again, this may affect shareholder confidence in the Company's financial reporting in the future, which could in turn have a material adverse effect on our business and stock price.

Although we believe we have remediated the material weakness associated with any prior restatements of our financial statements, if any additional 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. We have elected not to have a nominating and corporate governance committee in reliance on the "controlled company" exemptions. As of December 31, 2018, the majority of the board of directors do not consist of independent directors. 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:

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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, 2018, we had U.S. federal, state and foreign NOLs of approximately $232.3 million, $200.3 million and $0.2 million, respectively, which begin to expire in various years starting with 2022, if not utilized. As of December 31, 2018, we also had federal and state research and development tax credit carryforwards of approximately $6.5 million and $4.0 million, respectively. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, 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 2018 regarding the limitation of net operating loss and research and development credit carryforwards. As a result of the analysis, we have derecognized 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, 2018.

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.

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. 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.

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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 59.2% of our common stock as of December 31, 2018) 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, in order of lease expiration, summarizes the facilities we lease as of December 31, 2018, including the locations and size of the facilities and their designated uses.

Principal Properties Leased:	Approximate Square Feet	Operation	Lease Expiration Dates
Woburn, Massachusetts	8,153	Laboratory - Research, Office	May 2020
Culver City, California*	9,500	Laboratory - Research & Manufacturing	December 2020
El Segundo, California*	24,250	Laboratory - Research & Manufacturing	July 2023
San Diego, California	44,681	Laboratory - Research, Office	July 2023
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 the facility we own as of December 31, 2018.

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

In August 2018, a related party assigned an agreement to us for the use of a third-party research facility in Torrance, California, which provides us with the exclusive right to use and access to a portion of the third party's laboratory and vivarium premises. The lease expires in June 2027.

In September 2017, we purchased a commercial building with approximately 36,434 square feet in El Segundo, California. We intend to use the building as a warehouse and distribution facility as it is adjacent to the El Segundo, California, research and manufacturing facility.

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 (cGMP) laboratory. 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 $72,385 with annual increases of 3% beginning in July 2017.

We leased a total of approximately 2,550 square feet of office space in Cardiff-by-the-Sea, California, for general office use, pursuant to an operating lease. We amended this lease to extend the term of the lease through August 31, 2018. Our total monthly lease payment was $13,199. In August 2017, we subleased these premises for the remainder of the lease term for the same payment. The lease expired in August 2018 and we vacated the premises.

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 term of the lease is 48 months commencing on April 29, 2016. In June 2016, the lease was amended to add 260 square feet, for a total of 8,153 square feet. The base rent, including the amendment, is $19,363 per month with a $1 per square foot annual increase on each anniversary date.

In November 2015, we entered into a facility license agreement with NantWorks, effective in May 2015, for approximately 9,500 square feet of office space in Culver City, California, which we converted to a research and development laboratory and a cGMP facility. The term of the license extends through December 2020. We have the option to extend the license through December 2023. The monthly rent is $47,000 with annual increases of three percent (3%) beginning in January 2017.

In July 2015, we entered into a lease agreement for approximately 3,067 square feet of office space in Cary, North Carolina. The term of the lease was for 26 months commencing on July 1, 2015. In 2017, the lease was extended to December 31, 2017. The lease expired in December 2017 and we vacated the premises.

We entered into a lease agreement in June 2015 for approximately 44,681 square feet of laboratory/office space located in San Diego, California. The permitted use is research and development laboratory, related office and other related uses. The term of the lease extends for seven years commencing on August 1, 2016 and requires us to pay base monthly rent of $178,724 per month, with three percent (3%) annual increases on each anniversary of the lease commencement date. In July 2015, we entered into a sublease agreement with Novartis Institute for Functional Genomics, Inc., the tenant through July 31, 2016, to sublease this facility prior to the lease commencement date. We are currently subleasing approximately 2,000 square feet of the premises to a related party.

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.

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. Except as noted below, we are not currently a party to any other 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.

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 have been consolidated. Plaintiffs assert 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 seek 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 is scheduled for April 29, 2019.

Under the terms of the settlement, which is subject to final approval by the court, we agreed to pay $12.0 million to the plaintiffs as full and complete settlement of the litigation. We are responsible for $1.2 million of the settlement amount, while the remaining $10.8 million is being 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.

Management intends to continue to vigorously defend these proceedings. If for some reason the settlement is not approved and we are ultimately found liable, the liability could have a material adverse effect on our consolidated financial statements for the period or periods in which it is incurred.

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. No dividends have been declared or paid.

Holders of Record

As of March 8, 2018, we had 31 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

No cash dividends were declared for our common stock during the fiscal year ended in 2018. 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

In November 2015, the board of directors approved a share repurchase program (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 the Company's 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 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. The Company has financed and expects to continue to finance the purchases with existing cash balances. The repurchased shares are formally retired through board approval. At December 31, 2018, $18.8 million remained authorized for repurchase under the Company's stock repurchase program.

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs (1)	Maximum approximate dollar value of shares that may yet be purchased under the plans or programs (1)
October 1 - October 31	—	$ —	—	$19.1 million
November 1 - November 30	138,349	$ 1.65	138,349	$18.8 million
December 1 - December 31	—	$ —	138,349	$18.8 million
Total	138,349	$ 1.65	138,349	

(1) All repurchases were made under the terms of the 2015 Share Repurchase Program approved by the Company's board of directors in November 2015. Since its inception, the Company has repurchased 5,929,903 shares of its common stock under this program for a total cost of approximately $31.2 million. At December 31, 2018, approximately $18.8 million remains authorized for repurchase under the 2015 Share Repurchase Program. The Company has incurred approximately $0.1 million of broker commissions on the repurchases to date.

Use of Proceeds

On July 27, 2015, our Registration Statement on Form S 1, as amended (Reg. No. 333 205124) was declared effective in connection with the IPO of our common stock, pursuant to which we sold 9,531,200 shares at a price to the public of $25.00 per share. The offering closed on July 31, 2015, as a result of which we received net proceeds of approximately $221.5 million after underwriting discounts and offering expenses. Merrill Lynch, Pierce, Fenner & Smith, Incorporated, Citigroup Global Markets Inc., Jefferies LLC and Piper Jaffray & Co. acted as joint book-running managers for the offering, and MLV & Co. LLC Inc. acted as co-manager. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates. In November 2015, the board of directors approved a share repurchase program allowing the Chief Executive Officer or Chief Financial Officer, 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. We may use the proceeds from the IPO to conduct such repurchases. Accordingly, our use of proceeds from the IPO is as follows:

- approximately $48.0 million to fund expenses in connection with our clinical trials related to our NK product platforms (i.e., aNK, haNK, taNK, and t hank), however, we expect that we will need to use additional proceeds to fund future trials related to our product candidates;
- approximately $123.1 million to fund our planned cGMP manufacturing facilities and processes and the hiring of additional personnel; and
- the remaining amounts for other research and development activities, working capital and general corporate purposes, including up to $50.0 million to repurchase our common stock (exclusive of any commissions, markups or expenses) from time to time, in the open market or in privately negotiated transactions.

We may also use a portion of the net proceeds from the offering and our existing cash to in-license, acquire or invest in complementary business, technologies, products or assets. However, we have no current plans, commitments or obligations to do so.

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, 2018. 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, 2018, 2017 and 2016 and the selected consolidated balance sheet data as of December 31, 2018 and 2017 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, 2015 and 2014 and the selected consolidated balance sheet data as of December 31, 2016, 2015 and 2014 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)				
	2018	2017	2016	2015	2014
Revenue	$47	$45	$44	$236	$641
Operating expenses:					
Research and development (including amounts to related parties)	55,718	42,044	29,153	11,434	1,595
Selling, general and administrative (including amounts to related parties)	42,718	57,121	95,391	227,678	4,621
Total operating expenses	98,436	99,165	124,544	239,112	6,216
Loss from operations	(98,389)	(99,120)	(124,500)	(238,876)	(5,575)
Other income (expense):					
Investment income, net	1,857	2,665	3,097	2,988	20
Change in fair value of warrant liability	—	—	—	(1,366)	(158)
Interest expense (including amounts to related parties)	(433)	(618)	(66)	—	(471)
Other income, net (including amounts to related parties)	236	157	88	77	—
Total other income (expense)	1,660	2,204	3,119	1,699	(609)
Loss before income taxes	(96,729)	(96,916)	(121,381)	(237,177)	(6,184)
Income tax benefit (expense), net	503	493	572	301	(1)
Net loss	$(96,226)	$(96,423)	$(120,809)	$(236,876)	$(6,185)
Net loss per share:					
Basic and diluted	$(1.22)	$(1.20)	$(1.47)	$(3.31)	$(0.75)
Weighted average number of shares during the period:					
Basic and diluted	79,132,220	80,583,910	81,979,005	71,519,609	8,246,028

	As of December 31, (In thousands)				
	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	$16,821	$23,872	$8,083	$175,908	$59,104
Working capital	61,512	111,590	192,592	291,392	57,489
Total assets	181,950	250,440	317,496	366,849	59,996
Total liabilities	35,944	31,596	24,078	10,854	2,405
Total stockholders' equity	146,006	218,844	293,418	355,995	57,591

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

We are a pioneering clinical-stage immunotherapy company focused on harnessing the power of the innate immune system by using the natural killer cell 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 activated natural killer, or aNK, cell platform, as well as clinical testing and scale manufacturing of our leading product candidates. Natural killer, or 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 activation by other support molecules, typically required to activate adaptive immune cells such as T cells.

We hold the exclusive right to commercialize aNK cells, a commercially viable natural killer cell line, and a variety of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States (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 as a therapeutic to treat a spectrum of clinical conditions.

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

We believe that our proprietary NK cell line, coupled with our integrated discovery ecosystem, positions us to implement precision cancer medicine by leveraging 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 cells such as our activated NK cells.

Our Approach

Multiple Modes of 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 (1) Innate Killing, whereby all of our NK platforms recognize the abnormal proteins typically found on stressed cells, which upon binding, release toxic granules to immediately kill their targets; (2) Antibody Mediated Killing with our haNK and t-haNK platforms, which are NK 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 (3) Chimeric Antigen Receptor, or CAR, Directed Killing with our taNK and t-haNK platforms, which are NK cells engineered to express CARs that target tumor-specific proteins commonly found on the surface of cancer cells and, upon binding, induce cell death through the release of toxic granules directly into its 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 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, focusing on solid tumors and hematological malignancies. We eventually plan to advance therapies for 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 NK cells, our NK cells do not express the key inhibitory receptors that diseased cells often exploit to turn off the killing function of NK cells and escape elimination. We have developed a unique aNK cell, which omits many 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 (a) 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 (b) 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 its target by delivering a larger payload of lytic enzymes and cytokines responsible for both direct and indirect killing when compared to other NK cells isolated from healthy donors. We believe 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 clinical trials, we have further modified this 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 mediated antigen targeted killing, the t-haNK platform.

Antibody Mediated Killing - the haNK Platform. We have genetically engineered our aNK cells 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 NK 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 NK 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 NK 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 use in several phase Ib/II clinical trials.

CAR Mediated 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: (1) checkpoint ligands, such as PD-L1 and

B7 H4; (2) widely-established tumor proteins such as HER2 and CD19; (3) novel surface antigens associated with cancer stem cells such as CD123 and IGF R1; and (4) newly discovered proteins from individual patient tumor samples, known as neoepitopes. 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 Mediated and Antibody Mediated Killing - the t haNK Platform. Our newest 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 mediated 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 lead t haNK product candidates, PD L1.t haNK and CD19.t haNK, both currently at the IND filing stage, a pipeline of prominent CARs for t haNK are advancing through human enabling studies, including BCMA, HER2 and EGFR, 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 cells as the backbone of the therapy. 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 IL 15, 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 in comparison with current standards of care. We believe ultimately that employing our NK cell therapy in the context of NCV would 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: (1) 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; (2) 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; (3) 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; (4) 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 (5) 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, 2018, we had an accumulated deficit of approximately $595.0 million. Our net losses were approximately $96.2 million, $96.4 million and $120.8 million for the years ended December 31, 2018, 2017 and

2016, 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, 2018, we had 161 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.

IND Approval

A phase Ib/II Investigational New Drug, or IND, application for advanced cancers, that incorporates a novel cryopreserved haNK product as the backbone of a multi-agent tumor and immune conditioning regimen known as the NCV regimen, received authorization from the FDA, in October 2017 to proceed. Since then, multiple additional INDs in various cancer indications using cryopreserved haNK product as the backbone of the NCV regimen received authorization from the FDA.

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. Our Chairman and CEO is also the Vice Chairman of Viracta. 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. As of December 31, 2018 and 2017, $8.5 million was recorded as an investment in equity securities on the consolidated balance sheets. 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.

In June 2018, Viracta executed a 2018 Note and Warrant Purchase Agreement with existing and new investors. 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 is convertible into Preferred Stock, and a warrant to purchase Viracta's common shares. The convertible note accrues interest at 8% and has a one-year maturity date.

In September 2018, Viracta executed the milestone closing under the 2018 Note and Warrant Purchase Agreement, at which point we purchased a second convertible note, for $0.4 million, which is also convertible into Preferred Stock under certain circumstances, and a warrant to purchase Viracta's common shares. The convertible note accrues interest at 8% and has a nine-month maturity date.

We classified the convertible notes as debt securities, held-to-maturity, on the consolidated balance sheets.

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. The 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 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.

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, formally known as Altor BioScience Corporation. Altor is a related party, as it is a wholly owned subsidiary of NantCell. NantCell is an affiliate of NantWorks. Under the Co-Development Agreement, we agreed with Altor to exclusively collaborate on the development of therapeutic applications combining our proprietary natural killer 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 will grant 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 shall be 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 all 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 will own 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 dosed patients with N 803, an IL 15 superagonist, in several phase Ib/II trials during the years ended December 31, 2018 and 2017. No charges for supplies by Altor have been incurred in association with the above trials during the years ended December 31, 2018, 2017 and 2016.

Sorrento Therapeutics. In December 2014, we entered into a Joint Development and License Agreement with Sorrento Therapeutics, Inc., or Sorrento. The agreement expired in December 2017. Since no joint product candidates were identified during the exclusive term, Sorrento has no rights to use our NK cells or other technologies or intellectual property rights or to begin related research, development or commercialization activities and we are free to pursue, and are actively pursuing, research, development and commercialization activities with antibodies that may bind to various targets.

Licensing Agreements

Viracta License Agreement

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 natural killer cell therapies. Our Chairman and CEO is also the Vice Chairman of Viracta. 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.

Chemotherapeutisches Forschungsinstitut Georg-Speyer-Haus, or GSH, and DRK-Blutspendedienst Baden-Wurttemberg-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. In October 2018, we terminated this agreement in accordance with the terms of the agreement, largely due to the rapid advancement and clinical readiness of our virus-free tri- and quad-cistronic t haNK platforms.

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 (formally known as Liquid Genomics, Inc.), 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 year ended December 31, 2018, $0.3 million has been recognized in research and development expense on the consolidated statements of operations.

John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine

In 2017 and 2018, we entered into multiple agreements with John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine, or CSSIM, in El Segundo, California, to conduct various clinical trials. CSSIM is a related party as it is owned by two of our officers and NantWorks provides administrative services to CSSIM. One of our officers is an investigator for the trials on behalf of CSSIM. During the years ended December 31, 2018 and 2017, expense of $2.7 million and $0.8 million, respectively, has been recognized in research and development expense on the consolidated statements of operations.

Tensorcom, LLC

In April 2017, we entered into a sublease agreement with Tensorcom, LLC, or Tensorcom, formerly known as Tensorcom, Inc., 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, we recognized $0.1 million and $0.2 million, respectively, in other income on the consolidated statements of operations

under the sublease agreement.

VivaBioCell S.p.A.

In February 2017, we entered into a research grant agreement with VivaBioCell S.p.A., or VBC, a subsidiary of NantCell, Inc., or NantCell. NantCell is an affiliate of NantWorks. VBC conducted research and development activities related to our NK cell lines using VBC's proprietary technology. We paid $0.6 million to VBC, which was recorded in prepaid expenses and other current assets on the consolidated balance sheets, and we benefited from the research and development activities over a one-year timeframe. For the years ended December 31, 2018 and 2017, $0.1 million and $0.6 million has been recognized, respectively, in research and development expense on the consolidated statements of operations.

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 additional information, see Note 8 – Commitments and Contingencies – Financing Lease Obligation – El Segundo of the "Notes to Consolidated Financial Statements" included in Part II, Item 8 of this Annual Report. For the years ended December 31, 2018, 2017 and 2016, we recorded rent expense of $0.2 million, $0.2 million and $0.1 million, respectively, which is reflected in research and development expense on the consolidated statements of operations.

Altor

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 NantCell, which is an affiliate of NantWorks. Through December 31, 2018, no charges for supplies by Altor have been incurred in association with the trials.

NantBio, Inc.

In August 2018, NantBio, Inc., or NantBio, a NantWorks company, 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. We recognized the upfront payments as other current and non-current assets on the consolidated balance sheets, and we are amortizing such upfront payments over the expected remaining lease term.

In January 2018, we entered into a laboratory services agreement with NantBio. The agreement, effective December 1, 2017, includes a sublease of approximately 1,965 square feet of laboratory and office space at our San Diego, California, research facility. The term of the sublease is 24 months, but can be terminated by either party with 30 days prior written notice. The sublease converts to a month-to-month lease after the initial term, not to exceed the expiration of the lease agreement between us and the landlord. The monthly sublease and service fee of $10,000 is subject to an annual 3% increase on the agreement anniversary date. We recognized $0.1 million and $10,000, respectively, in other income on the consolidated statements of operations for the years ended December 31, 2018 and 2017.

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 NK cells and monoclonal antibodies in monotherapy and in combination immunotherapies. We benefited from the preclinical and clinical research conducted during the first three years under this agreement and provided the first, second and third year of funding under the five-year agreement. In each of April 2016, April 2017, and August 2018, we paid $0.6 million to the National Cancer Institute as a prepayment for services under the agreement. We recognize research and development expense ratably over a 12-month period and recorded $0.6 million, $0.6 million and $0.5 million, respectively, for the years ended December 31, 2018, 2017 and 2016.

NantWorks

In May 2018, we entered into an assignment agreement with NantWorks and a third-party construction firm. In conjunction 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 represents unutilized deposits that we had previously made with the construction company, which NantWorks can now utilize in applying such funds to future planned construction projects.

In November 2015, we entered into a shared services agreement with NantWorks under which NantWorks provides corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy, and other support services to us, effective August 1, 2015. 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. We will continue to be charged for the services at cost plus reasonable allocations for indirect costs that relate to the employees providing the services and will charge out our services in the same manner. For the years ended December 31, 2018, 2017 and 2016, we recorded $2.8 million, $3.6 million and $3.9 million, respectively, to selling, general and administrative expense, and $3.3 million, $3.2 million and $2.1 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. For the years ended December 31, 2018, 2017 and 2016, we recorded expense reimbursements of $0.6 million, $0.4 million and $0.1 million, respectively, to selling, general and administrative expense, and $2.6 million, $1.0 million and $0.2 million, respectively, to research and development expense. All amounts are recorded on the consolidated statement of operations under this arrangement.

In November 2015, we entered into a facility license agreement with NantWorks, 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. We have the option to extend the license through December 2023. The monthly rent is $47,000 with annual increases of 3% beginning in January 2017. For each of the years ended December 31, 2018, 2017 and 2016, we recorded rent expense of $0.2 million, 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 an affiliate of NantWorks, to 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 will own the data and results, as well as any other intellectual property it creates in performing these services for us. 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 by us or NantOmics. Either company has the right to terminate the agreement for convenience on 90 days prior written notice, or in the event there is a material uncured breach of the agreement by the other party. For the years ended December 31, 2018, 2017 and 2016, under this arrangement we recorded operating expense of $0.1 million, $0.1 million and $0.2 million, respectively, to research and development on the consolidated statements of operations.

NanoCav, LLC

In June 2015, we entered into an agreement with NanoCav, LLC, or NanoCav, a related party, pursuant to which we obtained access to NanoCav's virus-free cell transfection technologies on a non-exclusive basis. Under the agreement, NanoCav will conduct certain, mutually agreed feasibility studies, on a fee for service basis, to evaluate the use of its

cell transfection technologies with our aNK platform products and non-proprietary NK cells. We may elect to obtain NanoCav's cell transfection equipment, and rights to its associated protocols and other intellectual property, for use only for pre-clinical research, or also for use in clinical and commercial applications. If we choose to qualify the equipment and technologies for cGMP use with our products, we are obligated to pay NanoCav an annual license fee, which is determined based upon whether we elect to use NanoCav's technologies for pre-clinical purposes only, or also for clinical and commercial purposes. In addition, if we use the equipment for clinical and commercial purposes, we are obligated to pay an equipment fee on a cost-plus basis. We are also obligated to purchase any consumables we require to use with the NanoCav technologies from NanoCav, and to pay for those consumables on a cost-plus basis. In 2015, we made a feasibility study retainer payment of $45,000. 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 NanoCav and we may terminate if there is a material, uncured breach of the agreement by the other party. For the years ended December 31, 2018, 2017 and 2016, under this arrangement we recorded operating expense of $0, $0 and $0.1 million, respectively, to research and development on the consolidated statements of operations.

NantCell

In November 2018, we entered into an agreement with Etubics Corporation, or Etubics, a subsidiary of NantCell, which is an affiliate of NantWorks, pursuant to which 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 June 2015, we entered into a supply agreement with NantCell pursuant to which we have the right to purchase NantCell's proprietary bioreactors, made according to specifications mutually agreed to with NantCell. We also have the right to purchase reagents and consumables associated with such equipment from NantCell. 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.

During the years ended December 31, 2018 and 2017, we purchased bioreactors resulting in $1.1 million and $0.3 million in capitalized equipment, respectively, on the consolidated balance sheets. During the years ended December 31, 2018, 2017 and 2016, we recorded research and development expense of $0.1 million, $0.3 million and $0.2 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 an increased number of 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, 2018 as compared to the year ended December 31, 2017, we expect that our selling, general and administrative expenses during the year ended December 31, 2019, will remain relatively consistent with the previous year. 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, 2018, 2017 and 2016 (in thousands)

	For the Year Ended December 31,			Change	
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Revenue	$47	$45	$44	$2	$1
Operating expenses:					
Research and development (including amounts to related parties)	55,718	42,044	29,153	13,674	12,891
Selling, general and administrative (including amounts to related parties)	42,718	57,121	95,391	(14,403)	(38,270)
Total operating expenses	98,436	99,165	124,544	(729)	(25,379)
Loss from operations	(98,389)	(99,120)	(124,500)	731	25,380
Other income (expense):					
Investment income, net	1,857	2,665	3,097	(808)	(432)
Interest expense (including amounts to related parties)	(433)	(618)	(66)	185	(552)
Other income, net (including amounts to related parties)	236	157	88	79	69
Total other income	1,660	2,204	3,119	(544)	(915)
Loss before income taxes	(96,729)	(96,916)	(121,381)	187	24,465
Income tax benefit	503	493	572	10	(79)
Net loss	$(96,226)	$(96,423)	$(120,809)	$197	$24,386

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 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. We expect our research and development expenses to increase significantly for the foreseeable future as we advance an increasing number of our product candidates through clinical development and conduct our ongoing and planned clinical trials.

Research and development expense increased $12.9 million during the year ended December 31, 2017 as compared to the year ended December 31, 2016. The increase was primarily attributable to increases of $7.2 million for laboratory, pre-clinical and clinical trial costs driven by increased research and cGMP manufacturing activities, $5.3 million in compensation and related expenses driven by increased staff and fees for services rendered under our shared services agreement with NantWorks, and $3.2 million for laboratory and manufacturing facilities and depreciation expense, partially offset by decreases of $2.2 million for clinical and regulatory consultant costs due to bringing these functions in-house and $0.7 million in stock compensation expense, primarily related to forfeitures.

Selling, General and Administrative

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.

Selling, general and administrative expense decreased $38.3 million during the year ended December 31, 2017 as compared to the year ended December 31, 2016. The decrease was primarily attributable to a decrease of $36.1 million in stock compensation expense mainly driven by decreases of $18.9 million due to the timing of performance milestones being achieved by our Chairman and CEO, $10.3 million related to option awards that were fully vested in January and February 2017, $7.0 million related to initial public offering equity awards granted to our Chairman and CEO and our President and Chief Administrative Officer, or CAO, that were fully vested in July 2016, and $0.2 million for non-employee RSU terminations, partially offset by an increase of $0.4 million primarily driven by new grants in 2017.

In addition, selling, general and administrative expense decreased $1.9 million in professional and consulting fees for the ramp up in the first quarter of 2016 of accounting, tax, and Sarbanes-Oxley compliance related services in connection with operating as a public company and increased staff in relation to consultants and $0.6 million in contributions made, partially offset by an increase of $0.4 million in legal fees mainly due to shareholder litigation and USPTO appeal costs.

Other Income (Expense)

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.

Other income decreased by $0.9 million during the year ended December 31, 2017 as compared to the year ended December 31, 2016 due to $0.5 million in increased interest expense related to our capital lease and financing obligations and a $0.4 million decrease in investment income due to use of our investments for operations.

Income Tax Benefit

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

Income tax benefit decreased by $0.1 million during the year ended December 31, 2017 as compared to the year ended December 31, 2016. The decrease was primarily attributable to income tax benefits related to losses at our Korean subsidiary.

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.

As of December 31, 2018, we had cash and cash equivalents, and restricted cash of $17.0 million compared to $24.1 million as of December 31, 2017. The decrease was attributable to cash used in operating and financing activities of $63.4 million and $0.8 million, respectively, partially offset by net cash provided by investing activities of $57.1 million that was primarily driven by sales and maturities of marketable debt securities partially offset by the purchase of additional marketable debt securities driven by reinvestment of excess cash resources and purchases of property, plant and equipment.

Investments in marketable debt securities were $63.0 million as of December 31, 2018, of which $57.3 million were short-term investments as compared to $133.9 million as of December 31, 2017, of which $104.3 million were short-term investments.

Recent Equity Transactions

In November 2015, the board of directors approved a share repurchase program allowing our 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 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. During the year ended December 31, 2018, we repurchased 138,349 shares from a related party for approximately $0.2 million. All repurchases were made at the then current market price.

Cash Flows

The following table sets forth our primary sources and uses of cash for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
Cash provided by (used in):			
Operating activities	$(63,381)	$(48,780)	$(38,593)
Investing activities	57,101	99,552	(113,672)
Financing activities	(771)	(34,983)	(15,560)
Net increase (decrease) in cash, cash equivalents and restricted cash	$(7,051)	$15,789	$(167,825)

Operating Activities

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.

For the year ended December 31, 2016, our net cash used in operating activities of $38.6 million consisted of a net loss of $120.8 million, primarily attributable to $73.9 million in stock compensation expense as well as research and development and selling, general and administrative expenses, partially offset by $78.4 million in adjustments for non-cash items and $3.8 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of the $73.9 million in stock-based compensation expense, $3.6 million in depreciation and amortization and $2.2 million in amortization of premiums on marketable debt securities, reduced by $0.6 million in non-cash interest related to our investment in marketable debt securities, $0.6 million of deferred income tax benefit, and $0.1 million in gain on the sale of marketable debt securities. Changes in working capital consisted primarily of increases in accrued expenses and other liabilities of $2.1 million, $1.8 million of deferred rent, accounts payable of $0.9 million, due to related parties of $0.4 million, and other assets of $0.2 million, partially offset by an increase of $1.5 million in prepaid expenses and other current assets.

Investing Activities

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.

For the year ended December 31, 2016, net cash used in investing activities was $113.7 million, which was primarily attributable to $273.0 million in purchases of marketable debt securities as we invested the remainder of our excess cash and reinvested proceeds throughout 2016 as securities matured that were not needed for operating activities, and $6.6 million in purchases of property and equipment mainly related to our laboratory and cGMP build out in Culver City, California, and equipment purchases for the San Diego, California facility, partially offset by $165.9 million in sales or maturities of marketable debt securities.

Financing Activities

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 restricted stock units, or 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.

For the year ended December 31, 2016, net cash used in financing activities was $15.6 million, which consisted of $15.8 million used for stock repurchases and $1.1 million in net share settlement of option exercises and vesting of RSUs for payment of employee payroll taxes, partially offset by $1.4 million in proceeds from the exercise of stock options and warrants.

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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 Viracta and Altor;
- 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

Contingencies

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 have been consolidated. Plaintiffs assert 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 seek 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 is scheduled for April 29, 2019.

Under the terms of the settlement, which is subject to final approval by the court, we agreed to pay $12.0 million to the plaintiffs as full and complete settlement of the litigation. We are is responsible for $1.2 million of the settlement amount, which has been recognized in selling, general and administrative expense on the consolidated statements of operations, while the remaining $10.8 million is being 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.

Management intends to continue to vigorously defend these proceedings. If for some reason the settlement is not approved and we are ultimately found liable, the liability could have a material adverse effect on our consolidated financial statements for the period or periods in which it is incurred.

Contractual Obligations and Commitments

Our contractual obligations as of December 31, 2018 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					
Minimum lease obligations (1)	$17,193	$4,108	$7,491	$5,594	$ —
Supply agreements	141	141	—	—	—
Total contractual obligations	$17,334	$4,249	$7,491	$5,594	$ —

(1) Represents future minimum lease payments under all our leases as of December 31, 2018. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

Capital Lease

In April 2017, we entered into an agreement to purchase a commercial building with approximately 36,434 square feet, located in El Segundo, California. This facility is a warehouse and distribution facility and is adjacent to our El Segundo, California, research and manufacturing facility. Upon the execution of the purchase agreement, we made a deposit of $5.0 million to the escrow holder and entered into a lease agreement related to this facility commencing on May 1, 2017. There was no monthly base rent under the lease. The escrow closed in September 2017 and we paid the remaining purchase price, including closing costs, of $15.3 million and terminated the lease agreement.

We had a bargain purchase option to purchase the building upon termination of the escrow period and, initially, accounted for the lease as a capital lease. Upon purchase of the building in September 2017, which resulted in the termination of the capital lease, we accounted for the transaction as a single transaction and the carrying amount of the asset was adjusted for any differences between the carrying amount of the lease obligation and the initial carrying amount of the asset.

Financing Lease Obligations

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 current Good Manufacturing Practices, or cGMP, manufacturing facility. We were responsible for costs to build out the facility and incurred costs of approximately $30.4 million to complete the conversion. 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 November 2015, we entered into a facility license agreement with NantWorks, 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 manufacturing facility. We were responsible for the costs to build out the facility and incurred costs of approximately $3.5 million to complete the conversion. The term of the license extends through December 2020. We have the option to extend the license through December 2023. The monthly rent is $47,000 with annual increases of 3% beginning in January 2017.

Operating Leases

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. 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 March 2016, we entered into a lease agreement for approximately 7,893 square feet of laboratory and office space in Woburn, Massachusetts. The term of the lease is 48 months commencing on April 29, 2016. In June 2016, the lease was amended to add 260 square feet, for a total of 8,153 square feet. The base rent, including the amendment, is $19,000 per month with a $1 per square foot annual increase on each anniversary date.

In July 2015, we entered into a lease agreement for approximately 3,067 square feet of office space in Cary, North Carolina. The term of the lease was 26 months commencing on July 1, 2015. In 2017, the lease was extended to December 31, 2017. The lease expired on December 31, 2017 and we vacated the premises.

In June 2015, we entered into a lease agreement for an approximate 44,681 square foot facility in San Diego, California, for 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. In July 2015, we entered into a sublease for the building with the then existing lessee for a term of one year commencing August 1, 2015. There was no fixed rent or operating expenses due by us during the sublease term other than utilities. We are currently subleasing approximately 2,000 square feet of the premises to a related party. 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 leased a total of approximately 2,550 square feet of office space in Cardiff-by-the-Sea, California, for general office use, pursuant to an operating lease. We amended this lease to extend the term of the lease through August 31, 2018. Our total monthly lease payment was $13,200 per month. In August 2017, we subleased these premises for the remainder of the lease term for the same payment. The lease expired on August 31, 2018 and we vacated the premises.

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.

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 warrants, stock-based compensation, income taxes, preclinical and clinical trial accruals, useful lives of long-lived assets, and valuation of build-to-suit lease assets. 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, 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.

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, U.S. treasury 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, 2018, 2017 and 2016.

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, 2018, our cash equivalents and investments in marketable debt securities totaled $63.0 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

We record long-lived assets that include property, plant, equipment and intangible assets. Furthermore, we are deemed to be the owner, for accounting purposes, during the construction phase of certain long-lived assets under build-to-suit lease arrangements because of our involvement with the construction, our exposure to any potential cost overruns and our other commitments under the arrangements. In these cases, we recognize a build-to-suit lease asset under construction and a corresponding build-to-suit lease liability on the consolidated balance sheets.

Upon completion of construction, we evaluate the de-recognition of the asset and liability under the provisions of ASC 840 40, Leases – Sale-Leaseback Transactions. Where the lease does not meet the criteria for sale-leaseback accounting treatment, due to the continuing involvement in the project resulting from the significant collateral we provided to the landlord in the form of building improvements, we account for the lease as a financing obligation. Under the financing obligation, the deemed value of the building is capitalized as property, plant and equipment with an offsetting financing obligation on the consolidated balance sheets. The asset is then depreciated over the building's estimated useful life. At the end of the lease term, we will de-recognize both the net book values of the building and financing obligation.

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 asset using a discount rate determined by management to be commensurate with the risk inherent to our current business model.

Lease Obligations

We categorize leases at their inception as either operating or capital leases. On certain of our lease agreements, we may receive rent holidays and other incentives. We recognize lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. Additionally, incentives we receive for leases categorized as operating leases are treated as a reduction of our costs over the term of the agreement.

We established assets and liabilities for the estimated construction costs incurred under build-to-suit lease arrangements to the extent we are involved in the construction of structural improvements or take construction risk prior to commencement of a lease. Upon occupancy of facilities under build-to-suit leases, we assess whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If we continue to be the deemed owner, the facilities are accounted for as financing leases.

Stock-based Compensation

We account for stock-based compensation under the provisions of FASB ASC Topic 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. We estimate the fair value of employee options and warrants on the date of grant using the Black-Scholes-Merton option pricing model. The fair value of employee restricted stock units, or RSUs, is estimated using the intrinsic value method, wherein the fair value of an RSU is determined by the closing market price of our common stock on the date of grant. For employee awards subject to service-based vesting conditions, stock-based compensation expense is recognized over the service period using the straight-line method. 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.

During the fourth quarter of 2018, we adopted FASB Accounting Standards Update, or ASU, ASU 2018 07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, or ASU 2018 07, which supersedes ASC Subtopic 505 50, Equity-Based Payments to Non-Employees, or ASC 505 50. Pursuant to ASC 505 50, we had determined that the measurement date for RSUs granted to non-employees was the vesting/release date (i.e., the date the services required under the arrangement had been completed). In addition, we had determined that the fair value of the equity securities granted was more reliable than the fair value of the goods or services received. In order to recognize cost over the requisite service period we initially measured the fair value of the awards at the date of grant and at the end of each quarter the share-based payments were revalued at their then-current fair value, with an offsetting entry to additional paid-in capital on the consolidated balance sheets. At the measurement date (i.e., vesting/release date), a final fair value adjustment was made. Upon adoption of ASU 2018 07, the measurement and classification guidance for share-based payments granted to non-employees largely aligns with the guidance for share-based payments granted to employees. For additional information, see Note 2 – Summary of Significant Accounting Policies – Recent Accounting Pronouncements – Application of New and Revised Accounting Standards – Adopted of the “Notes to Consolidated Financial Statements” included in Part II, Item 8 of this Annual Report.

During the second quarter of 2016, we adopted ASU 2016 09, Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, or ASU 2016 09. As a result of the adoption, we made a policy election to record forfeitures of stock-based compensation awards as they occur rather than estimate the number of awards that we expect to vest. Following the adoption of ASU 2016 09, we are required to recognize excess tax benefits from share-based payment awards as income tax expense in net income and as an operating activity on the cash flow statement. We elected to apply these provisions of ASU 2016 09 under the modified-retrospective transition method. ASU 2016 09 also requires that we classify as a financing activity on the statement of cash flows the cash paid to a tax authority when shares are withheld to satisfy statutory income tax withholding obligations.

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 the Company’s 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 (NOLs) and Research and Development Credits

As of December 31, 2018, we had federal, state and foreign income tax NOLs of approximately $232.3 million, $200.3 million and $0.2 million, respectively, which will begin to expire at various dates starting with 2022. As of December 31, 2018, we also had federal and state research and development tax credit carryforwards of $6.5 million and $4.0 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 February 2018, the FASB issued ASU 2018 02, Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, or ASU 2018 02, which provides financial statement preparers with an option to reclassify stranded tax effects within accumulated other comprehensive income to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act is recorded. ASU 2018 02 is effective on January 1, 2019, with early adoption permitted. Adoption of ASU 2018 02 is not expected to 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 amendments in this update replace existing guidance 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 standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier, beginning on January 1, 2019. 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. We are currently evaluating the impact that this new standard will have on our consolidated financial statements. However, as the impact is dependent upon the investment held as of the adoption date, it is not possible to quantify the impact until the date of adoption. We plan to adopt the new guidance as of the effective date.

In February 2016, the FASB issued ASU 2016 02, Leases (Topic 842), which supersedes ASC Topic 840, Leases, or ASC 840. This new standard requires that lessees recognize on the balance sheet the assets and liabilities that arise from leases, including leases classified as operating leases under current U.S. GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019. In July 2018, the FASB further amended this standard to allow for a new transition method that offers the option to use the effective date as the date of initial application. We intend to elect this alternative transition method and therefore will not adjust comparative-period financial information. In addition, we intend to elect the package of practical expedients permitted under the transition guidance of the new standard to not reassess prior conclusions related to contracts that are or that contain leases, lease classification and initial direct costs. We do not expect that this standard will have a material impact on our consolidated statements of operations, but we do expect that upon adoption, it will have a material impact on our assets and liabilities on our consolidated balance sheets. The primary effect of adoption will be the requirement to record the present value of lease liabilities for current operating leases and corresponding right-of-use assets. Upon adoption, we estimate we will have additional liabilities ranging from $6 million to $7 million with corresponding right-of-use assets of a similar amount. We are currently finalizing the implementation of the new lease accounting guidance, documenting processes, and establishing internal controls to properly track, record and account for our lease portfolio. The new standard also provides practical expedients for the ongoing accounting. We also currently expect to elect the practical expedient to not separate lease and non-lease components for most of our asset

classes.

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, 2018 did not, or are not expected to, have a material effect on the Company's 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.

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, 2018, we had $16.8 million in cash and cash equivalents and $63.0 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, 2018, 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, 2018, 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, 2018 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.

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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, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

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 13, 2019

NantKwest, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$16,821	$23,872
Due from related parties	90	154
Prepaid expenses and other current assets	13,810	4,152
Marketable debt securities, available-for-sale	57,328	104,280
Notes receivable, held-to-maturity	723	—
Total current assets	88,772	132,458
Marketable debt securities, noncurrent	5,701	29,600
Property, plant and equipment, net	76,885	76,726
Investment in equity securities	8,500	8,500
Intangible assets, net	565	2,826
Other assets	1,527	330
Total assets	$181,950	$250,440
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$2,793	$5,865
Accrued expenses	21,104	11,267
Due to related parties	1,696	2,363
Other current liabilities	1,667	1,373
Total current liabilities	27,260	20,868
Build-to-suit liability, less current portion	—	4,909
Financing obligation, less current portion	5,945	1,741
Deferred rent	2,739	3,325
Deferred tax liability	—	498
Other liabilities	—	255
Total liabilities	35,944	31,596
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized; 79,087,734 and 79,021,878 issued and outstanding as of December 31, 2018 and December 31, 2017	8	8
Additional paid-in capital	741,246	717,930
Accumulated other comprehensive loss	(267)	(381)
Accumulated deficit	(594,981)	(498,713)
Total stockholders' equity	146,006	218,844
Total liabilities and stockholders' equity	$181,950	$250,440

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,		
	2018	2017	2016
Revenue	$47	$45	$44
Operating expenses:			
Research and development (including amounts to related parties)	55,718	42,044	29,153
Selling, general and administrative (including amounts to related parties)	42,718	57,121	95,391
Total operating expenses	98,436	99,165	124,544
Loss from operations	(98,389)	(99,120)	(124,500)
Other income (expense):			
Investment income, net	1,857	2,665	3,097
Interest expense (including amounts to related parties)	(433)	(618)	(66)
Other income, net (including amounts to related parties)	236	157	88
Total other income	1,660	2,204	3,119
Loss before income taxes	(96,729)	(96,916)	(121,381)
Income tax benefit	503	493	572
Net loss	$(96,226)	$(96,423)	$(120,809)
Net loss per share:			
Basic and diluted	$(1.22)	$(1.20)	$(1.47)
Weighted-average number of shares during the period:			
Basic and diluted	79,132,220	80,583,910	81,979,005

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,		
	2018	2017	2016
Net loss	$(96,226)	$(96,423)	$(120,809)
Other comprehensive income (loss), net of income taxes:			
Net unrealized gain (loss) on available-for-sale securities	114	(65)	5
Reclassification of net realized gains on available-for-sale securities included in net loss	—	(32)	(97)
Total other comprehensive income (loss)	114	(97)	(92)
Comprehensive loss	$(96,112)	$(96,520)	$(120,901)

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	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
Balance at December 31, 2015	81,311,686	$ 8	$ 606,555	$ (192)	$ (250,376)	$ 355,995
Exercise of stock options	2,398,883	—	1,373	—	—	1,373
Stock-based compensation expense	—	—	73,852	—	—	73,852
Vesting of restricted stock units	537,982	—	—	—	—	—
Net share settlement for restricted stock unit vesting and option exercises	(154,127)	—	(1,106)	—	—	(1,106)
Exercise of warrants	47,457	—	52	—	—	52
Change in accounting principle - ASU 2016-09 forfeiture adjustment	—	—	31	—	(31)	—
Repurchase of common stock	(2,157,944)	—	—	—	(15,847)	(15,847)
Other comprehensive loss	—	—	—	(92)	—	(92)
Net loss	—	—	—	—	(120,809)	(120,809)
Balance at December 31, 2016	81,983,937	$ 8	$ 680,757	$ (284)	$ (387,063)	$ 293,418
Exercise of stock options	614,136	—	1,154	—	—	1,154
Stock-based compensation expense	—	—	36,997	—	—	36,997
Vesting of restricted stock units	244,209	—	—	—	—	—
Net share settlement for restricted stock unit vesting and option exercises	(234,020)	—	(1,039)	—	—	(1,039)
Exercise of warrants	47,226	—	61	—	—	61
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
Vesting of restricted stock units	172,330	—	—	—	—	—
Net share settlement for restricted stock unit vesting and warrant exercises	(61,379)	—	(123)	—	—	(123)
Exercise of warrants	93,254	—	57	—	—	57
Repurchase of common stock	(138,349)	—	—	—	(228)	(228)
	—	—	—	—	186	186

Cumulative effect of the adoption of the new revenue standard	—	—	—	114	—	114
Other comprehensive income	—	—	—	—	(96,226)	(96,226)
Net loss	—	—	—	(267)	(594,981)	146,006
Balance at December 31, 2018	79,087,734	$ 8	$ 741,246	$	$	

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,		
	2018	2017	2016
Operating activities:			
Net loss	$(96,226)	$(96,423)	$(120,809)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	23,382	36,997	73,852
Depreciation and amortization	9,555	5,566	3,607
Amortization of net premiums on marketable debt securities	463	1,597	2,182
Non-cash interest items, net	291	720	(573)
Loss on disposal of assets	209	64	18
Deferred income tax benefit	(498)	(497)	(575)
Gain on sales of marketable debt securities	(3)	(32)	(137)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(9,818)	156	(1,458)
Other assets	(1,151)	458	153
Accounts payable	(1,100)	150	888
Accrued expenses and other liabilities	12,708	(299)	2,127
Due to related parties	(685)	1,562	378
Deferred rent and revenue	(508)	1,201	1,754
Net cash used in operating activities	(63,381)	(48,780)	(38,593)
Investing activities:			
Purchases of property, plant and equipment	(13,102)	(34,815)	(6,560)
Proceeds from sales of property, plant and equipment	412	—	—
Purchases of debt securities, held-to-maturity	(723)	—	—
Purchase of investment in equity securities	—	(8,500)	—
Purchases of marketable debt securities, available-for-sale	(94,770)	(111,355)	(272,999)
Sales/maturities of marketable debt securities	165,284	254,222	165,887
Net cash provided by (used in) investing activities	57,101	99,552	(113,672)
Financing activities:			
Principal payments of financing/capital lease obligations	(477)	(19,932)	(32)
Repurchase of common stock with commissions	(228)	(15,227)	(15,847)
Proceeds from exercise of stock options and warrants	57	1,215	1,425
Net share settlement for restricted stock unit vesting and warrant and option exercises	(123)	(1,039)	(1,106)
Net cash used in financing activities	(771)	(34,983)	(15,560)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(7,051)	15,789	(167,825)
Cash, cash equivalents and restricted cash, beginning of period	24,051	8,262	176,087
Cash, cash equivalents and restricted cash, end of period	$17,000	$24,051	$8,262
Reconciliation of cash, cash equivalents, and restricted cash at end of period:			
Cash and cash equivalents	$16,821	$23,872	$8,083
Restricted cash included in other assets	179	179	179
Cash, cash equivalents, and restricted cash, end of period	$17,000	$24,051	$8,262

Supplemental disclosure of cash flow information:			
Cash paid during the period for:			
Interest	$475	$668	$66
Income taxes	$4	$3	$2
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	$4,664	$9,500	$2,753
Unrealized gains (losses) on marketable debt securities	$123	$(97)	$(102)
Cashless exercise of stock options and warrants	$94	$16	$456
Estimated fair value of building under build-to-suit lease	$—	$—	$5,139
Lease incentive with a related party	$—	$—	$849

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

NantKwest, Inc.

Notes to Consolidated Financial Statements

1. Description of Business

Organization

NantKwest, Inc. (NantKwest, or the Company) 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. NantKwest is 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.

The Company is focused on harnessing the power of the innate immune system by using the natural killer cell to treat cancer and viral infectious diseases. A critical aspect of the Company's strategy is to invest significantly in innovating new therapeutic candidates, based upon the Company's activated natural killer (aNK) cell platform, as well as clinical testing and scale manufacturing of the Company's leading product candidates.

NantKwest holds the exclusive right to commercialize aNK cells, a commercially viable natural killer cell-line, and a variety of genetically modified derivatives capable of killing cancer and virally infected cells. The Company owns corresponding United States (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 as a therapeutic to treat a spectrum of clinical conditions.

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

Liquidity

As of December 31, 2018, the Company had an accumulated deficit of approximately $595.0 million. The Company also had negative cash flow from operations of approximately $63.4 million during the year ended December 31, 2018. The Company expects that it will likely need additional capital to further fund the development of, and seek regulatory approvals for, its product candidates, and begin to commercialize any approved products.

The Company is currently focused primarily on the development of immunotherapeutic treatments for cancers and debilitating viral infections using targeted cancer killing cell lines, and believes 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 the Company's product candidates, if approved, fail to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its 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 the Company when needed and, if available, financing may not be obtained on terms

favorable to the Company or its stockholders.

While the Company expects its existing cash, cash equivalents, and marketable debt securities, together with the ability to borrow from affiliated entities, will enable it to fund operations and capital expenditure requirements for at least the next 12 months, it may not have sufficient funds to reach commercialization. Failure to obtain adequate financing when needed may require the Company to delay, reduce, limit, or terminate some or all of its development programs or future commercialization efforts or grant rights to develop and market product candidates that the Company might otherwise prefer to develop and market itself, which could adversely affect the Company's ability to operate as a going concern. If the Company raises additional funds from the issuance of equity securities, substantial dilution to existing stockholders may result. If the Company raises 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 the Company's ability to operate its 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 (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 this uncertainty. The Company believes its existing cash, cash equivalents, and investments in marketable debt securities, and the 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 the Company's Chairman and CEO's intent and ability to support the Company's operations with additional funds, including loans from affiliated entities, as required. The Company 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, the Company may not be able to secure such financing in a timely manner or on favorable terms. Without additional funds, the Company may choose to delay or reduce its operating or investment expenditures. Further, because of the risk and uncertainties associated with the commercialization of the Company's products in development, the Company may need additional funds to meet its 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.

Principles of Consolidation

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

The Company applies the variable interest model under Accounting Standards Codification (ASC) Topic 810, Consolidation, to any entity in which the Company holds an equity investment or to which the Company has 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 (VIE), the Company considers whether it must consolidate the VIE or provide additional disclosures regarding the Company's involvement with the VIE. If the Company determines that it is the primary beneficiary of the VIE, the Company will consolidate the VIE. This analysis is performed at the initial investment in the entity or upon any reconsideration event.

For entities the Company holds as an equity investment and are not consolidated under the VIE Model, the Company considers whether its 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 the Company is able to exercise significant influence, but not control, are accounted for using the equity method. The Company's 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 the Company is 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, the Company will apply the measurement alternative under ASC 321, Investments—Equity Securities, pursuant to which the Company 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.

The Company owns non-marketable equity securities that are accounted for using the measurement alternative described above because the preferred stock held by the Company 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' 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 the Company 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 the Company's investment and the rights and preferences of those equity instruments compared to the Company's.

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, the Company evaluates its estimates, including those related to the valuation of warrants, stock-based compensation, the valuation allowance for deferred tax assets, preclinical and clinical trial accruals, impairment assessments, useful lives of long-lived assets, and the valuation of build-to-suit lease assets. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Risks and Uncertainties

Contingencies

The Company records accruals for loss contingencies to the extent that the Company concludes it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, 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, the Company records its rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with its third-party insurers and when receipt is deemed probable. This includes instances when the Company's third-party insurers have agreed to pay, on the Company's 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 the Company to concentrations of risk consist principally of cash and cash equivalents and marketable debt securities.

The Company's cash and cash equivalents are with one major financial institution in the U.S. and one in Korea.

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

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Cash, Cash Equivalents and Marketable Debt Securities

The Company invests its excess funds in investment grade short- to intermediate-term corporate debt securities, commercial paper, government sponsored securities, U.S. treasury securities and foreign government bonds and classifies these investments as available-for-sale. The Company considers 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.

The Company periodically evaluates whether declines in fair values of its 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 the Company's ability and intent to hold the investment until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it 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 the Company's investments, duration and severity of the decline in value and the Company's strategy and intentions for holding the investment. There were no other-than-temporary impairments recorded in the years ended December 31, 2018, 2017 and 2016.

The Company minimizes its credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of its primary financial institutions. While the Company maintains cash deposits in FDIC insured financial institutions in excess of federally insured limits, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on such accounts.

The Company has funded a certificate of deposit (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 the Company is 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

On 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 other income / (loss) on the consolidated statements of operations.

The Company is deemed to be the owner, for accounting purposes, during the construction phase of certain long-lived assets under build-to-suit lease arrangements because of its involvement with the construction, its exposure to any potential cost overruns and its other commitments under the arrangements. In these cases, the Company recognizes a build-to-suit lease asset under construction and a corresponding build-to-suit lease liability on the consolidated balance sheets.

Upon completion of construction, the Company evaluates the de-recognition of the asset and liability under the provisions of ASC 840 40, Leases – Sales-Leaseback Transactions. Where the lease does not meet the criteria for sale-leaseback accounting treatment, due to the continuing involvement in the project resulting from the significant collateral the Company provided to the landlord in the form of building improvements, the Company accounts for the lease as a financing obligation. Under the financing obligation, the deemed value of the building is capitalized as property, plant and equipment with an offsetting financing obligation on the consolidated balance sheets. The asset is then depreciated over the building's estimated useful life. At the end of the lease term, the Company will de-recognize both the net book values of the building and financing obligation.

Intangible Assets

Intangible assets consist of the cost of reacquiring a technology license during 2015. The Company calculates amortization expense for acquired technology licenses using the straight-line method over the estimated useful lives, which is 4 years.

Patents

The Company expenses patent costs, including related legal costs, as incurred and records such costs within general and administrative expenses on the consolidated statements of operations.

Impairments

The Company's long-lived assets include property, plant and equipment and intangible assets. The Company reviews 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 asset using a discount rate determined by management to be commensurate with the risk inherent to the Company's current business model. There were no impairment losses recognized during the years ended December 31, 2018, 2017 and 2016.

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 the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses 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 the Company 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. The Company's Level 1 assets consist of bank deposits, money market funds, and U.S. treasury securities.
- 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. The Company's 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, 2018, 2017 and 2016, no transfers were made into or out of the Level 1, 2 or 3 categories. The Company will continue to review the fair value inputs on a quarterly basis.

The Company utilizes a third-party pricing service to assist in obtaining fair value pricing for investments. 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, the Company is 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.

The Company estimates 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 the Company's behalf. In accruing clinical and research related fees, the Company estimates 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, the Company 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, the Company has 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

The Company categorizes leases at their inception as either operating or capital leases. On certain lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. Additionally, incentives the Company receives for leases categorized as operating leases are treated as a reduction of cost over the term of the agreement.

The Company establishes assets and liabilities for the estimated construction costs incurred under build-to-suit lease arrangements to the extent the Company is involved in the construction of structural improvements or takes construction risk prior to commencement of a lease. Upon occupancy of facilities under build-to-suit leases, the Company assesses whether these arrangements qualify for sales recognition under the sale-leaseback accounting guidance. If the Company continues to be the deemed owner, the facilities are accounted for as financing leases.

Income Taxes

The Company recognizes 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. The Company records valuation allowances to reduce deferred tax assets to the amount the Company believes is more likely than not to be realized.

The Company recognizes uncertain tax positions when the positions will be more likely than not upheld on examination by the taxing authorities based solely upon the technical merits of the positions. The Company recognizes interest and penalties, if any, related to unrecognized income tax uncertainties in income tax expense. The Company did not have any accrued interest or penalties associated with uncertain tax positions as of December 31, 2018 and 2017.

The Company is subject to U.S. federal income tax, as well as income tax in Korea, California and other states. The federal returns for tax years 2015 through 2018 remain open to examination; the California returns remain subject to examination for tax years 2014 through 2018. 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 the Company's 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. The Company has financed and expects to continue to finance the purchases with existing cash balances. As it is the intent for the repurchased shares to be retired, the Company has elected to account for the shares repurchased under the constructive retirement method. For shares repurchased in excess of par, the Company allocates the purchase price in excess of par value to accumulated deficit.

Revenue Recognition

Beginning January 1, 2018, the Company follows the provisions of Financial Accounting Standards Board (FASB) ASC Topic 606, Revenue from Contracts with Customers (ASC 606). The guidance provides a unified model to determine how revenue is recognized. The Company has applied the guidance to all contracts as of the date of initial application.

The Company derives substantially all of its revenue from non-exclusive license agreements with a limited number of pharmaceutical and biotechnology companies granting them the right to use the Company's 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 Company's licensee's products developed or manufactured using the Company's 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 affects the license. The Company concluded that these promises represent one performance obligation due to the highly interrelated nature of the promises. The Company provides 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.

The Company's license agreement with Intrexon (Note 7) included a nonrefundable upfront payment of $0.4 million, received when the Company entered into the contract in 2010. In this instance, the Company determined that under ASC 606 it would be appropriate to recognize the initial milestone payment at a point in time, when it 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, the Company adjusted its 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 the Company uses the most likely amount method to estimate this variable consideration. Given the

high degree of uncertainly around achievement of these milestones, the Company does not recognize revenue from these milestone payments until the uncertainty associated with these payments is resolved. The Company currently estimates variable consideration related to milestone payments to be zero and, as such, no revenue has been recognized for milestone payments. The Company will recognize revenue from sales-based royalty payments when or as the sales occur. On a quarterly basis, the Company will re-evaluate its estimate of milestone variable consideration to determine whether any amount should be included in the transaction price and recorded in revenue prospectively.

Upon adoption, the Company changed its 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, the Company has generated minimal revenue related to the non-clinical use of its cells lines and intellectual property. The Company has no products approved for commercial sale and has not generated any revenue from product sales. If the Company fails to complete the development of its product candidates in a timely manner or fails to obtain regulatory approval for them, the Company may never be able to generate substantial future revenue.

Research and Development Costs

Major components of research and development costs include cash compensation, 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 the Company's behalf. Costs incurred in research and development are expensed as incurred.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC Topic 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of employee options and warrants on the date of grant using the Black-Scholes-Merton option pricing model. The fair value of employee RSUs (Note 11) is estimated using the intrinsic value method, wherein the fair value of an RSU is determined by the closing market price of the Company's common stock on the date of grant. For employee awards subject to service-based vesting conditions, stock-based compensation expense is recognized over the service period using the straight-line method. For awards subject to performance-based vesting conditions, the Company assesses 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.

During the fourth quarter of 2018, the Company adopted FASB Accounting Standards Update (ASU) ASU 2018 07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting (ASU 2018 07), which supersedes ASC Subtopic 505 50, Equity-Based Payments to Non-Employees (ASC 505 50). Pursuant to ASC 505 50, the Company had determined that the measurement date for RSUs granted to non-employees was the vesting/release date (i.e., the date the services required under the arrangement had been completed). In addition, the Company had determined that the fair value of the equity securities granted was more reliable than the fair value of the goods or services received. In order to recognize cost over the requisite service period the Company initially measured the fair value of the awards at the date of grant and at the end of each quarter the share-based payments were revalued at their then-current fair value, with an offsetting entry to additional paid-in capital on the consolidated balance sheets. At the measurement date (i.e., vesting/release date), a final fair value adjustment was made. Upon adoption of ASU 2018 07, the measurement and classification guidance for share-based payments granted to non-employees largely aligns with the guidance for share-based payments granted to employees. For additional information, see Note 2 – Summary of Significant Accounting Policies – Recent Accounting Pronouncements – Application of New and Revised Accounting Standards – Adopted.

During the second quarter of 2016, the Company adopted ASU 2016 09, Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016 09). As a result of the adoption, the Company made a policy election to record forfeitures of stock-based compensation awards as they occur rather than estimate the number of awards that are expected to vest. Following the adoption of ASU 2016 09, the Company is required to recognize excess tax benefits from share-based payment awards as income tax expense on the consolidated statements of operations and as an operating activity on the consolidated statements of cash flows. The Company elected to apply these provisions of ASU 2016 09 under the modified-retrospective transition method. ASU 2016 09 also requires that the Company classify the cash paid to a tax authority when shares are withheld by it to satisfy

statutory income tax withholding obligations as a financing activity on the consolidated statements of cash flows.

Litigation Costs

The Company expenses 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). The Company's 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,		
	2018	2017	2016
Outstanding options	6,493,250	5,693,250	6,307,386
Outstanding RSUs	867,911	888,189	814,456
Outstanding warrants	17,589,250	17,721,088	17,768,314
Total	24,950,411	24,302,527	24,890,156

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. The Company’s chief operating decision maker is its CEO. The Company views its operations and manages its business as a single operating and reporting segment. As of December 31, 2018 and 2017, the majority of the Company’s assets were held in the U.S. For the years ended December 31, 2018, 2017 and 2016, all of the Company’s revenue was derived in the U.S.

Recent Accounting Pronouncements

Application of New or Revised Accounting Standards – Adopted

Effective January 1, 2018, the Company adopted ASU 2016 01, Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016 01), associated with the recognition and measurement of financial assets and liabilities. During the first quarter of 2018, the FASB issued further clarifications with the issuance of ASU 2018 03, effective for fiscal years beginning after December 15, 2017 and interim periods beginning after June 15, 2018, and ASU 2018 04, effective upon issuance. The Company has early adopted ASU 2018 03 and adopted ASU 2018 04 effective January 1, 2018, concurrently with ASU 2016 01. ASU 2016 01 requires that equity investments, except those accounted for under the equity method of accounting, be measured at fair value and changes in fair value are

recognized in net income. ASU 2016 01 also provides a new measurement alternative for equity investments that do not have a readily determinable fair value (cost method investments). These investments 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. The amendments related to equity securities without readily determinable fair values, including disclosure requirements, were applied prospectively to investments in equity securities that exist as of the date of adoption. Effective January 1, 2018, the Company elected to record its investment in Viracta's (Note 4) preferred stock, which does not have a readily determinable fair value, using the alternative method. Adoption of the updates did not have a material effect on the Company's accounting for investments in equity securities, fair value disclosures, and other disclosure requirements.

In May 2014, the FASB issued guidance codified in ASC 606, which amends the guidance in former ASC Topic 605, Revenue Recognition, and was initially to be effective beginning January 1, 2017. On August 12, 2015, the FASB issued guidance, which deferred the effective date of ASC 606 to January 1, 2018 for public companies. 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. The Company adopted ASC 606 on January 1, 2018 by recording the cumulative effect of the adoption to accumulated deficit. The Company applied the new guidance to contracts that were not complete as of January 1, 2018. Implementation of the new revenue guidance did not have a material impact on the Company's consolidated financial statements. For additional information, see Note 2 – Summary of Significant Accounting Policies – Revenue Recognition.

Effective January 1, 2018, the Company adopted ASU 2016 15, Classification of Certain Cash Receipts and Cash Payments (ASU 2016 15), which adds or clarifies guidance on the classification of certain cash receipts and payments in the statements of cash flows. Also, effective January 1, 2018, the Company adopted ASU 2016 18, Statement of Cash Flows: Restricted Cash, a consensus of the FASB's Emerging Issues Task Force (ASU 2016 18), which requires that the statements of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Entities are also required to reconcile such total to amounts on the balance sheets and disclose the nature of the restrictions. Prior periods were retrospectively adjusted to conform to the current period's presentation. There was no material impact on the Company's statements of cash flows on adoption of either ASU 2016 15 or ASU 2016 18.

Effective October 1, 2018, the Company adopted ASU 2018 07, which is part of the FASB's initiative to reduce complexity in accounting standards. ASU 2018 07, which supersedes ASC 505 50, largely aligns the measurement and classification guidance for share-based payments granted to non-employees with the guidance for share-based payments granted to employees. The Company elected to apply the provisions of ASU 2018 07 under the modified-retrospective transition method, wherein the Company made a final fair value adjustment for all of its then outstanding non-employee equity awards based on the closing market price of the Company's common stock as of the October 1, 2018 adoption date. Adoption of ASU 2018 07 did not have a material impact on the Company's consolidated financial statements and, therefore, the Company did not record a cumulative effect transition adjustment upon adoption. The effect of the adoption of ASU 2018 07 will be to minimize the volatility of expense related to stock-based awards issued to non-employees in the future. ASU 2018 07, which was issued in June 2018, is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. See Note 2 – Summary of Significant Accounting Policies – Stock-Based Compensation, for additional information.

Application of New or Revised Accounting Standards – Not Yet Adopted

In February 2018, the FASB issued ASU 2018 02, Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (ASU 2018 02), which provides financial statement preparers with an option to reclassify stranded tax effects within accumulated other comprehensive income or loss to retained earnings or accumulated deficit in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act is recorded. ASU 2018 02 is effective for the Company beginning January 1, 2019, with early adoption permitted. Adoption of ASU 2018 02 is not expected to have a significant impact on the Company's consolidated financial statements and disclosures.

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 interim and annual periods beginning on January 1, 2020, but may be

adopted earlier, beginning on January 1, 2019. 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. The Company is currently evaluating the impact that this new standard will have on its consolidated financial statements. However, as the impact is dependent upon the investment held as of the adoption date, it is not possible to quantify the impact until the date of adoption. The Company plans to adopt the new guidance as of the effective date.

In February 2016, the FASB issued ASU 2016 02, Leases (Topic 842), which supersedes ASC 840, Leases. This new standard requires that lessees recognize on the balance sheet the assets and liabilities that arise from leases, including leases classified as operating leases under current U.S. GAAP, and disclose qualitative and quantitative information about leasing arrangements. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019. In July 2018, the FASB further amended this standard to allow for a new transition method that offers the option to use the effective date as the date of initial application. The Company intends to elect this alternative transition method and therefore will not adjust comparative-period financial information. In addition, the Company intends to elect the package of practical expedients permitted under the transition guidance of the new standard to not reassess prior conclusions related to contracts that are or that contain leases, lease classification and initial direct costs. The Company does not expect that this standard will have a material impact on its consolidated statements of operations, but it does expect that upon adoption, the new standard will have a material impact on the Company's assets and liabilities on its consolidated balance sheets. The primary effect of adoption will be the requirement to record the present value of lease liabilities for current operating leases and corresponding right-of-use assets. Upon adoption, the Company estimates it will have additional liabilities ranging from $6 million to $7 million with corresponding right-of-use assets of a similar amount. The Company is currently finalizing the implementation of the new lease accounting guidance, documenting processes, and establishing internal controls to properly track, record and account for its lease portfolio. The new standard also provides practical expedients for the ongoing accounting. The Company also currently expects to elect the practical expedient to not separate lease and non-lease components for most of its asset classes.

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, 2018 did not, or are not expected to, have a material effect on the Company's consolidated financial statements.

3. Financial Statement Details

Prepaid expenses and other current assets

As of December 31, 2018 and 2017, prepaid expenses and other current assets were made up of (in thousands):

	As of December 31,	
	2018	2017
Insurance claim receivable	$10,882	$340
Prepaid rent	536	373
Prepaid supplies	532	210
Interest receivable - marketable debt securities	473	764
Prepaid insurance	343	572
Insurance premium financing asset	339	—
Prepaid equipment maintenance	329	123
Prepaid services	230	416
Prepaid license fees	104	597
Equipment deposits	—	482
Other	42	275
	$13,810	$4,152

Property, plant and equipment, net

As of December 31, 2018 and 2017, property, plant and equipment was made up of (in thousands):

	As of December 31,	
	2018	2017
Construction in progress	$2,480	$42,281
Buildings	59,356	23,811
Equipment	20,878	9,625
Leasehold improvements	4,087	3,918
Software	1,264	1,092
Furniture & fixtures	381	302
	88,446	81,029
Accumulated depreciation	(11,561)	(4,303)
	$76,885	$76,726

Depreciation expense related to property, plant and equipment was $7.3 million, $3.3 million and $1.0 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Buildings of $59.4 million include buildings under build-to-suit leases of $39.9 million and $19.5 million related to the Company's purchased warehouse and distribution facility. Building value under build-to-suit leases represents the estimated fair market value of the buildings and capitalized construction costs where the Company is the "deemed owner" of the assets, for accounting purposes only. See Note 8 – Commitments and Contingencies – Financing Lease Obligations for further information.

Intangible assets, net

As of December 31, 2018 and 2017, intangible assets were made up of (in thousands):

	As of December 31,	
	2018	2017
Technology license	$9,042	$9,042
Less accumulated amortization	(8,477)	(6,216)
	$565	$2,826

Amortization expense was $2.3 million, $2.3 million and $2.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. Amortization for the Company's technology license is included in research and development expense on the consolidated statements of operations.

As of December 31, 2018, the remaining amortization period for the technology license is 0.25 years.

Other assets

As of December 31, 2018 and 2017, other assets were made up of (in thousands):

	As of December 31,	
	2018	2017
Prepaid rent	$1,205	$—
Restricted cash	179	179
Security deposit	113	127
Other	30	24
	$1,527	$330

Accrued expenses

As of December 31, 2018 and 2017, accrued expenses were made up of (in thousands):

	As of December 31,	
	2018	2017
Litigation settlement accrual	$12,000	$—
Accrued construction costs	3,341	6,212
Accrued bonus	2,079	1,930
Accrued compensation	943	944
Accrued professional and service fees	912	1,048
Accrued preclinical and clinical trial costs	704	521
Accrued laboratory equipment and supplies	678	305
Accrued franchise, sales/use and property taxes	250	198
Other	197	109
	$21,104	$11,267

Other current liabilities

As of December 31, 2018 and 2017, other current liabilities were made up of (in thousands):

	As of December 31,	
	2018	2017
Financing obligation - current portion	$965	$284
Deferred rent - current portion	598	520
Build-to-suit lease liability - current portion	—	334
Other	104	235
	$1,667	$1,373

Investment income, net

Net investment income is as follows for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
Interest income	$2,317	$4,225	$5,168
Investment amortization accretion expense, net	(463)	(1,597)	(2,182)
Net realized gains on investments	3	37	111
	$1,857	$2,665	$3,097

Interest income includes interest from marketable debt securities, notes receivable, and interest from the Company's bank deposits. The Company did not recognize an impairment loss on any investments during the years ended December 31, 2018, 2017 and 2016.

4. Viracta Investment and Convertible Notes

In March 2017, the Company participated in a Series B convertible preferred stock financing and invested $8.5 million in Viracta Therapeutics, Inc. (Viracta), a clinical stage drug development company. In May 2017, the Company 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. See Note 7 – Collaboration and License Agreements – Royalties and In-licensing Agreements – Viracta License Agreement for further information.

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, the Company does not hold a controlling financial interest in Viracta and therefore is not consolidating 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, Fair Value Measurement, the Company has elected to apply the measurement alternative under ASC 321, Investments—Equity Securities, pursuant to which the Company measures its investment 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, 2018, the Company's qualitative impairment assessment did not indicate that there were events or changes in circumstances that may have had a significant adverse effect on the fair value of the investment. The Company has not recorded any impairments as of December 31, 2018, or on a cumulative basis. Further, the Company has not identified any downward or upward adjustments due to observable price changes in the investment as of December 31, 2018, or on a cumulative basis. As of December 31, 2018 and 2017, $8.5 million was recorded as an investment in equity securities on the consolidated balance sheets.

In June 2018, Viracta executed a 2018 Note and Warrant Purchase Agreement with existing and new investors, including the Company. The initial closing under the Purchase Agreement occurred in June 2018, at which point the Company purchased a convertible note, for $0.4 million, which under certain circumstances is convertible into Preferred Stock, and a warrant to purchase Viracta's common shares. The convertible note accrues interest at 8% and has a one-year maturity date.

In September 2018, Viracta executed the milestone closing under the 2018 Note and Warrant Purchase Agreement, at which point the Company purchased a second convertible note, for $0.4 million, which is also convertible into Preferred Stock under certain circumstances, and a warrant to purchase Viracta's common shares. The convertible note accrues interest at 8% and has a nine-month maturity date.

The Company classified the convertible notes as held-to-maturity notes receivable, on the consolidated balance sheets.

5. Financial Instruments – Investments in Debt Securities

As of December 31, 2018, all of the Company's marketable debt securities are classified as available-for-sale. At December 31, 2018, the Company's investments in debt securities are detailed below (in thousands):

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Weighted-Average				

	Remaining Contractual Life (in years)				
Current:					
Available-for-sale					
Corporate debt securities	0.3	$ 57,463	$ 1	$ (136)	$ 57,328
Total available-for-sale	0.3	57,463	1	(136)	57,328
Held-to-maturity, notes receivable (Note 4)	0.5	723	—	—	723
Current portion	0.3	58,186	1	(136)	58,051
Noncurrent:					
Available-for-sale					
Corporate debt securities	1.9	3,067	—	(76)	2,991
Government sponsored securities	1.5	2,756	—	(46)	2,710
Noncurrent portion	1.7	5,823	—	(122)	5,701
Total	0.4	$ 64,009	$ 1	$ (258)	$ 63,752

At December 31, 2017, the Company's investments in debt securities, including cash equivalents with original maturities greater than three months, are detailed below (in thousands):

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt securities	$82,188	$ 5	$ (84)	$82,109
Government sponsored securities	19,261	—	(28)	19,233
Foreign government bonds	6,441	—	(5)	6,436
Current portion	107,890	5	(117)	107,778
Noncurrent:				
Corporate debt securities	27,109	—	(226)	26,883
Government sponsored securities	2,760	—	(43)	2,717
Noncurrent portion	29,869	—	(269)	29,600
Total	$137,759	$ 5	$ (386)	$137,378

Included in foreign government bonds is $3.5 million of cash equivalents at December 31, 2017.

Available-for-sale investments that had been in an unrealized loss position for less than 12 months and for more than 12 months at December 31, 2018 and 2017 are as follows (in thousands):

	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)

	December 31, 2017			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	$67,522	$ (104)	$35,918	$ (206)
Government sponsored securities	9,744	(20)	12,205	(51)
Foreign government bonds	1,542	—	1,396	(5)
Total	$78,808	$ (124)	$49,519	$ (262)

At December 31, 2018, 38 of the securities and bonds are in an unrealized loss position. The Company evaluated its securities for other-than-temporary impairment and concluded that the decline in value was primarily caused by

current economic and market conditions. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases. Therefore, the Company did not recognize any other-than-temporary impairment loss during the years ended December 31, 2018, 2017 and 2016.

The Company recorded realized gains and losses on sales or maturities of available-for-sale securities as follows (in thousands):

	Gross Realized Gains	Gross Realized Losses	Net Realized Gains
2018	$ 3	$ —	$ 3
2017	52	(15)	37
2016	190	(79)	111

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, 2018 and 2017 (in thousands):

	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	$ —

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	$23,872	$20,374	$3,498	$ —
Corporate debt securities	82,109	—	82,109	—
Government sponsored securities	19,233	—	19,233	—
Foreign government bonds	2,938	—	2,938	—
Noncurrent:				
Corporate debt securities	26,883	—	26,883	—
Government sponsored securities	2,717	—	2,717	—
Total assets measured at fair value	$157,752	$20,374	$137,378	$ —

Non-recurring Valuation

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,

2018, 2017 and 2016.

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.

Exclusive Co-Development Agreement

In August 2016, the Company entered into an exclusive Co-Development Agreement (the Co-Development Agreement) with Altor BioScience, LLC (Altor), formerly known as Altor BioScience Corporation, a related party (Note 9). Under the Co-Development Agreement, the Company and Altor agreed to exclusively collaborate on the development of therapeutic applications combining the Company's proprietary natural killer 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.

The Company is 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 grant 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 (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, the Company shall be 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 all 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.

Altor and the Company each will own 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. The Company has dosed patients with N 803, an IL 15 superagonist, in several phase Ib/II trials. No charges for supplies by Altor have been incurred in association with the above trials during the years ended December 31, 2018, 2017 and 2016.

Joint Development and License Agreement

In December 2014, the Company entered into a Joint Development and License Agreement with Sorrento Therapeutics, Inc. (Sorrento). The agreement expired in December 2017. Since no joint product candidates were identified during the exclusive term, Sorrento has no rights to use the Company's NK cells or other technologies or intellectual property rights or to begin related research, development or commercialization activities and the Company is free to pursue, and is actively pursuing, research, development and commercialization activities with antibodies that may bind to various targets.

Royalties and In-licensing Agreements

Viracta License Agreement

In May 2017, the Company entered into an agreement with Viracta to grant the Company exclusive world-wide rights to Viracta's phase II drug candidate, VRx 3996, for use in combination with the Company's platform of natural killer cell therapies. The Company's Chairman and CEO is also the Vice Chairman of Viracta. In consideration for the license, the Company is 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. The Company 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 (GSH) and DRK-Blutspendedienst Baden-Wurttenberg-Hessen gGmbH (BSD) License Agreement

In August 2015, the Company entered into a license agreement with GSH and BSD under which the Company was granted an exclusive license to certain GSH BSD patents, materials and know-how that specifically targets ErbB2 expressing cancers. In addition, GSH granted the Company an exclusive license to certain GSH only technology and materials. In consideration for the licenses, the Company agreed to pay initial and annual licensing fees, regulatory and commercial milestones and low single-digit percentage royalties on net sales of licensed products. The Company 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, the Company terminated this agreement in accordance with the terms of the agreement.

Fox Chase Cancer Center License Agreement

In 2004 and amended in 2008, the Company entered into an exclusive license agreement with Fox Chase Cancer Center (Fox Chase) for the exclusive, worldwide right to certain patents and know-how pertaining to CD16 receptors bearing NK 92 cell lines. In consideration for this exclusive license, the Company 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 the Company receives from sublicensees.

Rush University Medical Center License Agreement

In 2004, the Company 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. The Company is required to pay low to mid-single digit percentage royalties on net sales depending upon the various fields of studies and other factors. The Company is 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 has a term of 12 years from 2006, the year in which royalty payments were first made, and includes customary termination rights for both parties. Beginning in 2019, this license converted to a perpetual, irrevocable, fully paid, royalty-free, exclusive license.

During the years ended December 31, 2018, 2017 and 2016, the Company recorded royalty expense of $4,200, $25,000 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, 2018, 2017 and 2016.

Out-Licensing Agreement

Intrexon License Agreement

In February 2010, the Company entered into a 17-year license agreement with Intrexon Corporation (Intrexon) pursuant to which the Company 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 the Company a one-time fee of $0.4 million. Prior to adoption of ASC 606, the 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, the Company adjusted its 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 the Company 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, 2018, 2017 and 2016, and, therefore, the Company recorded no milestone revenue for any of those years on the consolidated statements of operations.

8. Commitments and Contingencies

Contingencies

The Company records accruals for loss contingencies to the extent that the Company concludes it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company evaluates, 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, the Company records its rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with its third-party insurers and when receipt is deemed probable. This includes instances where the Company’s third-party insurers have agreed to pay, on the Company’s 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 have been consolidated. Plaintiffs assert 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 seek 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 is scheduled for April 29, 2019.

Under the terms of the settlement, which is subject to final approval by the court, the Company agreed to pay $12.0 million to the plaintiffs as full and complete settlement of the litigation. The Company is responsible for $1.2 million of the settlement amount, which has been recognized in selling, general and administrative expense on the consolidated statements of operations, while the remaining $10.8 million is being fully funded by the Company's insurance carriers under its directors' and officers' insurance policy. The Company and the insurance carriers paid the settlement amount into a settlement fund in January 2019.

Management intends to continue to vigorously defend these proceedings. If for some reason the settlement is not approved and the Company is ultimately found liable, the liability could have a material adverse effect on the Company's consolidated financial statements for the period or periods in which it is incurred.

Insurance Recoveries

The Company has reflected its right to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with its third-party insurers and receipt is deemed probable. This includes instances where the Company's third-party insurers have agreed to pay, on the Company's 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, 2018 and 2017 was $10.9 million and $0.3 million, respectively, and is included in prepaid expenses and other current assets on the Company's consolidated balance sheets.

Contractual Obligations - Leases

The Company leases: (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, through an assignment agreement with a related party, and (v) a research facility in Woburn, Massachusetts. See Note 9 – Related Party Agreements for further information.

Capital Lease

In April 2017, the Company entered into an agreement to purchase a commercial building with approximately 36,434 square feet, located in El Segundo, California. The Company intends to use this facility as a warehouse and distribution facility as it is adjacent to the El Segundo, California, research and manufacturing facility. Upon the execution of the purchase agreement, the Company made a deposit of $5.0 million to the escrow holder and entered into a lease agreement related to this facility commencing on May 1, 2017. There was no monthly base rent under the lease. The escrow closed in September 2017 and the Company paid the remaining purchase price, including closing costs, of $15.3 million and terminated the lease agreement.

The Company had a bargain purchase option to purchase the building upon termination of the escrow period and, initially, accounted for the lease as a capital lease. Upon purchase of the building in September 2017, which resulted in the termination of the capital lease, the Company accounted for the transaction as a single transaction and the carrying amount of the asset was adjusted for any differences between the carrying amount of the lease obligation and the initial carrying amount of the asset.

Financing Lease Obligation – El Segundo

In September 2016, the Company 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 current Good Manufacturing Practices (cGMP) manufacturing facility. The lease runs from July 2016 through July 2023. The Company has 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. The Company records the rent payments as (1) a reduction of the financing obligation; (2) imputed interest expense; and (3) rent expense on the imputed cost to lease the underlying land of the facility, which is considered an operating lease. Rent expense for this facility is recorded in research and development expense on the consolidated statements of operations and was $0.2 million, $0.2 million and $0.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

The Company was responsible for costs to build out the facility and has incurred costs of approximately $30.4 million. Additionally, in order for the facility to meet the Company's research and development laboratory and cGMP specifications, the Company made certain structural changes to the facility as part of the conversion. As a result of these changes, the Company concluded that it is the “deemed owner” of the building (for accounting purposes only) during the construction period. The Company recorded the build out costs as an asset with a corresponding build-to-suit liability, which was recorded as a component of other current and non-current liabilities on the consolidated balance sheets while the building was under construction.

Upon completion of construction of this building in May 2018, the Company evaluated the derecognition of the asset and liability under the provisions of ASC 840 40, Leases – Sale-Leaseback Transactions. The Company determined that the lease does not meet the criteria for sale-leaseback accounting treatment, due to the continuing involvement in the project resulting from the significant collateral the Company provided to the landlord in the form of building improvements. As a result, the building is being accounted for as a financing obligation. The underlying assets amount to approximately $35.6 million. The Company determined its incremental borrowing rate for the purpose of calculating the interest and principal components of each lease payment. However, as the use of any reasonable incremental borrowing rate resulted in a built-in-loss at the end of the lease (i.e., net book value exceeding the financing obligation), depreciation is being accelerated to eliminate such result. At the conclusion of the lease term, the Company will derecognize both the remaining net book values of the assets and financing obligation.

Financing Lease Obligation – Culver City

In November 2015, the Company entered into a facility license agreement with NantWorks (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 Company has the option to extend the license through December 2023. The monthly rent is $47,000, with annual increases of 3% beginning in January 2017. The Company records the rent payments as (1) a reduction of the financing obligation; (2) imputed interest expense; and (3) rent expense on the imputed cost to lease the underlying land of the facility, which is considered an operating lease. Rent expense for this facility is recorded in research and development expense on the consolidated statements of operations and was $0.2 million for each of the years ended December 31, 2018, 2017 and 2016.

Operating Leases

In August 2018, NantBio (Note 9) assigned an agreement to the Company for the use of a third-party research facility, which provides the Company 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, the Company 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 the Company at any time, with or without cause. In case of termination of the agreement, the third party will reimburse the Company for a pro-rata amount based upon the passage of time. The Company accounts for the upfront payments as other current and non-current assets on the consolidated balance sheets, and is amortizing such upfront payments over the expected remaining lease term.

In March 2016, the Company 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 term of the lease is 48 months commencing on April 29, 2016. In June 2016, the lease was amended to add 260 square feet, for a total of 8,153 square feet. The base rent, including the amendment, is $19,000 per month with a $1 per square foot annual increase on each anniversary date.

In July 2015, the Company entered into an agreement for approximately 3,067 square feet of office space in Cary, North Carolina. The lease expired as of December 31, 2017, and the Company vacated the premises.

In June 2015, the Company 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. In July 2015, the Company entered into a sublease for the building with the then existing lessee for a term of one year commencing August 1, 2015. There was no fixed rent or operating expenses during the sublease term other than utilities. The Company is currently subleasing approximately 2,000 square feet of the premises to a related party (Note 9).

The Company leased a total of approximately 2,550 square feet of office space in Cardiff-by-the-Sea, California, for general office use, pursuant to an operating lease. The lease term was extended through August 31, 2018. The Company’s total monthly lease payment was $13,200 per month. In August 2017, the Company subleased these premises for the remainder of the lease term for the same payment. The lease expired on August 31, 2018 and the Company vacated the premises.

The Company recognizes rent expense under operating leases on a straight-line basis. Rent expense for the years ended December 31, 2018, 2017 and 2016 was $2.8 million, $2.7 million, $2.7 million, respectively.

The following table summarizes the Company’s future minimum lease payments at December 31, 2018 (in thousands). Common area maintenance costs and taxes are not included in these payments.

Years ending December 31,	
2019	$4,108
2020	4,056
2021	3,435
2022	3,538
2023	2,056
Thereafter	—
Total minimum lease payments	$17,193

9. Related Party Agreements

The Company’s Chairman and CEO founded and has a controlling interest in NantWorks, LLC (NantWorks), which is a collection of multiple companies in the healthcare and technology space. The Company has entered into arrangements with NantWorks, and certain affiliates of NantWorks, as described below, to facilitate the development of new genetically modified NK cells for the Company’s product pipeline.

Share Repurchase

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

NantHealth Labs, Inc.

In March 2018, the Company entered into an agreement with NantHealth Labs, Inc. (NantHealth Labs), formally known as Liquid Genomics, Inc., 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. The Company is 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 year ended December 31, 2018, $0.3 million has been recognized in research and development expense on the consolidated statements of operations. As of year ended December 31, 2018, the Company owes NantHealth Labs $49,300, which is included in due to related parties on the consolidated balance sheets.

John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine

In 2017 and 2018, the Company entered into multiple agreements with John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine (CSSIM), in El Segundo, California, to conduct various clinical trials. CSSIM is a related party as it is owned by two officers of the Company and NantWorks provides administrative services to CSSIM. One of the Company's officers is an investigator for the trials on behalf of CSSIM. During the years ended December 31, 2018 and 2017, expense of $2.7 million and $0.8 million, respectively, has been recognized in research and development expense on the consolidated statements of operations. As of December 31, 2018 and 2017, the Company owed CSSIM $0.6 million and $0.8 million, respectively, which is included in due to related parties on the consolidated balance sheets.

Tensorcom, LLC

In April 2017, the Company entered into a sublease agreement with Tensorcom, LLC (Tensorcom), formerly known as Tensorcom, Inc., for a portion of the Company's 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, the Company recognized $0.1 million and $0.2 million, respectively, in other income on the consolidated statements of operations under the sublease agreement. At December 31, 2018 and 2017, there were no balances due between the parties.

VivaBioCell S.p.A.

In February 2017, the Company entered into a research grant agreement with VivaBioCell S.p.A. (VBC), a subsidiary of NantCell, Inc. (NantCell). NantCell is an affiliate of NantWorks. VBC conducted research and development activities related to the Company's NK cell lines using VBC's proprietary technology. The Company paid $0.6 million to VBC, which was recorded in prepaid expenses and other current assets on the consolidated balance sheets and benefited from the research and development activities over a one-year timeframe. For the years ended December 31, 2018 and 2017, $0.1 million and $0.6 million, respectively, has been recognized in research and development expense on the consolidated statements of operations and prepaid expenses and other current assets on the consolidated balance sheets was reduced by that amount.

605 Doug St, LLC

In September 2016, the Company entered into a lease agreement with 605 Doug St, LLC, an entity owned by the Company's 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. The lease runs from July 2016 through July 2023. The Company has 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. See Note 8 – Commitments and Contingencies – Financing Lease Obligation – El Segundo for further details on this lease. For the years ended December 31, 2018, 2017 and 2016, the Company recorded rent expense of $0.2 million, $0.2 million and $0.1 million, respectively, which is reflected in research and development expense on the consolidated statements of operations. At December 31, 2018 and 2017, no balances were due between the parties.

Altor

In August 2016, the Company entered into a Co-Development Agreement with Altor as described in Note 7. Altor is a related party of the Company as it is a wholly owned subsidiary of NantCell. NantCell is an affiliate of NantWorks. No charges for supplies by Altor have been incurred in association with the trials during the years ended

December 31, 2018, 2017 and 2016.

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NantBio, Inc.

In August 2018, NantBio, Inc. (NantBio), a NantWorks company, assigned an agreement to the Company for the use of a third-party research facility, which provides the Company 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, the Company 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 the Company at any time, with or without cause. In case of termination of the agreement, the third party will reimburse the Company for a pro-rata amount based upon the passage of time. The Company accounts for the upfront payments as other current and non-current assets on the consolidated balance sheets, and is amortizing such upfront payments over the expected remaining lease term.

In January 2018, the Company entered into a laboratory services agreement with NantBio. The agreement, effective December 1, 2017, includes a sublease of approximately 1,965 square feet of laboratory and office space at the Company's San Diego, California, research facility. The term of the sublease is 24 months, but can be terminated by either party with 30 days prior written notice. The sublease agreement converts to a month-to-month lease after the initial term, not to exceed the expiration of the lease agreement between the Company and the landlord. The monthly sublease and service fee of $10,000 is subject to an annual 3% increase on the agreement anniversary date. The Company recognized $0.1 million and $10,000, respectively, in other income on the consolidated statements of operations for the years ended December 31, 2018 and 2017. At December 31, 2018 and 2017, NantBio owed the Company $49,000 and $0.1 million, respectively, which is included in due from related parties 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 the Company. Under the agreement, the parties are collaborating on the preclinical and clinical development of proprietary recombinant NK cells and monoclonal antibodies in monotherapy and in combination immunotherapies. The Company benefited from the preclinical and clinical research conducted during the first three years under this agreement and provided the first, second, and third year of funding under the five-year agreement. In each of April 2016, April 2017, and August 2018, the Company paid $0.6 million to the National Cancer Institute as a prepayment for services under the agreement. The Company recognizes research and development expense ratably over a 12-month period and recorded $0.6 million, $0.6 million and $0.5 million, respectively, of expense for the years ended December 31, 2018, 2017 and 2016. At each of December 31, 2018 and 2017, the Company had a balance of $0.1 million included in prepaid expenses and other current assets related to this agreement, on the consolidated balance sheets.

NantWorks

In May 2018, the Company entered into an assignment agreement with NantWorks and a third-party construction firm. In conjunction with the agreement, the Company assigned its deposit of $0.4 million with the third-party firm to NantWorks, for which NantWorks reimbursed the Company. This assignment represents unutilized deposits that the Company had previously made with the construction company, 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. The Company is 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, 2018, 2017 and 2016, the Company recorded $2.8 million, $3.6 million and $3.9 million, respectively, to selling, general and administrative expense, and $3.3 million, $3.2 million and $2.1 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 the Company's benefit, which

have been reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks. In June 2016, the Company amended the existing shared services agreement with NantWorks whereby the Company can provide support services to NantWorks and/or any of its affiliates. For the years ended December 31, 2018, 2017 and 2016, the Company recorded expense reimbursements of $0.6 million, $0.4 million and $0.1 million, respectively, to selling, general and administrative expense and $2.6 million, $1.0 million and $0.2 million, respectively, to research and development expense. The Company owed NantWorks a net amount of $1.1 million and $1.5 million for all agreements between the two affiliates at December 31, 2018 and 2017, respectively, which is included in due to related parties on the consolidated balance sheets.

In November 2015, the Company 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. See Note 8 – Commitments and Contingencies – Financing Lease Obligation – Culver City for further details on this lease. The Company recorded rent expense of $0.2 million for each of the years ended December 31, 2018, 2017 and 2016, which is reflected in research and development expense on the consolidated statements of operations.

NantOmics, LLC

In June 2015, the Company entered into an agreement, as amended in May 2018, with NantOmics, LLC (NantOmics), an affiliate of NantWorks, to obtain genomic sequencing and proteomic analysis services, as well as related data management and bioinformatics services, exclusively from NantOmics. The Company 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 will own the data and results, as well as any other intellectual property it creates in performing these services on the Company's behalf. The Company is 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, 2018, 2017 and 2016, the Company recorded operating expense of $0.1 million, $0.1 million and $0.2 million, respectively, to research and development under this arrangement on the consolidated statements of operations. The Company owed NantOmics $24,000 and $0.1 million, respectively, at December 31, 2018 and 2017, which is included in due to related parties on the consolidated balance sheets.

NanoCav, LLC

In June 2015, the Company entered into an agreement with NanoCav, LLC (NanoCav), a related party, pursuant to which the Company obtained access to NanoCav's virus-free cell transfection technologies on a non-exclusive basis. Under the agreement, NanoCav will conduct certain, mutually agreed feasibility studies, on a fee for service basis, to evaluate the use of its cell transfection technologies with the Company's aNK platform products and non-proprietary NK cells. The agreement has an initial term of five years and renews automatically for successive one-year periods, unless terminated earlier. In September 2015, the Company made a $45,000 feasibility study retainer payment as required by the agreement. For the years ended December 31, 2018, 2017 and 2016, the Company recorded operating expense of $0, $0 and $0.1 million, respectively, to research and development under this arrangement on the consolidated statements of operations. At December 31, 2018 and 2017, no balance was due to either party.

NantCell

In November 2018, the Company entered into an agreement with Etubics Corporation (Etubics), a subsidiary of NantCell, which is an affiliate of NantWorks, pursuant to which the Company sold used laboratory equipment to Etubics for $0.3 million. In conjunction with this sale, the Company 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 June 2015, the Company also entered into a supply agreement with NantCell pursuant to which the Company has the right to purchase NantCell's proprietary bioreactors, made according to specifications mutually agreed to with NantCell. The Company also has the right to purchase reagents and consumables associated with such equipment from NantCell. 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.

During the years ended December 31, 2018 and 2017, the Company purchased bioreactors resulting in $1.1 million and $0.3 million in capitalized equipment, respectively, on the consolidated balance sheets. During the years ended December 31, 2018, 2017 and 2016, the Company recorded research and development expense of $0.1 million, $0.3 million and $0.2 million, respectively, on the consolidated statements of operations. At December 31, 2018 and 2017, the Company had $0.5 million and $0.2 million, respectively, included in prepaid expenses and other current assets on the consolidated balance sheets.

10. Stockholders' Equity

Stock Repurchase – In November 2015, the board of directors approved a share repurchase program (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 the Company's 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. The Company has financed and expects to continue to finance the purchases with existing cash balances. The shares are formally retired through board approval upon repurchase.

To date, the Company has repurchased 5,929,903 shares of the Company's common stock under the 2015 Share Repurchase program at a total cost of $31.2 million. In addition, the Company has paid approximately $0.1 million of broker commissions on repurchases. The Company repurchased 138,349 shares (Note 9), 3,633,610 shares, and 2,157,944 shares during the years ended December 31, 2018, 2017 and 2016, respectively, for a total of $0.2 million, $15.2 million, and $15.8 million, respectively. At December 31, 2018, $18.8 million remained authorized for repurchase under the 2015 Share Repurchase Program.

Common Stock Reserved for Future Issuance

The Company is authorized to issue up to 500,000,000 shares of common stock, par value $0.0001 per share at December 31, 2018. As of December 31, 2018, there were 79,087,734 shares of 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, 2018:

Outstanding stock options	6,493,250
Outstanding RSUs	867,911
Outstanding officer warrants	17,589,250
Total shares reserved for future issuance	24,950,411

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 (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 (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 the Company's 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 the Company's common stock issued in connection with an early exercise allowed by the Company may be repurchased by the Company upon termination of the optionee's service with the Company.

2015 Equity Incentive Plan – In July 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (2015 Plan). The 2015 Plan 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. There were 1,835,349 shares of common stock reserved for future grants pursuant to the 2015 Plan as of December 31, 2018. In addition, the shares reserved for future grants under the 2015 Plan will 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 the Company (provided that the maximum number of shares that may be added to the 2015 Plan pursuant to this provision is 4,237,800 shares as of December 31, 2018).

Stock-Based Compensation

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

	For the Year Ended December 31,		
	2018	2017	2016
Stock-based compensation expense:			
Warrants for common stock to an officer	$17,817	$31,584	$50,502
Employee stock options	4,057	4,267	14,720
Employee RSUs	1,193	894	8,166
Non-employee RSUs	315	252	464
	$23,382	$36,997	$73,852
Stock-based compensation expense in operating expenses:			
Research and development	$460	$102	$852
Selling, general and administrative	22,922	36,895	73,000
	$23,382	$36,997	$73,852

Stock Options

The following table summarizes stock option activity under all equity incentive plans for the years ended December 31, 2018, 2017 and 2016:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2015	8,777,893	$ 5.36	$ 116,273	7.2
Options exercised	(2,398,883)	$ 0.76		
Options forfeited/canceled	(71,624)	$ 2.00		
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
Vested and Exercisable at December 31, 2018	5,577,531	$ 7.82	$ 563	4.2

The vested and exercisable shares at December 31, 2017 and 2016 were 5,114,656 and 5,210,756, respectively.

The following table provides a summary of options outstanding and vested as of December 31, 2018:

Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (in years)	Number Exercisable	Weighted-Average Remaining Contractual Life (in years)
$0.22	134,800	0.3	134,800	0.3
$0.42	589,660	5.9	589,660	5.9
$1.76	699,060	6.0	699,060	6.0
$2.00	962,780	6.1	962,780	6.1
$2.20	1,851,500	0.2	1,735,781	0.2
$3.07	800,000	9.7	—	—
$25.00	1,455,450	6.6	1,455,450	6.6
	6,493,250	4.8	5,577,531	4.2

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $0.6 million, $1.7 million and $17.0 million, respectively. The cash received from exercised options was $0, $1.2 million and $1.4 million, respectively, for the years ended December 31, 2018, 2017 and 2016.

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, 2017 and 2016. No stock options were granted to non-employees during the years ended December 31, 2018, 2017 and 2016.

The total unrecognized compensation cost related to non-vested stock options as of December 31, 2018 is $2.4 million, which is expected to be recognized over a weighted-average period of 2.4 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 is 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 (RSUs) activity under the 2015 Plan:

	Number of RSUs Outstanding	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2015	1,129,638	$ 20.51

Granted	407,800	$ 7.76
Vested	(537,982)	$ 23.75
Forfeited/canceled	(185,000)	$ 11.75
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

During the years ended December 31, 2018, 2017 and 2016, the Company granted 90,906 RSUs, 77,250 RSUs and 67,500 RSUs, respectively, to non-employees. All of the 90,906 RSUs granted to non-employees were granted to employees of related companies under the Company’s shared services agreement with NantWorks (Note 9).

As of December 31, 2018, there was $2.5 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 2.1 years. Of that amount, $2.0 million of unrecognized expense is related to employee grants with a remaining weighted-average period of 2.2 years and $0.5 million of unrecognized expense is related to non-employee grants with a remaining weighted-average period of 1.4 years.

Warrants

The following table summarizes the Company's warrant activity:

Outstanding at December 31, 2015	17,819,616
Warrants exercised	(51,302)
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
Vested and exercisable at December 31, 2018	17,589,250

Common Stock Reserved for Future Grants under the 2015 Equity Incentive Plan

At December 31, 2018, there were 1,835,349 shares of common stock reserved for future grants of equity awards.

12. Income Taxes

The amount of loss before taxes is (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
U.S. loss before taxes	$(94,423)	$(94,734)	$(118,743)
Foreign loss before taxes	(2,306)	(2,182)	(2,638)
Loss before income taxes	$(96,729)	$(96,916)	$(121,381)

Income tax (benefit) expense for the years ended December 31, 2018, 2017 and 2016 consists of the following (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
Current:			
Federal	$—	$—	$—
State	3	4	3
Foreign	—	—	—
Total Current	3	4	3
Deferred:			
Federal	—	—	—
State	(8)	—	—
Foreign	(498)	(497)	(575)
Total Deferred	(506)	(497)	(575)
Income tax benefit	$(503)	$(493)	$(572)

The components that comprise the Company's net deferred tax assets at December 31, 2018 and 2017 consist of the following (in thousands):

	As of December 31,	
	2018	2017
Deferred tax assets:		
Stock compensation	$79,281	$73,336
Net operating loss carryforwards	61,915	42,784
Leases and other accrued liabilities	2,909	1,868
Tax credits	845	845
Accrued compensation	795	682
Accrued legal expenses	308	—
Total deferred tax assets	146,053	119,515
Deferred tax liabilities:		
Foreign intangibles	(1)	(499)
Depreciation and amortization	(1,279)	(494)
Total deferred tax liabilities	(1,280)	(993)
Net deferred tax assets	144,773	118,522
Valuation allowance	(144,773)	(119,020)
Net deferred tax liability	$—	$(498)

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,		
	2018	2017	2016
Tax computed at federal statutory rate	21.0 %	34.0 %	34.0 %
Section 382/383 NOL	—	—	8.6
State income taxes, net of federal tax benefit	6.2	5.3	3.6
Tax rate adjustment	(0.3)	4.8	1.5
Tax Cuts and Jobs Act	—	(53.4)	—
Research and development credits	0.1	0.6	1.3
Stock-based compensation	(0.1)	(0.3)	(0.3)
Other	0.3	0.8	(0.5)
Valuation allowance	(26.7)	8.7	(47.7)
Effective income tax rate	0.5 %	0.5 %	0.5 %

On December 22, 2017, the Tax Cuts and Jobs Act (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 (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 has reduced the deferred tax asset balance as of December 31, 2017 by $51.7 million. Due to the Company's full valuation allowance position, the Company has also reduced the valuation

allowance by the same amount.

In December 2017, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 (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 (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. The Company has completed its evaluation of the potential impacts of IRC Section 162(m) as amended by the TJCA on its December 31, 2018 consolidated financial statements, resulting in no adjustment for the years ended December 31, 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. The Company completed an IRC Section 382/383 analysis through 2018 regarding the limitation of net operating loss and research and development credit carryforwards. The Company has derecognized the deferred tax assets for net operating losses and federal and state research and development credits of $0.8 million from its deferred tax asset schedule as of December 31, 2018. 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, the Company has not recognized the deferred tax asset for research and development credits carryforwards as of December 31, 2018 and 2017 because the Company is a part of a controlled group of affiliated companies with common ownership and cannot complete its calculation of the credit until the time that all members of the controlled group complete their analysis and calculation of qualified research expenditures. The Company does 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 the Company's 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, the Company has recorded a full valuation allowance of $144.8 million at December 31, 2018. The change in the valuation allowance for the year ended December 31, 2018 was an increase of $25.8 million. 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.

The Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters. The Company does 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. The Company is subject to U.S. federal income tax, as well as income tax in California and other states. The federal returns for tax years 2015 through 2018 remain open to examination and the California returns remain subject to examination for tax years 2014 through 2018. 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, 2018, the Company has federal net operating losses (NOLs) of approximately $232.3 million, state NOLs of $200.3 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, 2018, the Company also had federal research tax credit carryforwards of approximately $6.5 million and California research tax credits of $4.0 million. The federal research tax credit carryforwards begin to expire in 2034 and the state research tax credit carryforwards begin to expire in 2029.

The following table summarizes the changes to the amount of unrecognized tax benefits (in thousands):

Unrecognized tax benefits at December 31, 2016	$4,634
Decrease for prior year tax positions	(812)
Increase for current year tax positions	2,755
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

Included in the balance of unrecognized tax benefits at December 31, 2018, is $10.9 million that, if recognized, would not impact the Company's income tax benefit or effective tax rate as long as the deferred tax asset remains subject to a full valuation allowance. The Company does not expect any significant increases or decreases to its 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 2018 and 2017 (in thousands, except for share and per share amounts):

	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

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2017				
Revenue	$11	$14	$8	$12
Operating expenses	25,475	23,834	24,450	25,406
Operating loss	(25,464)	(23,820)	(24,442)	(25,394)
Net loss	(24,515)	(23,452)	(23,969)	(24,487)
Net loss per share - basic and diluted	$(0.30)	$(0.29)	$(0.30)	$(0.31)
Shares used in calculating net loss per share - basic and diluted	82,138,438	81,440,816	79,440,591	79,358,861

14. Employee Benefits

Defined Contribution Benefit Plan – In December 2015, the Company adopted a 401(k) retirement and savings plan (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. The Company made contributions of $0.5 million, $0.4 million and $0.2 million during the years ended December 31, 2018, 2017 and 2016, respectively.

Compensated Absences – Under the Company’s vacation policy, certain salaried employees are provided unlimited vacation leave. Therefore, the Company does not record an accrual for paid leave related to these employees since the Company is unable to reasonably estimate the compensated absences that these employees will take.

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 (CEO) and Chief Financial Officer (CFO), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. 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, 2018, our CEO and CFO have concluded that, as of December 31, 2018, 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, 2018, 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, 2018, 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.

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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, 2018, 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.

None.

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 2019 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, 2018, 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.

(a) 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

		Incorporated by Reference Herein			
Exhibit Number	Description	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.	8-K	001-37507	3.2	August 4, 2015
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
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 and forms of agreements thereunder.	S-1/A	333-205124	10.3	July 15, 2015
10.4+	Executive Incentive Compensation Plan.	S-1/A	333-205124	10.4	July 15, 2015

Exhibit Number	Description	Incorporated by Reference Herein Form	File No.	Exhibit	Filing Date
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	Joint Development and License Agreement between the Company and Sorrento Therapeutics, Inc. dated December 18, 2014.	S-1	333-205124	10.9	June 19, 2015
10.10	License Agreement between the Company and Intrexon Corporation, dated February 23, 2010.	S-1	333-205124	10.10	June 19, 2015
10.11	UHN-ZelleRx License Agreement between University Health Network and the Company, dated May 9, 2005.	S-1	333-205124	10.11	June 19, 2015
10.12	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
10.13	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
10.14	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
10.15	Form of Warrant to Purchase Common Stock issued pursuant to the Securities Purchase Agreement dated April 1, 2014.	S-1	333-205124	10.15	June 19, 2015
10.16	Common Stock Purchase Warrant issued March 24, 2015 to Patrick Soon-Shiong, M.D.	S-1	333-205124	10.16	June 19, 2015
10.17	Form of Warrant to Purchase Common Stock issued March 14, 2008.	S-1	333-205124	10.17	June 19, 2015
10.18	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
10.19	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
10.20		10-K	001-37507	10.22	

	Shared Services Agreement by and between the Company and NantWorks, LLC, dated November 10, 2015.				March 30, 2016
10.21	Facility License Agreement by and between the Company and NantWorks, LLC, dated November 10, 2015.	10-K	001-37507	10.23	March 30, 2016
10.22+	Offer Letter between Sonja Nelson and the Company, dated April 7, 2016.	10-Q	001-37507	10.1	May 16, 2016
10.23	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
10.24	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
10.25+	Letter Agreement with Barry Simon dated May 3, 2018.	10-Q	001-37507	10.1	August 06, 2018
10.26+	Offer of Employment Letter with Sonja Nelson dated June 11, 2018.	10-Q	001-37507	10.2	August 06, 2018

Exhibit Number	Description	Incorporated by Reference Herein Form	File No.	Exhibit	Filing Date
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.

†Portions of the exhibit have been omitted pursuant to an order granted by the Securities and Exchange Commission for confidential treatment.

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 13, 2019 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
	Chairman of the Board of Directors and Chief Executive Officer	
/s/ Patrick Soon-Shiong Patrick Soon-Shiong	(Principal Executive Officer)	March 13, 2019
/s/ Barry J. Simon Barry J. Simon	President, Chief Administrative Officer and Director	March 13, 2019
	Chief Financial Officer	
/s/ Sonja Nelson Sonja Nelson	(Principal Financial and Accounting Officer)	March 13, 2019
/s/ Steve Gorlin Steve Gorlin	Vice Chairman of the Board of Directors	March 13, 2019
/s/ Michael D. Blaszyk Michael D. Blaszyk	Director	March 13, 2019
/s/ Frederick W. Driscoll Frederick W. Driscoll	Director	March 13, 2019
/s/ John C. Thomas, Jr. John C. Thomas, Jr.	Director	March 13, 2019