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, 2021

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 001-39370

Nkarta, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-4515206**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
6000 Shoreline Court, Suite 102 South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

(415) 582-4923
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

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

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

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

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 equity held by non-affiliates of the registrant, based on the closing price of a share of common stock on June 30, 2021 as reported by The Nasdaq Stock Market on such date was approximately $441.4 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 14, 2022, the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 33,000,863.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for the 2022 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, and the information incorporated herein by reference, particularly in the sections captioned “Business” under Part I, Item 1, “Risk Factors” under Part I, Item 1A, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under Part II, Item 7, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “should,” “will,” or “would,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. In addition, these statements are based on our management’s beliefs and assumptions and on information currently available to our management as of the date of this Annual Report on Form 10-K. While we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. You should read the sections titled “Risk Factor Summary” below and “Risk Factors” set forth in Part I, Item 1A of this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements, which such factors may be updated or supplemented from time to time by subsequent reports we file with the Securities and Exchange Commission.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Cautionary Note Regarding Forward-Looking Statements" and Part I, Item 1A, "Risk Factors" in this Form 10-K. The below summary is qualified in its entirety by those more complete discussions of such risks and uncertainties. You should consider carefully the risks and uncertainties described under Part I, Item 1A, "Risk Factors" in this Form 10-K as part of your evaluation of an investment in our common stock.

- *We have a limited operating history and do not have any products approved for sale.*
- *We have incurred significant losses since our inception and we expect to continue to incur significant losses for the foreseeable future.*
- *We have never generated revenue from product sales and may never achieve or maintain profitability.*
- *We will require additional capital, which, if available, may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.*
- *Our business and the business or operations of our research partners and other third parties with whom we conduct business have been and could continue to be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have business operations.*
- *Our business depends upon the success of our CAR-NK cell technology platform.*
- *Utilizing CAR-NK cells represents a novel approach to the treatment of cancer, and we must overcome significant challenges in order to develop, commercialize and manufacture our product candidates.*
- *Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.*
- *Our business is highly dependent on the success of our product candidates, and on the success of NKX101 and NKX019 in particular, and we may fail to develop NKX101, NKX019 and/or our other product candidates successfully or be unable to obtain regulatory approval for them.*
- *Our preclinical pipeline programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.*
- *The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Initial success in any clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.*
- *If any of our product candidates, or any competing product candidates, demonstrate relevant, serious adverse events, we may be required to halt or delay further clinical development.*
- *We have entered into a research collaboration with CRISPR Therapeutics regarding certain product candidates, and we may enter into additional collaborations with third parties to develop or commercialize other product candidates. Our prospects with respect to those product candidates will depend in significant part on the success of those collaborations, and we may not realize the benefits of such collaborations.*
- *If we fail to compete effectively with academic institutions and other biopharmaceutical companies that develop similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected.*
- *Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.*

- *We rely on third parties to manufacture certain of our product candidates, and certain materials for use in the production of our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or materials, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.*
- *We are reliant on a sole supplier for certain steps of our manufacturing process.*
- *Delays in commissioning and receiving regulatory approvals for our manufacturing facilities could delay our development plans and thereby limit our ability to develop our product candidates and generate revenues.*
- *If our license agreement with National University of Singapore and St. Jude's Children's Research Hospital, Inc. is terminated, we could lose our rights to key components enabling our NK cell engineering platform.*
- *If any patent protection we obtain is not sufficiently robust, our competitors could develop and commercialize products and technology similar or identical to ours.*
- *If any of our product candidates are approved for marketing and commercialization and we have not developed or secured marketing, sales and distribution capabilities, either internally or from third parties, we will be unable to successfully commercialize such products and may not be able to generate product revenue.*
- *Our product candidates, including NKX101 and NKX019, could be subject to regulatory limitations following approval, if and when such approval is granted.*
- *The market price for our common stock may be volatile, which could contribute to the loss of all or part of your investment.*
- *Concentration of ownership of our shares of common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.*

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of allogeneic, off-the-shelf engineered natural killer ("NK") cell therapies to treat cancer. We currently have two co-lead product candidates, NKX101 and NKX019, in ongoing Phase 1 clinical trials. Both product candidates were generated using our NK cell engineering platform. Our platform incorporates proprietary technologies that enable us to generate an abundant supply of NK cells, improve the persistence of these cells for sustained activity in the body, engineer enhanced NK cell recognition of tumor targets, enhance cell fitness and tumor microenvironment evasion, and freeze, store and thaw our engineered NK cells for off-the-shelf use for the treatment of cancer. Our product candidates are designed to be allogeneic and off-the-shelf, which means they are produced using cells from a different person than the patient treated, and they are produced in quantity, then frozen and therefore available for treating patients without delay, unlike autologous cell therapies, which are derived from a patient's own cells. Based on published data from clinical trials of certain NK cell therapies, we believe that engineered NK cells have the potential to be an effective cancer therapy, be well tolerated, and avoid some of the toxicities observed with other cell therapies.

Our modular NK cell engineering platform allows us to generate new product candidates in a rapid and cost-efficient manner. Our approach for engineering NK cells involves chimeric antigen receptors ("CARs") on the surface of an NK cell to enable the cell to recognize specific proteins or antigens that are present on the surface of tumor cells. Our engineered chimeric antigen receptor-natural killer ("CAR-NK") cells generally consist of an NK cell engineered with a targeting receptor, OX40 costimulatory domain, CD3ζ signaling moiety, and a membrane-bound form of the cytokine IL15 or mbIL-15. We believe the modular nature of our platform and the proprietary technologies we use for the multiplex engineering of NK cells are advantages that can support the rapid generation of new Investigational New Drug applications ("INDs") for product candidates with enhanced properties and/or new targeting receptors for additional disease indications.

Our Product Candidates and Discovery Programs

NKX101 is designed to enhance the power of innate NK biology to detect and kill cancerous cells. The primary activating receptor for NK cells is known as NKG2D, which works through the detection of stress ligands displayed by cancerous cells. We have engineered NKX101 to increase the cancer cell killing ability of our engineered NK cells by raising levels of NKG2D at least ten-fold as compared to non-engineered NK cells and by adding a costimulatory domain, which is an additional signaling element for white blood cells.

In November 2020, we announced that the first patient was treated in the multi-center Phase 1 clinical trial of NKX101 for the treatment of relapsed/refractory acute myeloid leukemia ("AML") or higher risk myelodysplastic syndromes ("MDS"). This ongoing first-in-human study evaluates the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX101. The clinical trial consists of dose-finding followed by dose-expansion and is designed to identify the recommended Phase 2 dose. We expect to announce initial data from the dose-finding portion of the Phase 1 NKX101 study in the first half of 2022.

NKX019 is based on the ability to treat a variety of B-cell malignancies by targeting the CD19 antigen that is found on these types of cancerous cells, where CD19-targeted engineered NK cells, T cells and monoclonal antibodies have demonstrated clinical activity. In October 2021, we announced that we had dosed the first patients with NKX019 in the Phase 1 clinical trial. This ongoing, first-in-human study evaluates the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX019 at multiple centers in the U.S. and Australia. The clinical trial consists of dose-finding followed by dose-expansion and is designed to identify the recommended Phase 2 dose. We expect to announce initial data from the dose-finding portion of the Phase 1 NKX019 study in 2022.

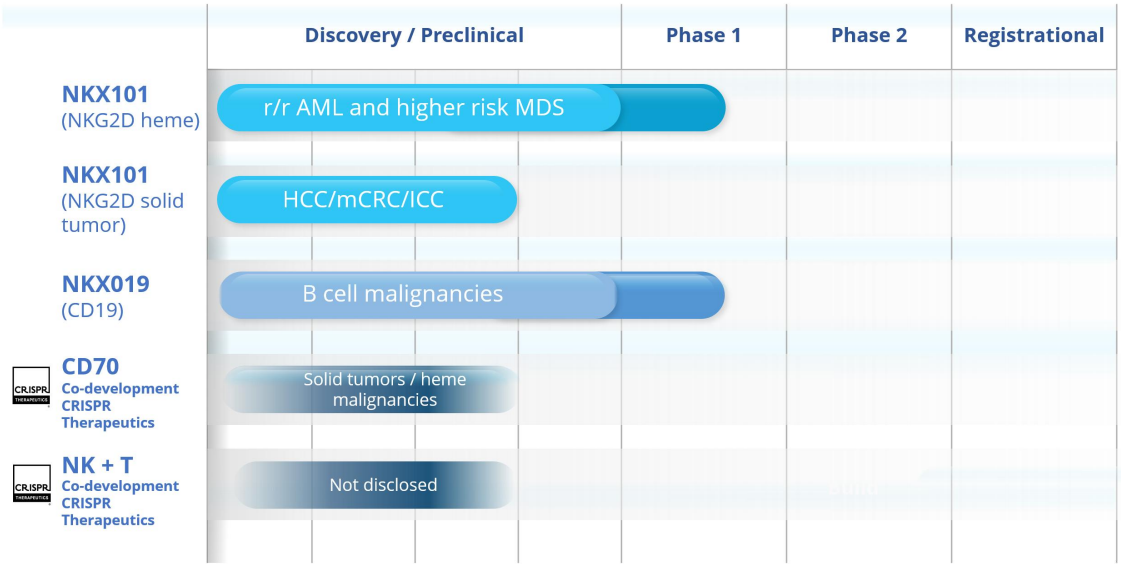
In addition to our two co-lead product candidates, we are engaged in extensive discovery and preclinical stage activities directed to expansion of our pipeline of product candidates over time. As part of our collaboration with CRISPR Therapeutics AG ("CRISPR"), we are conducting discovery efforts for an allogeneic, off-the-shelf CAR-NK product candidate targeting the CD70 tumor antigen ("CD70 CAR-NK") for the treatment of solid tumors and an allogeneic, off-the-shelf product candidate that comprises both engineered NK cells and engineered T cells ("NK+T") to take advantage of both the innate and adaptive immune systems. This NK+T program is designed to harness multiple aspects of human immunology to treat a variety of cancers.

On May 5, 2021, we entered into a Research Collaboration Agreement (the “CRISPR Agreement”) with CRISPR. Pursuant to the CRISPR Agreement, CRISPR and Nkarta will establish research plans for the purpose of collaboratively designing and advancing up to two (2) allogeneic, gene-edited NK cell therapies and one (1) allogeneic, gene-edited NK+T cell therapy for use in the treatment of oncology, autoimmune disease, or infectious disease up to the filing of an application to a regulatory authority to request the ability to start a clinical trial. Additionally, under the CRISPR Agreement, CRISPR will also grant non-exclusive licenses to us on up to five gene-editing targets to enable us to independently research, develop and commercialize NK cell therapies that have been gene-edited using CRISPR’s gene-editing technology.

We have an intensive focus on manufacturing capabilities and technology. We are currently manufacturing NKX019 at our 2,700-square foot clinical current good manufacturing ("cGMP") facility located in South San Francisco, California. We are also currently designing an 88,000 square foot facility in South San Francisco to support pivotal clinical trials and potential commercial supply of our product candidates.

Our Pipeline

Our current pipeline of product candidates and discovery programs is shown below.



i.v.: intravenous administration. i.a.: intraarterial administration through the hepatic artery.

Our Strategy

We are developing novel engineered, allogeneic, off-the-shelf cell therapies to improve the lives of cancer patients and their overall survival by leveraging our NK cell engineering platform. Key elements of our strategy to achieve this include:

Next generation platform enlists natural, healthy human donor NK cells for optimal product candidates

Our cell engineering platform utilizes healthy adult donors as our source for NK cells. By enlisting this natural source of NK cells, we start with bona fide NK cells already endowed with inherent cytotoxic and tumor-recognizing capabilities, as compared to other more complex cell sources where these basic therapeutic features must be painstakingly designed and synthetically added to the cells. Healthy donor-derived NK cells are also available in abundance, providing a large quantity of cells with which to begin each manufacturing run. Finally, healthy donor-derived adult cells consist of a diverse repertoire of NK cells. By utilizing a cell source that contains the full range of naturally occurring NK cells, we believe we can capitalize on the inherent diversity of the innate immune system and select for different NK cell sub-populations with desired characteristics.

Develop NKX101 for blood cancers and solid tumors.

We have engineered NKX101 to overexpress NKG2D receptor. Because NKG2D is the primary activating receptor responsible for innate immune surveillance for cancerous cells, we believe that NKX101 presents a broad opportunity to potentially treat a variety of blood cancers and solid tumors, which represent approximately 90% of all cancer incidences in the United States. Therefore, upon clinical proof-of-concept from our ongoing NKX101 Phase 1 clinical trial for AML and MDS, we plan to pursue a broad clinical development plan for multiple tumor types including solid tumors. In November 2020, we announced that patient dosing began in a Phase 1 monotherapy clinical trial investigating NKX101 for the treatment of relapsed or refractory AML and higher-risk MDS.

Develop NKX019 for B-cell malignancies.

NKX019 is designed to treat a variety of B-cell malignancies by targeting the clinically and commercially validated CD19 antigen that is found in different B-cell malignancies. Because the targeting of CD19 has demonstrated clinical activity with both CAR-T and CAR-NK cell therapies as well as monoclonal antibodies, we believe that NKX019 presents an opportunity to treat a variety of B-cell malignancies while addressing the limitations of existing autologous CAR-T therapies. In October 2021, we announced that we had dosed the first patients with NKX019 in the Phase 1 clinical trial.

Apply our NK cell engineering platform to build a broad pipeline of product candidates incorporating engineered NK cells.

Our proprietary NK cell engineering platform is based on a modular and generalizable approach that we believe enables us to generate new product candidates in a rapid and cost-efficient manner. Our engineered CAR-NK cells generally consist of an NK cell engineered with a targeting receptor, OX40 costimulatory domain, CD3ζ signaling moiety, and mbIL-15. We believe the modular nature of our platform and the proprietary technologies we use for the multiplex engineering of NK cells are advantages that can support the rapid generation of new INDs for product candidates with enhanced properties and/or new targeting receptors for additional disease indications. With these attributes, we plan to continue to build out a pipeline with product candidates focused on novel targets as well as clinically and commercially validated targets. With our partner, CRISPR, we are also engaged in preclinical research for CD70 CAR-NK and NK+T, which may provide advantages of both the innate and adaptive immune responses.

Continue to build proprietary manufacturing capabilities to enable speed, control, flexibility, scalability, and cost efficiency.

We believe that internal cGMP manufacturing capabilities will facilitate clinical product supply, lower the risk of manufacturing disruptions, and enable more cost-effective manufacturing for clinical and commercial supply of our product candidates. We are currently manufacturing NKX019 product for the Phase 1 clinical trial at our 2,700-square foot clinical cGMP facility on-site at our primary corporate location in South San Francisco, California. We intend to manufacture NKX101 and at our cGMP facility in 2022, and in the future, we intend to manufacture the proprietary, engineered K562 stimulatory cells (“NKSTIM”) in house. We believe this clinical cGMP facility will supply our anticipated non-pivotal clinical trial needs.

We are also currently designing a separate, larger commercial cGMP facility for manufacturing. In July 2021, we entered a lease agreement for an 88,000 square foot facility in South San Francisco to support research and development and future manufacturing of Nkarta's cell therapy products and product candidates, including engineered NK cells for pivotal clinical trials and potential commercial supply. This new facility will also serve as our future headquarters with office space and research facilities.

Continue to opportunistically evaluate enabling, adjacent or potential competing technologies, and where advantageous, seek licenses or collaborations regarding those technologies, to advance our platform.

We will continue to evaluate technologies that may enable or enhance our various product candidates, and we will maintain awareness of those that may provide a broader cell therapy engineering or manufacturing platform for us. To facilitate the advancement of our engineering and manufacturing platforms, we routinely engage in partnering and licensing discussions with a range of biotechnology or pharmaceutical companies and academic institutions.

COVID-19 Business Update

The COVID-19 pandemic has affected and may continue to affect our business and operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct and enrollment of current and future clinical trials. For a discussion regarding the impact of the COVID-19 pandemic on our business, see Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations-Overview of our Business" in this Form 10-K.

The Immune System and Cancer

In recent decades there has been a significant level of innovation and improvement in the treatment of different cancers with the introduction of new therapeutic approaches and the approval of new therapies. Despite these advances, many of the most common cancers remain burdened with substantial unmet medical need. Immuno-oncology therapies seek to stimulate or supplement a person's own immune system to attack cancer cells selectively without affecting normal cells, or deliver certain immune system components in order to inhibit the spread of cancer. Immuno-oncology therapy has emerged as an important mode of cancer treatment, alongside more established options such as surgery, chemotherapy, targeted therapy and radiation therapy.

The ability of the immune system to recognize and destroy tumors has been known for over 100 years. More recently, a growing understanding of molecular mechanisms underlying recognition of cancer cells by the immune system and their evasion of detection has allowed scientists to develop new classes of immuno-oncology therapies. These therapies either undermine the tumor's ability to resist immune attack or enhance immune targeting and killing of cancer cells.

Cellular Immunotherapies

Cellular immunotherapy is a type of immuno-oncology therapy whereby human cells are engineered to recognize and destroy cancer cells in a more targeted manner. Most cellular immunotherapies are focused on modulating or enhancing the activity of different lymphocytes, a subtype of white blood cell that are responsible for defending the body against infectious pathogens and other foreign material, as well as killing cancerous cells within the body. There are several different classes of lymphocytes which differ in their natural function. T cells are a type of lymphocyte that primarily serves to protect from infectious invaders such as bacteria, viruses, fungi and parasites. Every individual T cell recognizes a different specific antigen, or proteins found on the surface of infectious pathogens or foreign tissue. This type of lymphocyte is activated and divides rapidly only when it detects its specific antigen. Accordingly, T cells are the foundation of the adaptive immune system, because they selectively respond to different threats when they occur.

NK cells are the foundation of the innate immune system. While T cells are activated by unique antigens specific to each individual T cell, the activity of NK cells is tightly regulated by a common set of activating receptors on these cells that serve to recognize and kill cancerous or virally infected cells, as well as a set of inhibitory receptors that identify healthy cells from the same individual. This balance of inhibition and activation spares healthy cells from the surveillance and killing effects of the innate immune system. The primary activating receptor for NK cells is known as NKG2D and functions by detecting eight known stress ligands, or signals that cancerous or virally infected cells produce. The detection of these stress ligands by NKG2D on the surface of the NK cells is the primary basis for tumor surveillance by NK cells and is the basis of the mechanism of action for our product candidate NKX101.

A frequently used approach for cellular immunotherapy involves CARs on the surface of a lymphocyte that enable the cell to recognize specific proteins or antigens that are present on the surface of tumor cells. The concept of a CAR builds upon and enhances the normal biology of T cells and NK cells, whereby naturally occurring receptors serve to activate these cells when a foreign pathogen or cancerous cell is detected. The key components of CARs used today often include the following elements:

- **Target binding domain.** At one end of the CAR is a binding domain that is specific to a target antigen or protein. This domain extends out from the surface of the engineered lymphocyte, where it can recognize the target antigen or antigens. The target binding domain may be based upon a naturally occurring receptor, such as the NKG2D receptor for NKX101, or a binder derived from a monoclonal antibody against a target antigen, such as the CD19 binder for NKX019.
- **Transmembrane domain and hinge.** This middle portion of the CAR links the target binding domain to the activating elements inside the cell. This transmembrane domain anchors the CAR in the cell's membrane. In addition, the transmembrane domain may also interact with other transmembrane proteins that enhance CAR function. The hinge domain, which extends to the exterior of the cell, connects the transmembrane domain to the binder and provides structural flexibility to facilitate binding to the target antigen on the surface of the cancer cell.
- **Activating domains.** The other end of the CAR, inside the lymphocyte, includes domains responsible for activating the lymphocyte when the CAR binds to its target antigen. The first, found in almost all CAR constructs, is called CD3ζ and is the natural basis for lymphocyte activation. The second is called a costimulatory domain, is found in the most recent generation of CARs under development today and provides an additional activating signal. Together, these signals trigger lymphocyte activation, resulting in proliferation of the CAR cells and killing of the cancer cell. In addition, activated CAR cells stimulate the secretion of cytokines and other molecules that can thereby recruit and activate additional immune cells to increase killing of the cancer cells.

The United States Food and Drug Administration ("FDA") has approved five CAR-based T cell therapies for the treatment of certain types of cancer affecting B-cells since 2017. Each of these therapies is an autologous therapy, or derived from a patient's own cells, which necessitates a complex, individualized manufacturing process for every patient treated. The approvals of these patient-specific cell therapies were a landmark event for many reasons, including the ability to treat and provide long-term remission for otherwise deadly disease; achieving the run-to-run product consistency required by the FDA despite the complex manufacturing required; and achieving successful reimbursement in the U.S. and other countries of several hundred thousand dollars per treatment.

Limitations of Current CAR-T Therapies

Despite the ability of the approved autologous CAR-T therapies to achieve anti-tumor responses and extend the survival of patients with advanced B-cell malignancies, these therapies have certain features that are believed to limit their broader adoption. These features include:

- **Adverse events.** According to the product labels for the three approved CAR-T therapies, cytokine release syndrome ("CRS") was observed in 46% to 94% of patients treated in the respective pivotal clinical trials. In addition, neurotoxicity was seen in 35% to 87% of patients treated in such trials. Because of the frequency and severity of these adverse events, patients treated with the approved CAR-T therapies can require a lengthy stay in an intensive care unit and costly ancillary care.

- **Limited availability.** As a condition of FDA approval, treatment with approved CAR-T therapies is currently limited to select centers due to safety, logistical and regulatory reasons under a Risk Evaluation and Mitigation Strategy ("REMS") Program.
- **Lengthy manufacturing time.** Due to the individualized manufacturing process, patients must wait approximately two to four weeks to be treated with their engineered cells. In the registrational trials for the first four approved CAR-T therapies, 7% to 34% of enrolled patients did not receive CAR-T cells, for reasons including manufacturing failure as well as patient progression or death while waiting for manufacturing.
- **Variable potency.** In many cases, patients have T cells that have been damaged or weakened due to prior chemotherapy or hematopoietic stem-cell transplant ("HSCT"). Compromised T cells may not proliferate well during manufacturing or may produce engineered T cells with insufficient potency that cannot be used for patient treatment. This can result in outright manufacturing failures as well as cells with poor expansion and activity in a patient. The individualized nature of autologous manufacturing, together with the inconsistency in patients' T cells, can cause variable and unpredictable treatment outcomes.
- **High manufacturing complexity and cost.** The manufacture of autologous T cell therapy is individualized and labor-intensive. The collection of T cells through leukapheresis from each individual patient is a time-consuming and costly step in the autologous manufacturing process. In contrast to traditional pharmaceutical manufacturing where a single manufacturing run generates product for hundreds or thousands of patients, a full manufacturing run of autologous T cell therapy generates product for a single patient. In addition, autologous T cell therapy requires specialized infrastructure to maintain a strict chain of custody and identity of patient cells throughout collection, manufacturing and delivery, adding significant cost to the process and limiting the ability to scale.

These limitations are difficult to address as many are inherent to fundamental aspects of T cell biology. CRS, which accounts for many of the adverse events which in part limit availability, is believed to be a consequence of the exponential expansion of T cells upon detection of a target antigen. Manufacturing time, product variability, and cost are due in great part to the autologous nature of approved CAR T therapies. These limitations might be mitigated by using donor-derived allogeneic T cells, but application of allogeneic T cells without additional gene edits, human leukocyte antigen ("HLA"), matching or modifications carries a high risk that donor T cells might recognize the recipient as "non-self" and cause graft-versus-host disease ("GVHD"), a serious or life-threatening condition where the donor's T cells attack the recipient's body.

Allogeneic Cell Therapies

The development of allogeneic, off-the-shelf cell therapies addresses certain limitations of autologous CAR-T cells by offering these potential advantages:

- **Availability.** Because an allogeneic cell therapy is produced in quantity with cells from a healthy donor and then frozen, it would be available for the treatment of patients without delay.
- **Consistency.** By using cells from a healthy donor as starting material, and producing large numbers of doses per manufacturing run, an allogeneic cell therapy provides the opportunity for more rigorous quality control and release of consistent engineered cells.
- **Cost of manufacturing.** An allogeneic cell therapy provides an opportunity to spread manufacturing costs across a large number of doses, thereby significantly lowing the cost per dose produced.

The Opportunity for Engineered NK Cells in Treating Cancer

The development of CAR-NK therapies can capitalize on the knowledge and experience gained from decades of CAR-T research. Furthermore, the biology of NK cells offers potential advantages as the starting cell type for allogeneic, off-the-shelf engineered cell therapy. These advantages include:

- **Inherent anticancer activity.** We conducted a systematic literature review of published clinical trial results of allogeneic NK cells in cancer, which identified a 34% composite response rate ("Aggregate CR Rate") among 103 patients with relapsed or refractory AML who were treated with non-engineered NK cells across six academic clinical studies. The Aggregate CR Rate includes complete remission with hematologic recovery ("CR"), complete remission with incomplete hematologic recovery ("CRi"), and morphologic leukemia free state ("MLFS"). These data demonstrate the anticancer activity of endogenous NK cells, and support the opportunity for increasing the activity of NK cells through engineering.
- **Allogeneic and off-the-shelf without gene editing or other modifications.** Because NK cells are not generally activated by "non-self" cells, further modification of NK cells is not necessary to avoid the risk of GVHD and thereby produce an allogeneic, off-the-shelf engineered NK cell therapy.
- **Modest clonal expansion and therefore potential reduced CRS risk.** While T cells experience exponential growth when activated by a target antigen, NK cells expand only modestly upon activation. The explosive growth of T cells is believed to be the basis of the risk of CRS when CAR-T cells are administered to patients. However, a significant incidence of CRS has not been reported in medical literature for NK cell therapy.
- **Balance of activation and inhibition.** The activity of NK cells is tightly regulated by a common set of activating receptors that serve to recognize and kill cancerous or virally infected cells, as well as a set of inhibitory receptors that identify healthy cells from the same individual. This balance of inhibition and activation spares healthy cells from the surveillance and killing effects of the innate immune system. Therefore, the fundamental biology of CAR-NK cells drives their ability to discriminate between healthy and tumor cells.
- **Ability to overcome tumor evasion of the immune system.** Many solid tumors are able to evade the immune system by creating an immunosuppressive environment around the cancerous cells, which can dramatically reduce the normal tumor-killing ability of the immune system. This tumor microenvironment involves down-regulators of immune response, including regulatory T cells and myeloid-derived suppressor cells. However, these cell types also display NKG2D ligands, and preclinical models demonstrate that clearance of these cells can reduce immune suppression from the tumor microenvironment. Therefore, by acting through NKG2D, CAR-NK cells may be able to reduce the immune suppression of the tumor microenvironment, and therefore uncover a broader opportunity for immuno-oncology cell therapy development for the treatment of solid tumors.

Clinical Activity and Tolerability of Non-CAR NK Cells

In early 2019, we conducted a systematic literature review of clinical trial results published in English from 2005 onwards that described the effect of allogeneic NK cell transfusions from healthy donors in the treatment of cancer patients. We identified a total of 32 academic clinical trials that enrolled a combined total of 586 patients. Key findings from this systematic literature review include:

- The most common indications were AML and a related disease, MDS, with a combined 57% of subjects having one of these diseases. In addition, 20% had solid tumors, most commonly neuroblastoma (6% overall) and sarcoma (3% overall).
- Most patients (57% overall) received non-engineered, allogeneic NK cells along with HSCT, which is a potentially curative procedure for certain blood cancers. Cyclophosphamide and fludarabine ("Cy/Flu") lymphodepleting ("LD") conditioning was used most frequently when cells were administered in the non-transplant setting (60% of these patients). This lymphodepleting chemotherapy temporarily prevents the clearance of the transfused NK cells by the recipient's immune system, providing an opportunity for the transfused cells to kill cancerous cells.

- The most common source of NK cells was haplomatched related donors, those from a close relative with at least 50% matching for a set of proteins known as HLA. These haplomatched donor/recipient pairs comprised 95% of the patients we identified.
- In general, systemic NK cell transfusions were well tolerated. Commonly reported adverse events included low-grade symptoms such as fever and chills. Higher-grade events reported were low numbers of various blood cells, or cytopenias, and infections which most often arose after HSCT. In the non-HSCT setting, no GVHD and minimal CRS events and neurotoxicities were reported.
- Although there was inconsistency in sampling for donor NK cell persistence, peak levels of allogeneic NK cells occurred at a median of 10 to 11 days post-infusion across the various trials. Another academic study demonstrated that the transfused allogeneic NK cells were cleared commensurate with recovery of the patient's immune system after lymphodepleting chemotherapy, generally within 14 to 21 days.
- Among the 103 patients with relapsed or refractory AML treated with non-engineered NK cells after lymphodepleting chemotherapy in the non-transplant setting across seven published studies, 35 patients (34%) achieved a response to NK cell therapy alone. These responses included 20 CRs, 12 CRis, 2 complete responses with incomplete platelet recovery ("CRp"), and 1 patient who obtained a MLFS.

Clinical Activity and Tolerability of CAR-NK Cells

Early clinical data with CAR-NK cells also support the opportunity for using engineered NK cells to treat cancer. In 2020, a team of researchers at M.D. Anderson Cancer Center in Houston, Texas reported in the New England Journal of Medicine on a cohort of patients in a single-site study with various B-cell malignancies, including diffuse large B-cell lymphoma ("DLBCL"), chronic lymphocytic leukemia ("CLL"), and follicular lymphoma, who were treated with freshly prepared CAR-NK cells targeting CD19. These CAR-NK cells were derived from umbilical cord blood and engineered to express a secreted form of IL-15 as well as a CAR construct containing a CD19-targeting binder and a CD28 costimulatory domain. Of the 11 patients treated, eight achieved responses within 30 days of single infusion, with seven achieving a complete response and five receiving post-remission therapy. The patients had already received a median of four prior rounds of therapy, and four patients had relapsed after stem cell transplant, which is considered the only curative therapy after the failure of front-line treatment for these diseases. No GVHD, CRS or neurotoxicity was reported.

We believe that the clinical activity and tolerability profile of these allogeneic CAR-NK cells further validate the opportunity for engineering NK cells to treat cancer.

Challenges with Developing NK Cell Therapies

We believe that the emerging data from the aforementioned studies of NK cell products along with the prior academic experience with NK cells validate the opportunity for NK cells for the treatment of different cancers. To achieve a commercially viable engineered NK cell therapy, we believe that a number of challenges inherent with NK cells must be addressed. These include the following:

- **Expansion.** One of the historical challenges in treating patients with NK cells has been the lack of robust techniques to grow these cells in large numbers without causing exhaustion, or the inability of the expanded NK cells to kill tumor cells with the same potency as native NK cells.
- **Engineering.** Primary NK cells have been reported to be difficult to engineer efficiently. Poor efficiency of engineering could limit the potency and consistency of engineered NK cell therapies.
- **Persistence.** Non-engineered human NK cells turn over rapidly, with a half-life of seven to 10 days in the body. This short lifetime limits the cancer-killing ability of these NK cells.
- **Cryopreservation.** Without cryopreservation, a truly off-the-shelf engineered NK cell therapy would be challenging to commercialize. However, freezing then thawing NK cells while maintaining cancer cell killing potency is difficult to achieve using standard techniques for T cell cryopreservation.

Our NK Cell Engineering Platform

Our cell engineering platform is designed to operationalize the full therapeutic potential of NK cells and address the limitations and challenges of current technologies for engineering T cells and NK cells. The platform is a result of our internal expertise and deep understanding of NK cell biology. It includes proprietary technologies for NK cell expansion, persistence, targeting and cryopreservation. This enables us to generate an abundant supply of NK cells, engineer enhanced NK cell recognition of tumor targets, improve the persistence of these cells for sustained activity in the body, and to freeze, transport and store our engineered NK cells for off-the-shelf use for the treatment of cancer.

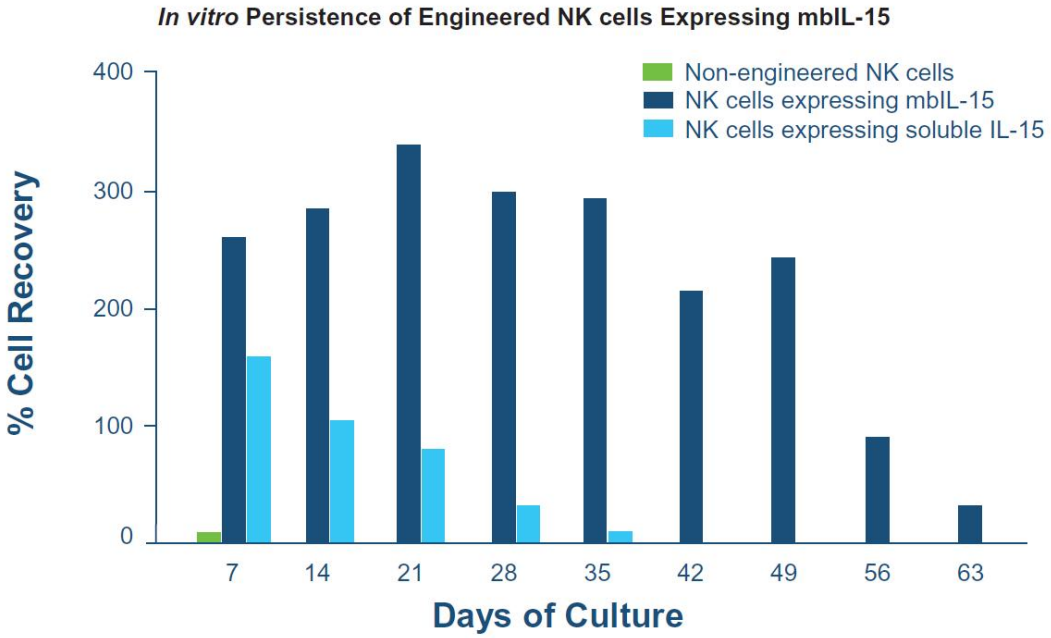
We have chosen to use healthy adult donors as our source for NK cells. We believe this offers a number of advantages including:

- Starting with bona fide NK cells with inherent cytotoxic and tumor-recognizing capabilities, as compared to other cell sources such as stem cells, where these fundamental features must be engineered into the cells;
- A large number of NK cells as starting material for each manufacturing run, as compared to other potential sources of NK cells;
- The ability to select donors with consistent and favorable NK cell characteristics, thereby avoiding challenges with patient-derived or other cell sources; and
- A diverse repertoire of NK cells. Different NK cell sub-populations have different characteristics, and by utilizing the entire natural gamut of NK cells as our cell source, we can capitalize on the inherent diversity of the innate immune system.

Below are the five core technologies that comprise our proprietary platform. Each of these technologies is part of an integrated approach to develop potent, scalable, and consistent NK cell products:

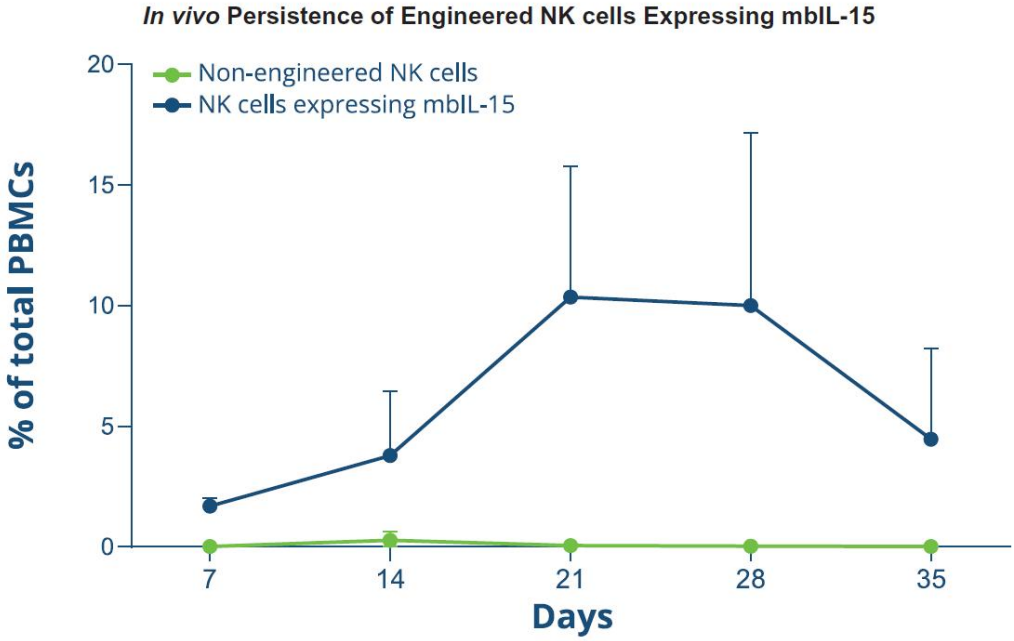
Expansion. The first pillar of our technology platform enables NK cell expansion without causing cell exhaustion. Our academic founder, Dario Campana, M.D., Ph.D., developed a proprietary cell line based on engineering of a publicly available cancer cell line called K562. Our proprietary, engineered K562 stimulatory cell line has been engineered with mbIL15 as well as a protein named 4-1BB ligand ("4-1BBL"). IL-15 is a naturally occurring growth protein that induces cell proliferation in NK cells. 4-1BBL binds to 4-1BB, a receptor normally found on NK cells that stimulates NK cell division and expansion. Therefore, our proprietary, engineered K562 cell line is selectively able to stimulate the expansion of NK cells as compared to other leukocytes, and thereby provide large numbers of NK cells. Based on our pilot scale experiments and early cGMP manufacturing experience, we believe that we can produce many hundreds of doses from a single manufacturing run. We also believe that we can achieve a cost of manufacturing for commercial NKX101 and NKX019 at peak capacity of approximately $2,000 per dose, based on achieving 500 doses per manufacturing run at a dose of one billion CAR-NK cells per dose and on our current estimates for the costs of raw materials, consumables, rent, construction, equipment, labor and overhead.

Persistence. Pharmacokinetics of allogeneic NK cells will be limited by both immune suppression of allogeneic cells following lymphodepletion, and by the intrinsic half-life of the administered cells. The second component of our technology platform is engineering NK cells with mbIL-15 to enhance persistence relative to non-engineered NK cells. We believe increased persistence could result in improved clinical activity. Because IL-15 is a selective driver of NK activation and expansion, tethering IL-15 to the surface of our engineered NK cells serves to stimulate the naturally occurring IL-15 receptor on these NKs, and thereby provide weeks of persistence in immune-deficient animal models. Because mbIL-15 selectively stimulates NK cells without elevating soluble IL-15 concentration, we believe that mbIL-15 provides meaningful advantages as compared to secreted IL-15 or the systemic administration of other cytokines such as IL-2 or IL-21. The first graph below shows data from a cell culture experiment which demonstrates the increase of the number and persistence of NK cells engineered with mbIL-15, as compared to unmodified NK cells or NK cells expressing soluble IL-15. The second graph below shows the increased number and persistence in mice of NK cells engineered with mbIL-15, as compared to unmodified NK cells, as a percentage of total peripheral blood mononuclear cells ("PBMCs").



Evaluation of the effect of soluble IL-15 and mbIL-15 on the numbers of NK cells in cell culture.

Source: Imamura et al., Blood. 2014 Aug 14;124(7):1081-8

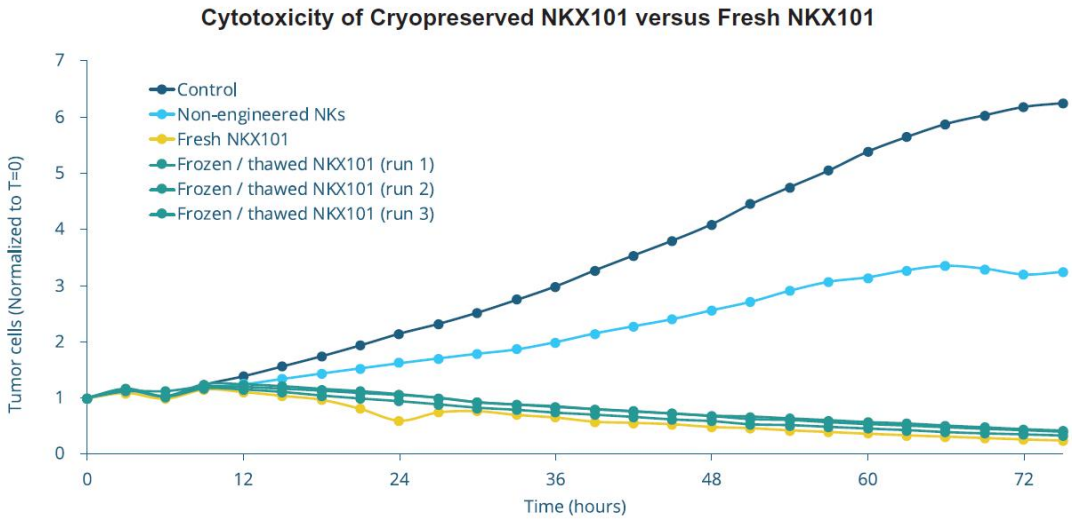


Effect of the addition of mbIL-15 to the longevity of circulating NK cells in a mouse model. At day 0, comparable numbers of NK cells were introduced to all mice in both experimental arms.

Targeting and Signaling. The third element of our technology platform is CARs optimized for NK cells, based on extensive preclinical evaluation of different possible constructs. We have performed extensive optimization of the CARs that serve to target our engineered NK cells to cancer cells as well as provide signals that engage the cancer cell killing activity found naturally in NK cells. For both NKX101 and NKX019, we have found that using the OX40 costimulatory domain enhances the ability of the engineered NK cells to kill cancerous cells repeatedly in several *in vitro* models, as compared to CAR-NK cells that include other costimulatory domains commonly used for CAR-T cells. We confirmed these findings in animal models for both product candidates.

Gene Editing. The fourth component of our platform is the ability to edit our NK cells using CRISPR Cas9 technology. Through our collaboration with CRISPR, we have identified a number of genomic modifications that serve to further enhance the cytotoxicity and resistance to tumor-mediated immune suppression. We have shown that knocking out certain genes can prolong the persistence and activity of CAR-NK cells, and improve their resistance to suppression by the tumor microenvironment.

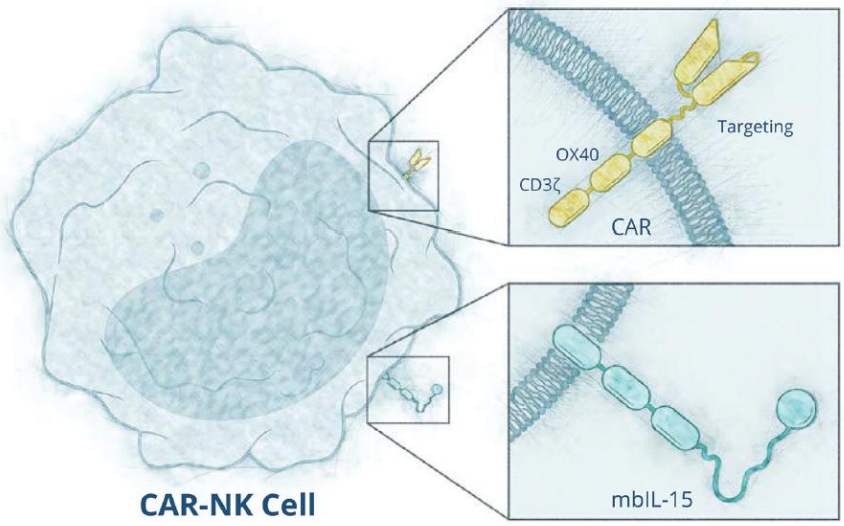
Cryopreservation. The fifth constituent of our technology platform is cryopreservation of our engineered NK cells, the ability to freeze and store these cells for an extended time. The development of robust cryopreservation techniques is a result of our insight into the biology of engineered NK cells as well as extensive experimental optimization. Based on our preclinical data, we are able to freeze and subsequently thaw individual doses of engineered NK cells without significant loss of cancer cell killing potency of our engineered NK cells as shown in the graph below. Cryopreservation of our allogeneic CAR-NK cells will enable their off-the-shelf use in medical centers around the world, for administration to a patient at any time. Therefore, we believe that our cryopreservation of CAR-NK cells will enable us to achieve the attractive commercial profile of an off-the-shelf, allogeneic cell therapy.



Cryopreserved NKX101 retains cytotoxicity similar to fresh NKX101 in a long-term assay.

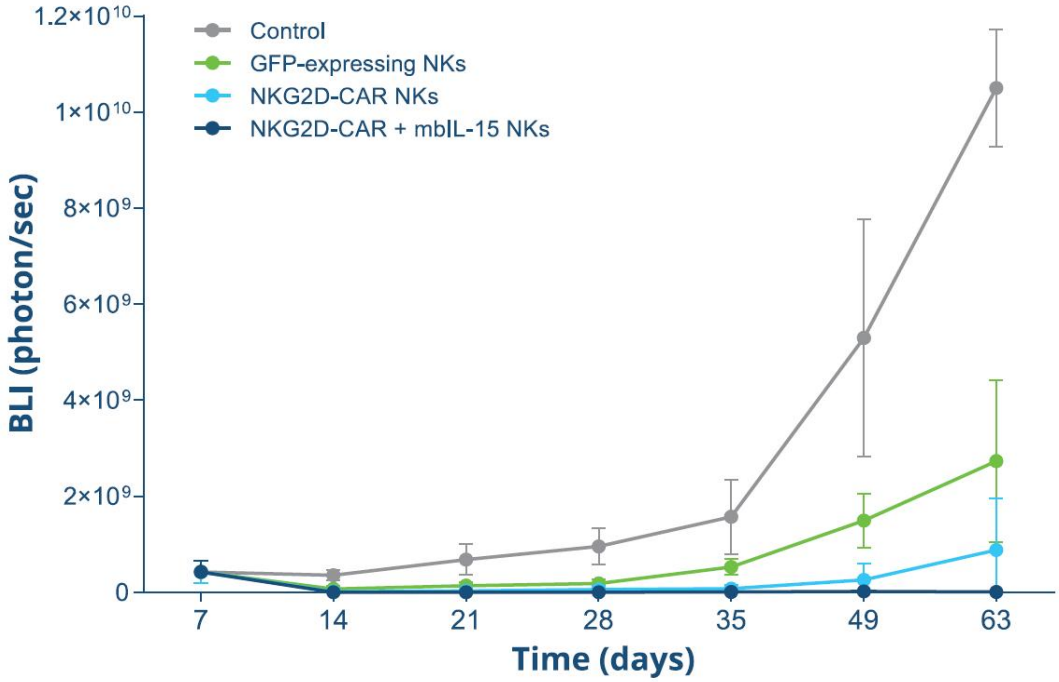
We believe that these key elements of our technology platform have the potential to grant us a key competitive advantage if our product candidates are approved. As illustrated in the image below, our engineered CAR-NK cells generally consist of an NK cell engineered with a swappable targeting receptor, OX40 costimulatory domain, CD3ζ signaling moiety, and mbIL-15.

Key Components of our Engineered CAR-NK cells



We demonstrated the potential power of combining the different elements of our technology platform in the discovery and preclinical development of NKX101. In a model of osteosarcoma, the treatment of mice with NK cells engineered to express mbIL-15 and an early version of the NKG2D ligand targeting CAR resulted in durable suppression of tumor cell growth for 63 days whereas treatment of mice with NK cells engineered to express the CAR alone, or with NK cells lacking a CAR, resulted in a significant reduction in the control of tumor growth. The effect on tumor growth when we combine an NKG2D-CAR with mbIL-15 is shown visually and graphically in the figure below.

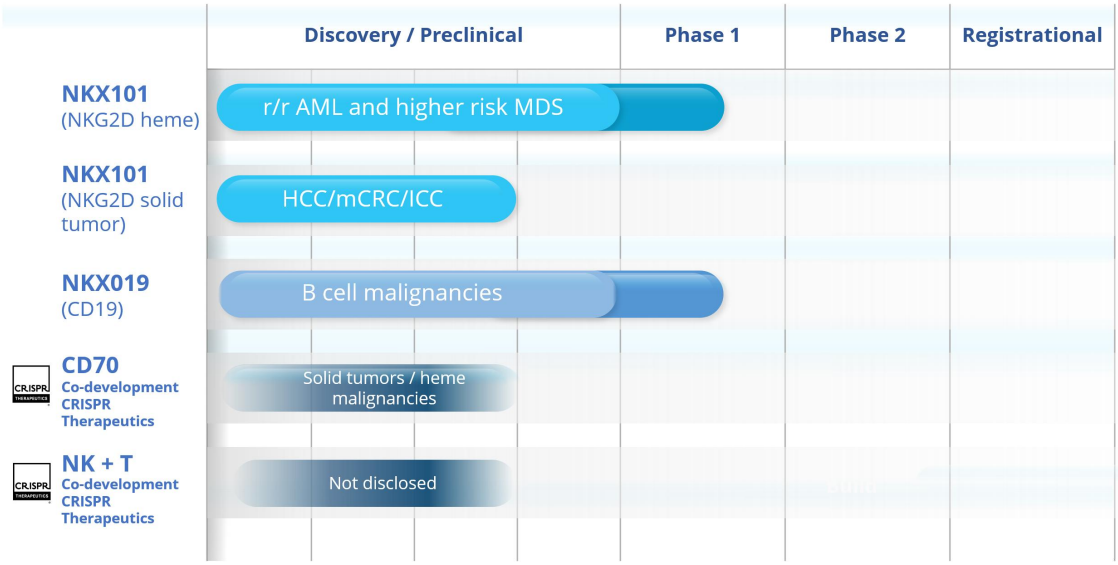
***In vivo* Suppression of Tumor Growth with NKG2D-CAR NK cells and NKG2D-CAR + mbIL-15 NK cells (graphical)**



The graphical data above are an average of the mice studied in the osteosarcoma mouse model shown above.

Our Pipeline of Product Candidates and Discovery Programs

All of our product candidates and discovery programs incorporate each of the four components of our technology platform, which we believe provides the best opportunity for achieving clinically meaningful results in our development program. Our current pipeline of product candidates and discovery programs is shown below.

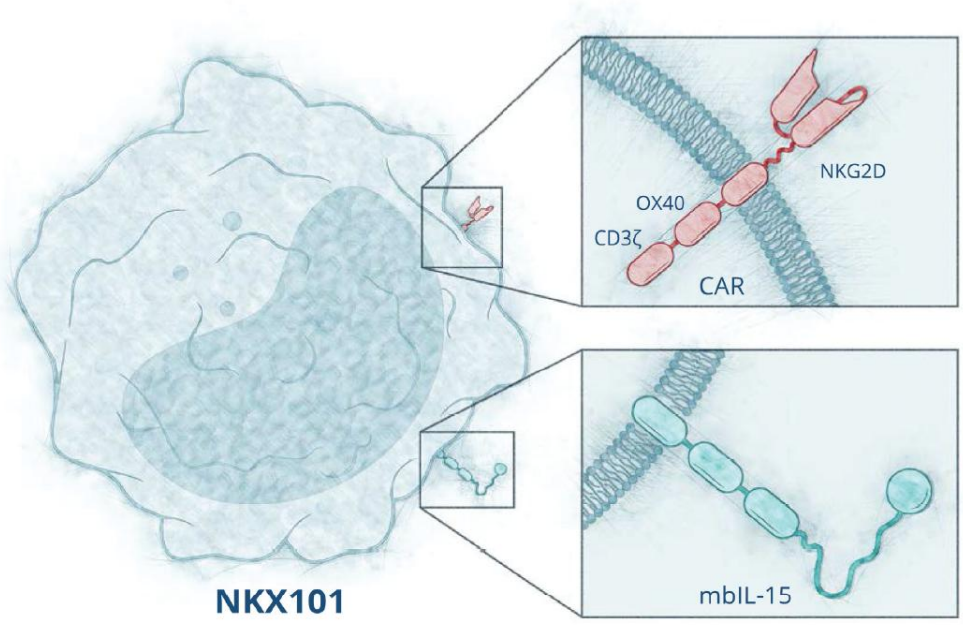


NKX101

Our product candidate NKX101 consists of allogeneic, donor-derived and expanded NK cells that have been genetically engineered to express mbIL-15 along with a CAR containing an NKG2D activating receptor, an OX40 costimulatory domain and a CD3ζ signaling moiety. We have designed NKX101 to increase longevity, potency and activity as compared to non-engineered NK cells. NKG2D is the primary activating receptor for NK cells and functions by detecting eight known stress ligands, signals produced by cancerous or virally infected cells. The detection of these stress ligands by NKG2D is the primary basis for tumor surveillance by NK cells and is the basis of the mechanism of action for NKX101. We believe the activity of non-engineered NKs in treating cancer validates targeting NKG2D ligands through the NKG2D receptor as the mechanism of action for NKX101. In November 2020, we announced that patient dosing began in a Phase 1 monotherapy clinical trial investigating NKX101 for the treatment of relapsed or refractory AML and higher-risk MDS. This multi-center, first-in-human study evaluates the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX101 administered in a cycle of either three weekly infusions (Regimen A) or two weekly infusions (Regimen B) following lymphodepletion. Based on tumor response and tolerability, multiple treatment cycles can be administered. The clinical trial consists of dose-finding followed by dose-expansion and is designed to identify the recommended Phase 2 dose.

In December 2021, we announced that the FDA granted orphan drug designation to NKX101 for treatment of AML. We also plan to advance the development of NKX101 in solid tumor indications, including liver cancer, a bile duct cancer known as cholangiocarcinoma, as well as surgically removed colon cancer cases where only liver metastases remain. In February 2022, we filed a protocol amendment with the FDA for the ongoing Phase 1 clinical trial of NKX101 to optimize the study design for maximum benefit and flexibility as the company prepares for potential dose expansion cohorts. The amended protocol allows for a higher dose of cyclophosphamide for lymphodepletion, enrollment of patients who have received as few as 1 to 2 prior lines of therapy, and increased dosing of NKX101.

Schematic of NKX101



We created NKX101 based on our understanding of NK cell biology, including extensive comparison and optimization of different ways to enhance natural NKG2D signaling and targeting of cells which display NKG2D ligands. Based on our preclinical studies, we believe levels of NKG2D are increased at least ten-fold in NKX101 as compared to non-engineered NK cells. Because NKG2D is the primary activating receptor for NK cells, through its detection of stress ligands displayed by cancerous cells, NKX101 is thereby designed to increase the natural cancer cell killing ability of NK cells. Although some cancer cells are able to evade detection and killing by NK cells through shedding of NKG2D ligands, thereby reducing ligand display on the cell surface and creating soluble decoys, NKX101 maintains its ability to recognize tumor cells through increased numbers of NKG2D receptors and more potent signaling from those engineered receptors. Furthermore, we found in preclinical studies that the addition of mbIL-15 and the OX40 costimulatory domain each increase the activity of engineered NK cells. Because NKG2D is the primary activating receptor responsible for innate immune surveillance of cancerous cells, we believe that NKX101 presents a broad opportunity to treat a variety of blood cancers, as well as, potentially, solid tumors, which collectively represent approximately 90% of all cancer incidences in the United States.

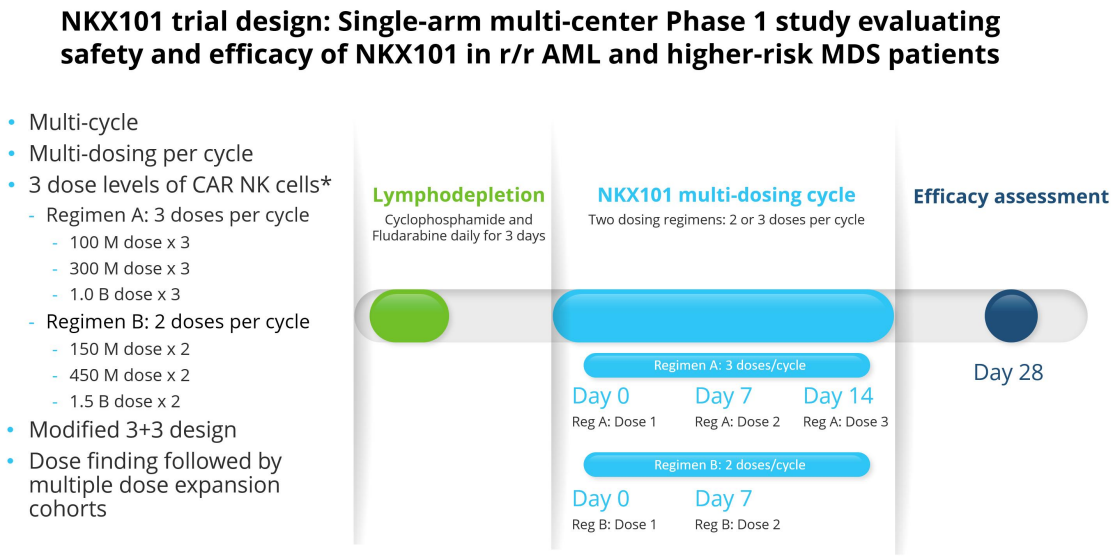
NKX101 for Blood Cancers

In November 2020, we announced that the first patient in a Phase 1 clinical trial of NKX101 for the treatment of relapsed/refractory AML or higher risk MDS had been treated. This multi-center clinical trial is designed to evaluate safety, pharmacokinetics, and preliminary anti-tumor activity of NKX101. According to the federal Surveillance, Epidemiology, and End Results Program database ("SEER"), the incidence of AML in the United States is approximately 20,000 cases per year, and newly-diagnosed patients have a five-year survival rate of approximately 30%. We believe there is a substantial unmet medical need for patients with relapsed or refractory AML and higher-risk MDS and that these diseases represent a significant market opportunity.

Our ongoing Phase 1 clinical trial comprises standard dose-finding and dose expansion phases. Patients are expected to receive lymphodepleting chemotherapy prior to administration of NKX101 in order to allow our engineered NK cells the opportunity to kill cancerous cells without first being cleared by the patient's immune system. The lymphodepletion regimen being used in the NKX101 clinical trial is based upon the most commonly used regimen found in our systematic literature review of allogeneic cells and is also similar to that used for the four approved CAR-T therapies.

The relationship between the degree of HLA matching and the clearance of donor NK cells by the patient's immune system has not been conclusively demonstrated. We initiated the dose escalation Phase 1 clinical trial for NKX101 using NK cells from haplorelated donors manufactured in a patient-specific manner. Our intention is to develop and commercialize NKX101 without any HLA matching, and we modified the clinical protocol by submitting an amendment to the FDA in the first quarter of 2021. This amendment was subsequently approved by the FDA and allows for the evaluation of unrelated donor, off-the-shelf NKX101 in the ongoing dose finding cohort. Furthermore, the amendment includes an overall shorter waiting period between enrollment of patients, and an additional two-dose regimen which increases patient convenience and delivers more CAR NK cells earlier in each treatment cycle. This first-in-human study is currently evaluating the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX101, administered in a cycle of either three weekly infusions (Regimen A) or two weekly infusions (Regimen B) following lymphodepletion in multiple centers in the US. The clinical trial consists of parallel dose-finding in both Regimens followed by dose-expansion and is designed to identify the recommended Phase 2 dose.

The dosing schema is shown in the graphic below. Our starting dose of 100 million cells is based upon the established tolerability of non-engineered NK cells from academic literature.



*Protocol amendment includes option for increased dosing of NKX101

While we expect that the initial subjects treated with NKX101 in clinical studies will be hospitalized for a minimum of 24 hours observation after infusion, a favorable tolerability profile may potentially allow for administration of NKX101 in an outpatient setting. This could represent a significant competitive advantage for NKX101 and our engineered NK product candidates more generally, as compared to the approved CAR-T therapies.

NKX101 for Solid Tumors

We also plan to evaluate NKX101 in patients with solid tumors. We expect our initial solid tumor clinical trial to include patients with liver cancer, a bile duct cancer known as intrahepatic cholangiocarcinoma, as well as patients with surgically removed colon cancer where only liver metastases remain. These tumors represent an

attractive opportunity for the initial solid tumor indication for NKX101 for several reasons, including the overexpression of NKG2D ligands in many liver cancers, the opportunity to deliver NKX101 directly to the liver and the substantial unmet medical need for the treatment of these cancers. According to the federal SEER database, the incidence of liver and intrahepatic cholangiocarcinoma in the U.S. is approximately 42,000 cases per year, and the five-year survival rate is approximately 20%.

We plan to deliver our engineered NK cells directly to the site of the tumor by injection into the hepatic artery, a standard technique for delivering anticancer drugs to the liver which has also been used for the delivery of CAR-T cells and unmodified NK cells to the liver. This method takes advantage of the differential blood supply in the liver and the localization of tumor tissue, where tumor tissue is predominantly supplied by the hepatic artery and surrounding liver is predominantly supplied by the portal vein. By injecting into the hepatic artery, this technique allows us to concentrate cells specifically to the tumor area. Because the liver to some degree naturally excludes the immune cells that can clear allogeneic NK cells, lymphodepleting chemotherapy prior to administration is not planned. However, we may choose to add this element based on data from this clinical trial.

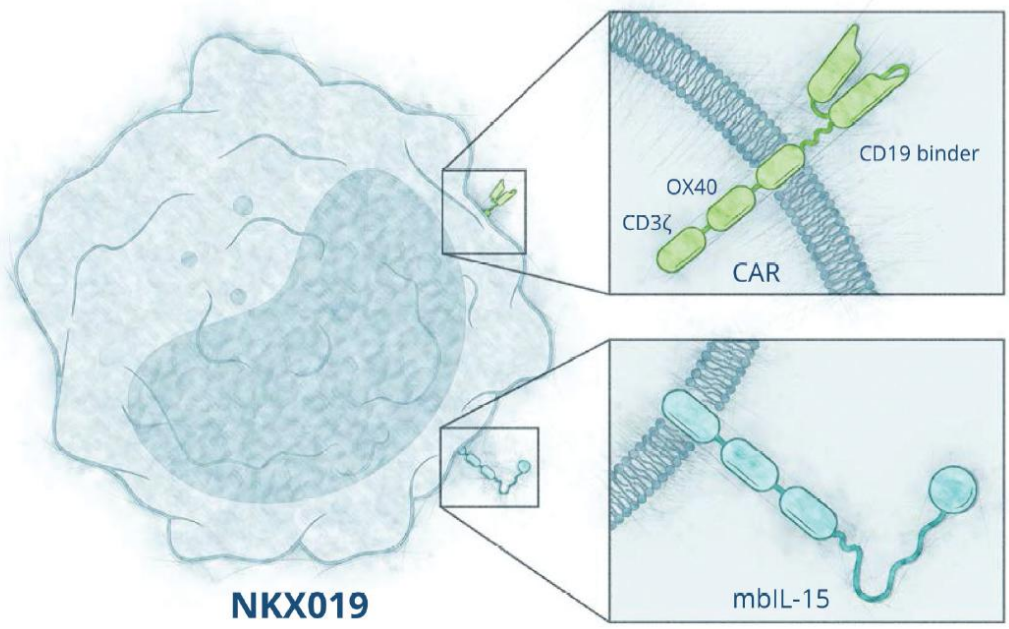
We are planning to file an IND amendment for this clinical program in the second half of 2022, with the first patient receiving NKX101 thereafter. The NKX101 Phase 1 trial in solid tumors may also incorporate a dose-finding and dose-expansion component and potential combinations.

If this program is successful, we believe that it would establish proof of concept for treating solid tumors with engineered NK cells, and enable us to evaluate a broader solid tumor clinical development program.

NKX019

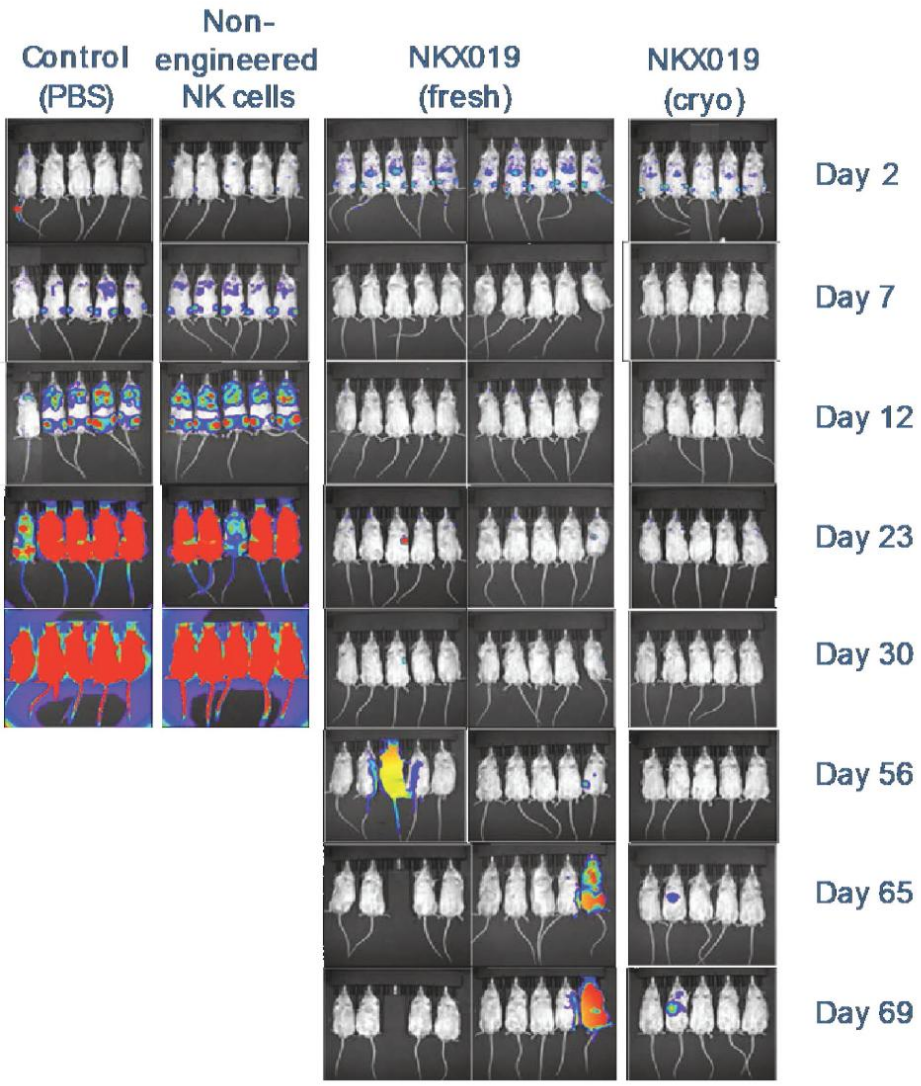
Our product candidate NKX019 is for the treatment of various B-cell malignancies, including DLBCL, ALL, and several other B-cell malignancies. NKX019 consists of allogeneic, donor-derived and expanded NK cells that have been genetically engineered to express mbIL-15 along with a CAR containing a CD19 binder, an OX40 costimulatory domain and a CD3ζ signaling moiety. We chose to target CD19 based on the clinical validation provided by Kymriah®, Yescarta®, Tecartus® and Breyanzi® which have all shown to improve remission rates and overall survival in patients with various B-cell malignancies, as well as the significant unmet medical need that remains for treating B-cell malignancies despite these recent approvals.

Schematic of NKX019

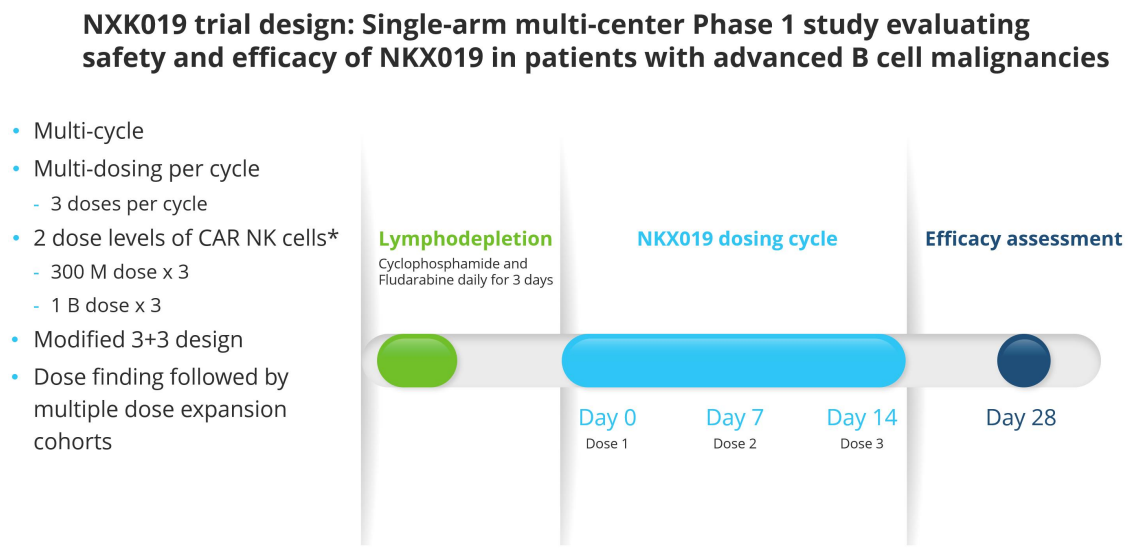


Our preclinical studies have demonstrated activity of NKX019 in a mouse model of leukemia, and have also shown that cryopreserved NKX019 administered after thawing maintains the anti-cancer activity of freshly-prepared NKX019.

***In vivo* Anti-Cancer Activity of Cryopreserved and Freshly-Prepared NKX019**



Our IND for NKX019 for the treatment of B-cell malignancies was accepted by the FDA in April 2021, and the clinical trial notification was filed with TGA following appropriate Human Research Ethics Committees approval in Australia in May 2021. In October 2021, we announced that we had dosed the first patients with NKX019 in the Phase 1 clinical trial. This first-in-human study evaluates the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX019, administered in a cycle of three weekly infusions following lymphodepletion in multiple centers in the U.S. and Australia. Based on tumor response and tolerability, multiple treatment cycle(s) can be administered. The clinical trial consists of dose-finding followed by dose-expansion and is designed to identify the recommended Phase 2 dose. We plan to treat all subjects in the clinical trial with off-the-shelf NKX019, manufactured from healthy donors without any planned HLA matching. In January 2022, we filed a protocol amendment with the FDA for the ongoing Phase 1 clinical trial of NKX019 to optimize the study design for maximum benefit and flexibility as the company prepares for potential dose expansion cohorts. The amended protocol allows for administration of a consolidation cycle of NKX019 to patients following a complete response to NKX019, and increased dosing of NKX019.



*Protocol amendment includes option for increased dosing of NKX019

Partnership with CRISPR Therapeutics

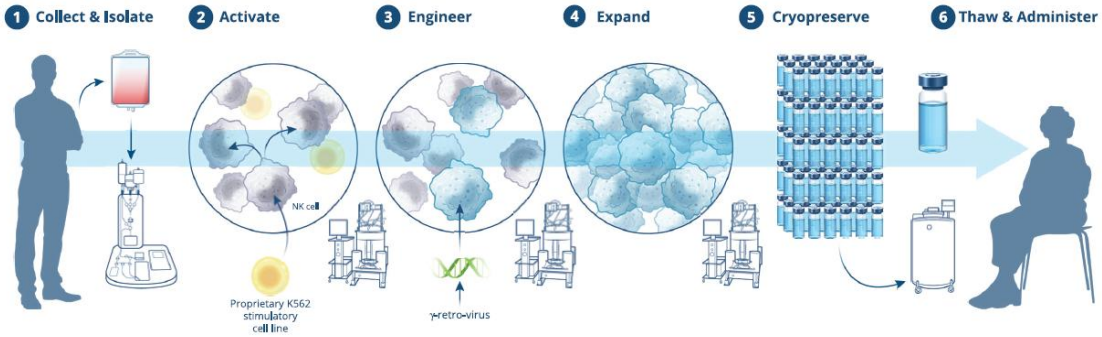
On May 5, 2021, we entered into the CRISPR Agreement. Pursuant to the CRISPR Agreement, CRISPR and Nkarta will establish research plans for the purpose of collaboratively designing and advancing up to two (2) allogeneic, gene-edited NK cell therapies and one (1) allogeneic, gene-edited NK+T cell therapy for use in the treatment of oncology, autoimmune disease, or infectious disease up to the filing of an application to a regulatory authority to request the ability to start a clinical trial. The first allogeneic, gene-edited NK cell therapy being developed in partnership with CRISPR is targeting cancers expressing the CD70 antigen. Together with CRISPR, we may advance this product candidate for the treatment of solid tumors and blood cancers. The NK+T program combines CAR-NK cells and CAR-T cells, bringing together the advantages of the innate and adaptive immune systems. We expect that this will be one product, NK+T, and will incorporate all of the core elements of our NK cell engineering platform and CRISPR's experience developing gene-edited, allogeneic CAR-T cells with reduced risk of GVHD and enhanced resistance to immunosuppression. We are also evaluating potential antigens and targets for this product candidate. The NK+T product candidate could incorporate two different targets into the CAR-NK and CAR-T cells, based on the differing pharmacokinetic and pharmacodynamic profile of these two cell types. Additionally, under the CRISPR Agreement, CRISPR will also grant non-exclusive licenses to us on up to five gene-editing targets to enable us to independently research, develop and commercialize NK cell therapies that have been gene-edited using CRISPR's gene-editing technology.

Manufacturing

Our process for the generation of an allogeneic, off-the-shelf NK cell therapy requires multiple steps. To achieve a commercially viable product, we believe that each of these steps must be scalable, reproducible and cost-effective and must provide consistent cancer cell killing potency of our CAR-NK cells once these cells are frozen and then thawed. Therefore, we have focused on developing a manufacturing process that incorporates the following elements:

- starting material consisting of bona fide NK cells with inherent cytotoxic and tumor-recognizing capabilities, as compared to other NK cell sources in which these fundamental features must be engineered into the cells;
- a cell source which provides high numbers of easily characterized NK cells;
- expansion technology which increases the number of NK cells by orders of magnitude, without inducing exhaustion;
- techniques for genetic engineering of NK cells which are cost-effective and which introduce a controlled and specified range of the number of copies of the gene into each cell;
- cryopreservation techniques that permit bulk CAR-NK cells to be frozen in individual doses; and
- techniques for thawing the frozen NK cell product that are easy to adopt in different clinical settings, and that provide consistent CAR-NK cell recovery, viability and potency.

Our overall manufacturing scheme is shown in the diagram below.



The source material for production of our off-the-shelf NK cell therapy product candidates is NK cells collected from healthy donors by leukapheresis, the selective collection of white blood cells from plasma. We then isolate the NK cells from the other cells in the leukapheresis product. Next, we selectively activate the NK cells by co-culture with our proprietary, engineered K562 stimulatory cell line. After initial expansion, we engineer the expanded NK cells using a gamma-retrovirus to express mbIL-15 and the CAR. We further expand the NK cells, followed by harvesting and cryopreservation to form the final cell product. For off-the-shelf administration, clinical sites will thaw the CAR-NK product candidate for administration to patients at the clinical site.

We believe that establishing our own internal cGMP manufacturing capabilities will facilitate clinical product supply, lower the risk of manufacturing disruptions, and enable more cost-effective manufacturing for clinical and commercial supply of our product candidates. In 2020, we completed the construction of a 2,700-square foot clinical cGMP facility within our primary corporate location in South San Francisco, California. The total expense to complete the construction, including laboratory and manufacturing equipment, was approximately $6 million. This facility is currently producing clinical supply of NKX019 for the Phase 1 clinical trial. We currently manufacture clinical supply of NKX101, the K562 stimulatory cell line, and the gamma-retrovirus at third-party contract manufacturing sites. In 2022, we intend to initiate manufacturing of NKX101 at our cGMP facility. We believe that

this clinical cGMP facility will be capable of supplying our anticipated non-pivotal clinical trial needs. Also, in the future, we intend to manufacture the proprietary, engineered K562 stimulatory cells in house.

We are also in the late stages of the design and engineering phase of a separate, larger commercial cGMP facility for manufacturing engineered NK cells for pivotal clinical trials as well as for eventual commercial supply. In July 2021, we announced that we leased a property in South San Francisco, CA where we plan to build a facility for the commercial-scale manufacture of our product candidates.

During our process development of NKX019 for cGMP manufacturing, we have produced NKX019 with greater than 3,000 fold expansion of the NK cell starting material. We believe that we can achieve comparable expansion efficiency for commercial production.

We believe that we can achieve a cost of manufacturing for commercial NKX101 and NKX019 at peak capacity of approximately $2,000 per dose, based on achieving 500 doses per manufacturing run at a dose of one billion CAR-NK cells per dose and on our current estimates for the costs of raw materials, consumables, rent, construction, equipment, labor and overhead.

Compliance with government regulations related to the manufacture of our product candidates may require significant effort and financial resources. The design, construction, qualification and regulatory approvals for our cGMP manufacturing facilities require substantial capital and technical expertise. The facilities will be subject to inspection by the FDA and other regulatory agencies to ensure compliance with cGMP. Any delays in receiving regulatory approvals for our manufacturing facilities or any failure by us to comply with applicable regulations at our manufacturing facilities could delay our development and commercialization activities. In addition, if our product candidates fail to meet the required specifications after manufacture or if we change the manufacturing process, we may need to obtain additional regulatory approvals. If we are not able to obtain the necessary additional regulatory approvals, we may need to perform additional clinical trials or manufacturing runs or further refine our manufacturing processes, which could delay development and commercialization of our product candidates and cost substantial additional capital. Any delays in our development and commercialization activities could have a material effect on our business, financial position, results of operations and competitive position.

Patents, Trademarks and Proprietary Technology

We protect our intellectual property rights and proprietary technology with a combination of patent rights that we own or license in certain fields of use, trademark rights, confidentiality procedures and contractual provisions. We seek not only to protect our intellectual property rights and proprietary technology in select key global markets, but also to supplement our intellectual property portfolio with new filings and applications to enhance such protection and support commercialization of current and future product candidates. To that end, we continue to seek protection for our technological innovations and branding efforts by filing new patent and trademark applications when and where appropriate. Our patent portfolio consists of a combination of issued patents and pending patent applications licensed from third parties, jointly owned with third parties, and assigned solely to us based on our ongoing development activities. The patents and applications in our portfolio can be categorized as related to our NK cell engineering platform (e.g., natural killer cell expansion and/or persistence), NKX101, NKX019, CD70 CAR-NK, or future pipeline product candidates and alternative technologies. Some of our issued patents and licensed patent applications are exclusively licensed to us in therapeutic fields of use from the National University of Singapore, St. Jude Children’s Research Hospital, Inc., or both (collectively "Licensors"). As of December 31, 2021, the patent portfolio that is assigned to us, jointly owned with others, or licensed to us includes at least 15 issued utility patents and at least 95 pending utility patent applications.

At least 15 of the issued utility patents and at least 50 of the pending utility patent applications in our portfolio are related to our NKX101 product candidate, and include manufacturing process, treatment and compositions of matter claims (e.g., targeting NKG2D ligand-expressing tumors, local delivery to tumors and combination therapies). These issued utility patents include patents in the United States, Europe, Japan, and other jurisdictions outside the United States and are licensed from Licensors. These pending utility patent applications include applications in the United States, Europe, Japan, the Patent Cooperation Treaty ("PCT"), and other jurisdictions outside the United States. Of these pending patent applications, at least 20 are owned or co-owned by us, with the remaining licensed from Licensors. The estimated expiration dates of the issued utility patents are between

approximately 2024 and 2035 (with certain commercially relevant patents extending through approximately 2035), and the estimated expiration dates of these pending utility patent applications are between approximately 2024 and 2042 (with certain commercially relevant patent applications extending through approximately 2042).

At least 10 of the issued utility patents and at least 35 of the pending utility patent applications in our portfolio are related to our NKX019 product candidate, and include manufacturing process, treatment and compositions of matter claims (e.g., targeting CD-19-expressing tumors). These issued utility patents include patents in the United States, Europe, Japan, and other jurisdictions outside the United States and are owned by us or licensed from Licensors. These pending utility patent applications include applications in the United States, Europe, Japan, the PCT, and other jurisdictions outside the United States. Of these pending patent applications, at least 15 are owned by us, with the remaining licensed from Licensors. The estimated expiration dates of the issued utility patents are between approximately 2024 and 2040 (with certain commercially relevant patents extending through approximately 2040), and the estimated expiration dates of these pending utility patent applications are between approximately 2024 and 2040 (with certain commercially relevant patent applications extending through approximately 2040).

At least 10 of the issued utility patents and at least 30 of the pending utility patent applications in our portfolio are related to our CD70 CAR-NK program, and include manufacturing process, treatment and compositions of matter claims (e.g., targeting CD70-expressing tumors). These issued utility patents include patents in the United States, Europe, Japan, and other jurisdictions outside the United States and are licensed from Licensors. These pending utility patent applications include applications in the United States, Europe, Japan, the PCT, and other jurisdictions outside the United States. Of these pending patent applications, at least six are owned or co-owned by us, with the remaining licensed from Licensors. The estimated expiration dates of the issued utility patents are between approximately 2024 and 2035 (with certain commercially relevant patents extending through approximately 2035), and the estimated expiration dates of these pending utility patent applications are between approximately 2024 and 2041 (with certain commercially relevant patent applications extending through approximately 2041).

At least 10 of the issued utility patents and at least 25 of the pending utility patent applications in our portfolio are related to our NK cell engineering platform, and include manufacturing process, treatment and compositions of matter claims relating to NK cell expansion and/or NK cell persistence. These issued utility patents include patents in the United States, Europe, Japan, and other jurisdictions outside the United States and are licensed from Licensors. These pending utility patent applications include applications in the United States, Europe, Japan, the PCT, and other jurisdictions outside the United States. Of these pending patent applications, at least one is owned by us, with the remaining licensed from Licensors. The estimated expiration dates of the issued utility patents are between approximately 2024 and 2035 (with certain commercially relevant patents extending through approximately 2035), and the estimated expiration dates of these pending utility patent applications are between approximately 2024 and 2040 (with certain commercially relevant patent applications extending through approximately 2040).

In August 2016, we entered into a license agreement with the Licensors. Pursuant to this license, the Licensors granted to us an exclusive, worldwide, royalty-bearing, sublicensable license under specified patents and patent applications related to NK cell technology in the field of therapeutics. Payments to the Licensors pursuant to the license agreement include single-digit royalty payments on commercial sales, a portion of any sublicensing revenue, patent expenses, license maintenance fees and milestone payments upon completion of certain regulatory and commercial milestones related to the clinical development and commercialization of our product candidates, in an aggregate amount of up to 5 million Singapore Dollars ("SGD"). The License Agreement also includes certain performance objectives which obligate us to meet various milestones related to the clinical development and commercialization of our product candidates over time for up to 120 months after the effective date of the License Agreement. The term of the license agreement extends until expiration of the last of the patent rights licensed to us by the Licensors, which is currently expected to occur in approximately 2039. We may terminate the license agreement at will upon 90 days' prior written notice to the Licensors. The Licensors may terminate the license agreement for certain conditions such as uncured material breach by us, the cession of our business, or our insolvency, liquidation, or receivership.

The U.S. government has certain rights in some of our licensed patents (including U.S. Patent Nos. 7,435,596, 8,026,097 and certain related U.S. patent applications, which relate to our NK cell engineering platform) in accordance with the Bayh-Dole Act of 1980. These rights in certain technology developed under government-funded research include, for example, a license to use those inventions for governmental purposes and the right to require us to grant exclusive licenses to such inventions to a third party under certain circumstances. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. For further details about risks related to the government's rights in such inventions, see "—The U.S. government could choose to exercise certain rights in technology developed under government-funded research, which could eliminate our exclusive use of such technology or require us to commercialize our product candidates in a way we consider sub-optimal," in the section titled "Risk Factors" in Part I, Item 1a in this Annual Report on Form 10-K.

Our continuing research and development activities, technical expertise and contractual arrangements supplement our existing intellectual property protection and help us maintain our competitive position, and we rely on trade secrets to protect our proprietary information and technologies, especially where we do not believe patent protection is appropriate or obtainable, or where such patents would be difficult to enforce. In order to maintain such trade secrets and other proprietary information, we rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators and other advisors.

We also protect our brand through trademark rights. As of December 31, 2021, we are the listed owner of the U.S. registered trademark, NKARTA, and at least 15 related foreign registered and pending trademarks. In order to supplement the protection of our brand, we also have a registered internet domain name.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, the FDA regulates investigational drugs, including biological products, under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Marketing authorization of a biological product via a biologics license application ("BLA") occurs under section 351 of the Public Health Service Act ("PHSA"). The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal by the FDA to approve applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and the Department of Justice ("DOJ") or other governmental entities. The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are governed by extensive regulation by governmental authorities in the United States and other countries. The FDA, under the FDCA and PHSA, regulates biopharmaceutical products in the United States. The steps required before a product candidate may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests conducted under Good Laboratory Practices ("GLP");
- the submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials commence;

- approval by an independent institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for each indication and conducted in accordance with Good Clinical Practices ("GCP");
- the preparation and submission to the FDA of a BLA;
- FDA acceptance, review and approval of the BLA, which might include an advisory committee review; and
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product, or components thereof, are made to assess compliance with cGMPs and in the case of cell-based advanced therapy, additionally, current Good Tissue Practices.

The testing and approval process typically requires many years and substantial effort and financial resources, and the receipt and timing of any approval is uncertain. The actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. For example, the FDA has, at times, taken longer than its usual 30-day window to complete its review of certain first-of kind IND applications. In addition, the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unreasonable and significant health risk.

Preclinical and Human Clinical Trials in Support of a BLA

Preclinical studies generally include laboratory evaluations of product chemistry, formulation, and toxicity, as well as animal studies to assess the potential safety and bioactivity of the product candidate. The conduct of preclinical trials is subject to federal regulations and requirements including GLP regulations. The results of the preclinical studies, together with manufacturing information and analytical data, among other things, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. If outstanding concerns cannot be resolved, the FDA will place the clinical trial, or a portion of it, on clinical hold. A partial clinical hold stops new patients from enrolling in a clinical trial. A complete clinical hold further requires all patients currently enrolled to discontinue treatment with the product candidate being evaluated. The FDA may also initiate a clinical hold after the 30 days if, for example, significant public health risks arise during the trial, if FDA believes the study is not being conducted in accordance with FDA regulations, or if results from additional preclinical studies are required by the FDA to evaluate the potential risk and benefit to patients for such a trial. Clinical holds may be temporary or permanent.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with federal regulations, in compliance with GCP requirements, and in accordance with a protocol submitted to FDA as part of the IND detailing the objectives of the trial, the parameters used to monitor safety, and the effectiveness criteria, if any, to be evaluated. Each clinical trial and informed consent information must also be reviewed and approved by an independent IRB at each of the sites at which the trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions if it believes that the patients are subject to unacceptable risk.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases prior to approval, but the phases may overlap or be combined. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects. In Phase 1 trials of cellular therapies, the product candidate is tested for safety, including adverse effects.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (i) evaluate the efficacy of the product candidate for specific indications, (ii) determine dosage tolerance and optimal dosage and (iii) identify possible adverse effects and safety risks.

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within a larger number of patients, typically at geographically dispersed clinical trial sites.

Phase 4. Phase 4 clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA (post-approval commitments) or required by the FDA (post-approval requirements). Failure to promptly conduct any required Phase 4 clinical trials could result in enforcement action or withdrawal of approval.

A Phase 2/3 trial design is often used in the development of pharmaceutical and biological products. The trial includes Phase 2 elements, such as an early interim analysis of safety or activity, and Phase 3 elements, such as larger patient populations with less restrictive enrollment criteria. With appropriate statistical restrictions, an early interim analysis of clinical or physiologic activity and/or safety may provide for the trial to be stopped, changed or continued before a large number of patients have been enrolled, while still allowing all data from enrolled patients to count in the analysis used to support approval.

A pivotal trial is a clinical trial that is designed to meet regulatory requirements to demonstrate a product candidate's safety and efficacy to support the approval of the drug or biologic. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from any phase clinical trial if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations in which there is an unmet medical need and the results are sufficiently robust.

The FDA, the IRB or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, an independent group of qualified experts organized by the clinical trial sponsor, often known as a Data Safety Monitoring Board ("DSMB") or committee, may oversee some clinical studies. Depending on the trial design, this group may provide authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and the competitive climate.

Clinical trials require substantial time, effort and financial resources. The costs associated with running clinical trials typically increase as a product candidate advances to later stage clinical trials, since the later stage clinical trials typically involve a larger number of patients than the early-stage clinical trials. If a clinical trial for one of our product candidates is put on clinical hold by the FDA (or another regulatory authority in a foreign country), further development and any eventual commercialization of that product candidate would be delayed or may not be possible at all. Any delays in our clinical trials or termination of a program due to a clinical hold could materially adversely affect our business, financial conditions, results of operations, growth prospects and competitive position.

Submission and Review of a BLA

The results of preclinical studies and clinical trials, together with detailed information on the product's manufacture, composition, quality, controls and proposed labeling, among other things, are submitted to the FDA in the form of a BLA, requesting approval to market the product. The cost of preparing and submitting a BLA is substantial. The application must also be accompanied by a significant user fee payment, which typically increases annually, although waivers may be granted in limited cases. Under an approved BLA, the applicant is also subject to an annual program fee. The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the Agency's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has substantial discretion in the approval process and may refuse to accept an application or decide that the data are insufficient for approval and require additional preclinical, clinical or other studies.

Once a BLA has been accepted for filing, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. The FDA has agreed to certain performance goals to complete the review of BLAs. This is typically ten months from the date that the FDA accepts the BLA for filing for standard review BLAs. Applications classified as Priority Review are reviewed within six months of the date the FDA accepts the BLA for filing. A BLA can be classified for Priority Review when the FDA determines the biologic product has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process can be extended by FDA requests for additional information or clarification. The FDA reviews BLAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may also refer applications for novel biologic products, or biologic products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee—typically a panel that includes clinicians, statisticians and other experts—for review, evaluation, and a recommendation as to whether the BLA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities comply with cGMP. Additionally, the FDA will typically inspect one or more clinical trial sites for compliance with GCP and integrity of the data supporting safety and efficacy.

During the approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS, and the FDA will not approve the application without an approved REMS, if required. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. A REMS can substantially increase the costs of obtaining approval. The FDA could also require a special warning, known as a boxed warning, to be included in the product labeling in order to highlight a particular safety risk. The FDA may delay approval of a BLA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require substantial post-marketing testing and surveillance to monitor safety or efficacy of a product.

On the basis of the FDA's evaluation of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA will issue either an approval of the BLA or a Complete Response Letter, detailing the deficiencies in the submission and the additional testing or information required for reconsideration of the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the biologic with specific prescribing information for specific indications. Even with submission of this additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

If we are unable to obtain a BLA for a product candidate accepted or approved, commercialization of that product candidate will be delayed or we may not be able to commercialize that product candidate at all. This would have a material effect on our business, financial conditions, results of operations, growth prospects and competitive position.

Expedited Programs, Accelerated Approval Programs, and Breakthrough Therapy Designation

A sponsor may seek approval of its drug candidate under programs designed to accelerate FDA's review and approval of BLAs. For example, the FDA may grant Fast Track Designation to a drug intended for treatment of a serious or life-threatening disease or condition that has potential to address unmet medical needs for the disease or condition. The key benefits of fast track designation are the eligibility for priority review, rolling review (submission of portions of an application before the complete marketing application is submitted) and accelerated approval, if the application meets relevant criteria. 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. The FDA generally requires post-marketing studies or completion of ongoing studies after marketing authorization to verify the drug's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

Based on results of the Phase 3 clinical trials or trials submitted in a BLA, upon the request of an applicant, the FDA may grant the BLA a priority review designation, which sets the target date for FDA action on the application at six months after the FDA accepts the application for filing. The FDA grants priority review where there is evidence that the proposed drug would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. If the criteria for priority review are not met, the application is subject to the standard FDA review period of ten months after 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.

In addition, a sponsor may seek FDA designation of its drug candidate as a breakthrough therapy if the drug can, alone or in combination with one or more other drugs, treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A breakthrough therapy designation allows companies to work earlier, more closely, and frequently with the FDA, and they may be eligible for priority review and accelerated approval. The sponsor of a new biologic product candidate may request that the FDA designate the candidate for a specific indication as a Breakthrough Therapy concurrent with, or after, the submission of the IND for the biologic product candidate. The FDA must determine if the biological product qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request.

Special Protocol Assessment

A company may reach an agreement with the FDA under the Special Protocol Assessment ("SPA") process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. Under the FDCA and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the clinical trial begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and the FDA agree to the change in writing, or if the clinical trial sponsor fails to follow the protocol that was agreed upon with the FDA.

Regenerative Medicine Advanced Therapies and Priority Medicine Designation

Cell-based advanced therapies intended to treat, modify, reverse or cure a serious medical condition can receive Regenerative Medicine Advanced Therapy ("RMAT") designation from the FDA once preliminary clinical evidence has been obtained demonstrating the therapy has the potential to address unmet medical needs for the condition. Similar to breakthrough therapy designation, the RMAT allows companies developing regenerative medicine therapies to work earlier, more closely, and frequently with the FDA, and RMAT designated products may be eligible for priority review and accelerated approval. Interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The timing of a sponsor's request for designation and

FDA response are the same as for the breakthrough therapy designation program. Like the other expedited development programs previously mentioned, RMAT designation does not change the scientific or medical standard for approval or the quality of evidence necessary to support approval. In Europe, the European Medicines Agency ("EMA") can grant PRIority MEdicine ("PRIME"), designation to support development of product candidates that may address unmet needs and improve quality of life, based on the potential to benefit patients from early clinical data.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clintrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. National Institutes of Health's ("NIH") Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation must be requested before submitting a BLA. If the FDA grants orphan drug designation, the identity of the biological product and its potential orphan disease use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan drugs may be eligible for certain incentives, including tax credits for qualified clinical testing. In addition, a BLA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated. In December 2021, we announced that the FDA granted orphan drug designation to our product candidate NKX101 for treatment of AML.

Generally, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. A product can be considered clinically superior if it is safer, more effective or makes a major contribution to patient care. Competitors, however, may receive approval of different active moieties for the same indication or obtain approval for the same active moiety for a different indication. In some cases, orphan drug status is contingent on a product with an orphan drug designation demonstrating that it is clinically superior to a previously approved product or products.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), new drug applications ("NDAs") or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by the

FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA or BLA submitted on or after August 18, 2020.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009 ('BPCIA") creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of Health and Human Services waives a required element. A biosimilar product may be deemed interchangeable with a previously approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. To date, a small number of biosimilar products and no interchangeable products have been approved under the BPCIA. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to biosimilar product implementation, which is still being evaluated by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure, or BLA approval, of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the biosimilar abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Post-Approval Requirements

Approved drugs and biologics that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion including standards and regulations for direct-to-consumer advertising, off label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Biologics may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling and reporting of adverse experiences with the product.

The FDA may impose a number of post-approval requirements as a condition of approval of a BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance programs to further assess and monitor the product's safety and effectiveness after commercialization or the FDA may place conditions on an approval that could restrict the distribution or use of the product. The FDA may also require a REMS, which could involve requirements for, among other things, medication guides, special trainings for prescribers and dispensers, patient registries and elements to assure safe use.

In addition, entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA has promulgated specific requirements for drug cGMP. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay product distribution and require significant time and financial expenditures. 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 trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or
- suspension or revocation of product 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 strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and other geographies, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Coverage, Reimbursement and Pricing

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and the adequacy of reimbursement from third-party payors. Third-party payors include government authorities and private entities, such as managed care organizations, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor’s reimbursement payment rate may not be adequate or may require co-payments that patients find unacceptably high. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they provide reimbursement for use of such therapies.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Thus, obtaining and maintaining reimbursement status is time-consuming and costly.

The U.S. and foreign governments regularly consider reform measures that affect healthcare coverage and costs. For example, the U.S. and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") contains provisions that may reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. The Centers for Medicare and Medicaid Services ("CMS") may develop new payment and delivery models, such as bundled payment models. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, the focus on cost containment measures, particularly in the United States, has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if we attain favorable coverage and reimbursement status for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

European Union Coverage Reimbursement and Pricing

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular drug candidate to currently available therapies, or so called health technology assessments, in order to obtain reimbursement or pricing approval.

For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company.

Healthcare Laws and Regulations

Physicians, other healthcare providers, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors are and will be subject to various federal, state and foreign fraud and abuse laws and other healthcare laws and regulations. These laws and regulations may impact, among other things, our arrangements with third-party payors, healthcare professionals who participate in our clinical research programs, healthcare professionals and others who purchase, recommend or prescribe our approved products, and our proposed sales, marketing, distribution and education programs. The U.S. federal and state healthcare laws and regulations that may affect our ability to operate include, without limitation, the following:

- The federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs, such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value;
- The federal civil and criminal false claims laws, including, without limitation, the federal civil monetary penalties law and the civil False Claims Act (which can be enforced by private citizens through qui tam actions), prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which creates federal criminal laws that prohibit, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as certain healthcare providers, health plans and healthcare clearinghouses and their respective business associates who use, disclose, store or otherwise process HIPAA-protected health information on their behalf;
- The federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid or the Children's Health Insurance Program ("CHIP") to report to the Department of Health and Human Services ("HHS") information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, that impose similar restrictions and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers;
- State laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers;
- State and local laws requiring the registration of pharmaceutical sales representatives;
- State health information privacy and data breach notification laws, which govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts; and
- State unfair and deceptive trade practices statutes, pursuant to which significant statutory fines and penalties can be imposed against pharmaceutical companies alleged to have engaged in consumer fraud.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Government regulators have been very active in the last several years in revising existing regulations and promulgating new regulations. Government enforcement regulators have also become increasingly active in bringing enforcement actions based on these laws. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

If we are found to be in violation of these laws, we may be subject to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and reputational harm, in which case we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Healthcare Reform

The legislative landscape in the United States continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In March 2010, the ACA was enacted, which includes measures that have significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drug agents or biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts to 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, unless the drug is subject to discounts under the 340B drug discount program;
- 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;
- 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 under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct, comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board, which, if and when impaneled, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs; and
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, including efforts to repeal or replace certain aspects of the ACA. Since January 2017, former President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 28, 2021, however, President Biden rescinded those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandates." Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On February 10, 2021, the Biden Administration withdrew DOJ's support for this lawsuit. On June 17, 2021, the U.S. Supreme Court dismissed the case, finding that the plaintiffs lacked standing to bring the action. There can be no assurances that opponents to the ACA, and other healthcare reform measures, will not attempt to repeal and/or replace the ACA.

Additionally, on January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the "BBA") among other things, amends the ACA to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress could consider other legislation to repeal or replace certain elements of the ACA.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 pursuant to the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). However, the Medicare sequester reductions under the Budget Control Act of 2011 will be suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Subsequent legislation extended the sequester reductions through 2030. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. Payment adjustments for the Medicare quality payment began in 2019. At this time, it is unclear how the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating

power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. On July 24, 2020 and September 13, 2020, the former presidential administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The likelihood of implementation of any of the other former U.S. presidential administration's reform initiatives is uncertain, particularly in light of the new presidential administration. Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, making this area subject to ongoing uncertainty. In addition, the probability of success of other policies enacted over the final months of the Trump Administration and their impact on the U.S. prescription drug marketplace is unknown. There are likely to be political and legal challenges associated with implementing these reforms as they are currently envisioned, and the January 20, 2021 transition to a new Democrat-led presidential administration created further uncertainty. Following his inauguration, President Biden took immediate steps to order a regulatory freeze on all pending substantive executive actions in order to permit incoming department and agency heads to review whether questions of fact, policy, and law may be implicated and to determine how to proceed. Because Congress and the executive branch could make changes to the federal budget in the future, it is impossible to predict the impact any additional spending cuts may have on our business.

At the state level, individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states’ ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in foreign countries that impose similar obligations.

Anti-Corruption Laws

The Foreign Corrupt Practices Act (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. These anti-corruption laws prohibit any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. This could become relevant in the conduct of international clinical trials where the sites for such trials may be a government-owned hospital. The FCPA also obligates companies whose securities are listed in the United States to comply with

accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight and debarment from government contracts.

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.

Competition

The biopharmaceutical industry in general, and the cell therapy field in particular, is characterized by rapidly advancing and changing technologies, intense competition and a strong emphasis on intellectual property. We face substantial and increasing competition from many different sources, including large and specialty biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions. Competitors may compete with us in hiring scientific and management personnel, establishing clinical study sites, recruiting patients to participate in clinical trials and acquiring technologies complementary to, or necessary for, our programs.

Our known biopharmaceutical competitors developing allogeneic CAR-NK or CAR-T cell therapies include Allogene, Artiva Biosciences, Bristol-Myers Squibb, Cellectis, Celularity, Celyad, CRISPR Therapeutics, Fate Therapeutics, Gamida Cell, Gilead, Glycostem, Gracell, ImmunityBio, Intellia, Legend Biotech, NKGen, Novartis, Precigen, Precision BioSciences, Sanofi, Takeda, and Vor Biopharma, each of which has clinical-stage allogeneic programs. Biopharmaceutical companies with potentially competitive cell therapies in preclinical development include 2seventy Bio, Astellas, Caribou, Century, CytoImmune, Cytovia, Editas, Indapta Therapeutics, ONK Therapeutics, Senti, Shoreline Biosciences, Surface Oncology, and WuGen. The autologous CAR-T therapies Kymriah®, Yescarta®, Tecartus® and Breyanzi®, which have been commercially approved, are direct competitors to our product candidate NKX019. Furthermore, a number of companies are seeking to harness NK or T cell biology through engagers which seek to direct a patient's own NK or T cells to the site of a tumor. Such competitors include Affimed, Amgen, Dragonfly Therapeutics, GT Biopharma, Innate Pharma, and Servier. Several companies are investigating other types of immune cells, such as gamma delta and NKT. These companies include Acepodia, Adicet, Appia Bio, Athenex, Gadeta, In8Bio, Portage, and Takeda.

In addition, numerous academic institutions are conducting preclinical and clinical research in these areas. Furthermore, a number of biopharmaceutical companies and academic groups are focused on engineering other white blood cell types including NKT cells and gamma-delta T cells, which may offer some of the same advantages as engineered NK cells. Finally, research in immuno-oncology is one of the most active areas for the discovery and clinical development of new anticancer therapies in the biopharmaceutical industry. New approaches, such as bispecific antibodies, as well as refinements of existing modalities, such as immune checkpoint inhibitors, are constantly emerging.

Many of our current or potential competitors have significantly greater financial, technical and human resources, as well as more expertise in research and development, manufacturing, preclinical testing, conducting clinical studies and trials and commercializing and marketing approved products, than us. Mergers and acquisitions in the biopharmaceutical industry may result in even greater resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, either alone or through collaborative arrangements with large and established companies.

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. 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. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, price and degree of reimbursement.

Human Capital

We believe that our values – patient first, data driven, intellectually honest, transparent, diverse, inclusive, work/life balance, respectful, humble, creative, and ethical – are the foundations for our team and our behaviors for promoting creativity, innovation and productivity. As of December 31, 2021, we had 136 full-time employees, 43 of whom have Ph.D., M.D. or J.D. degrees. Of these full-time employees, 119 employees are engaged in research and development activities and 17 employees are engaged in finance, business development and other general and administrative functions. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We believe that a diverse and inclusive work environment is critical for driving innovation, workforce productivity and the development of new cell therapies. We embrace the principles of workplace development, diversity and inclusion set forth by the Biotechnology Innovation Organization. As part of comprehensive approach to diversity, equity and inclusion at Nkarta, we rely on data to identify gaps, set priorities and enable ongoing measurement of our progress. We publish these quarterly data on our website in the spirit of shared responsibility and accountability. Nothing on our website shall be deemed incorporated by reference into this Annual Report on Form 10-K.

Compensation, Benefits and Well-being

We strive to offer fair, market-competitive compensation and benefits that support our employees' overall well-being. To ensure alignment with our short- and long-term objectives, our compensation programs for all employees include base pay, short-term incentives, and opportunities for long-term incentives. Our well-being and benefit programs focus on four key pillars: physical, emotional, financial and community. We offer a wide array of benefits including comprehensive health insurance, generous time-off and leave, and retirement and financial support.

In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees as well as the communities in which we operate. This includes having many of our employees not in research or manufacturing work from home, while implementing additional safety measures for employees continuing critical on-site work. We also provide flexible work hours and paid time off for employees who cannot work due to circumstances related to COVID-19. We have actively encouraged employees to structure their days and work to best help address caregiving responsibilities they have with family members as well as taking care of themselves personally.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as all of the other information contained in this Annual Report on Form 10-K, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could significantly harm our business, financial condition, results of operations and growth prospects. In such case, the trading price of shares of our common stock could decline, and you may lose part or all of your investment. This Annual Report on Form 10-K also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to our Financial Position

We have a limited operating history and do not have any products approved for sale.

We are a development-stage biopharmaceutical company without any products approved for commercial sale, and have not generated any revenue from product sales. We are focused on developing genetically-engineered human cells as therapeutics and our technologies are new and largely unproven. Since our inception in 2015, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain and in-house manufacturing capability, conducting business planning, raising capital and providing general and administrative support for these operations. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. We have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in the rapidly evolving biotechnology industry. If we do not address these risks, our business, financial condition, results of operations and growth prospects will be materially adversely affected.

We have incurred significant losses since our inception, and we expect to continue to incur significant losses for the foreseeable future.

Since our inception in 2015, we have incurred significant operating losses. Our net losses were $86.1 million and $91.4 million for the years ended December 31, 2021 and 2020, respectively. Our accumulated deficit was $204.1 million as of December 31, 2021. We expect to continue to incur increasing operating losses for the foreseeable future as we continue to develop our product candidates. In addition, we anticipate that our expenses will increase substantially if, and as, we:

- continue the clinical development of NKX101 and NKX019;
- advance additional product candidates to clinical trials, including product candidates under the collaboration with CRISPR Therapeutics AG ("CRISPR");
- develop our current product candidates for additional disease indications;
- seek to discover and develop additional product candidates;
- establish and qualify our own clinical- and commercial-scale clinical current good manufacturing practice ("cGMP") facilities;
- submit a biologics license application ("BLA"), or marketing authorization application, (“MAA”), for NKX101 and/or NKX019 and/or seek marketing approvals for any of our other product candidates that successfully complete clinical trials;
- seek regulatory approval of our product candidates in various jurisdictions for commercial sale;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;

- incur additional costs associated with operating as a public company;
- develop or secure marketing, sales and distribution capabilities, either internally or with third parties, to support commercialization; and
- increase our employee headcount and related expenses to support the foregoing activities.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We continue to incur significant research and development and other expenses related to ongoing operations and the development of our co-lead product candidates, NKX101 and NKX019. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. Neither the United Sates Food and Drug Administration ("FDA") nor any other regulatory authority has approved NKX101, NKX019 or any of our other product candidates, and we do not anticipate generating revenues from product sales unless and until such time as NKX101, NKX019 or another of our product candidates has been approved by the FDA or another regulatory authority, if ever, and we are able to successfully market and sell a product candidate. Our ability to generate revenues from product sales depends on our, or potential future collaborators', success in:

- completing clinical development of our product candidates;
- seeking and obtaining regulatory approvals for product candidates for which we successfully complete positive clinical trials, if any;
- launching and commercializing product candidates, by establishing a commercial infrastructure or, alternatively, collaborating with a commercialization partner;
- qualifying for adequate coverage and reimbursement by government and third-party payors for our product candidates;
- establishing, maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for each of our cell therapy product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a viable treatment option;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, know-how, and trademarks;
- avoiding and defending against third-party interference or infringement claims; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our current expectations if we are required by the FDA or other global regulatory authorities to perform clinical trials and other preclinical studies in addition to those that we currently anticipate.

Even if we are able to generate revenues from the sale of any approved products, we may not become profitable or be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value of our company and impair our ability to raise capital, thereby limiting our research and development programs and efforts to expand our business or continue our operations.

We will require additional capital, which, if available, may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

We have financed our operations primarily through private placements of our preferred stock, proceeds from our previous collaboration with GlaxoSmithKline and proceeds from our IPO completed in July 2020. We intend to continue to use the proceeds from our IPO to, among other uses, advance NKX101 and NKX019 through clinical development. Developing pharmaceutical products and conducting preclinical studies and clinical trials is expensive. As of December 31, 2021, we had cash, cash equivalents, restricted cash and short-term investments of $240.2 million. Our research and development expenses increased from $36.2 million for the year ended December 31, 2020 to $63.4 million for the year ended December 31, 2021.

Until and unless we can generate substantial product revenue, we expect to finance our cash needs through the proceeds from our IPO, a combination of equity offerings and debt financings, including pursuant to our ATM Offering Program (as defined below), and potentially through additional license and development agreements or strategic partnerships with third parties. Financing may not be available in sufficient amounts or on reasonable terms. In addition, market volatility resulting from the COVID-19 pandemic or other factors could adversely impact our ability to access capital as and when needed. We have no commitments for any additional financing and will likely be required to raise such financing through the sale of additional securities. If we sell equity or equity-linked securities, our current stockholders may be diluted, and the terms may include liquidation or other preferences that are senior to or otherwise adversely affect the rights of our stockholders. Moreover, if we issue debt, we may need to dedicate a substantial portion of our operating cash flow to paying principal and interest on such debt and we may need to comply with operating restrictions, such as limitations on incurring additional debt, which could impair our ability to acquire, sell or license intellectual property rights which could impede our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Attempting to secure additional financing may also divert our management from our day-to-day activities, which may impair or delay our ability to develop our product candidates. In addition, demands on our cash resources may change as a result of many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the COVID-19 pandemic or other causes, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs.

Our business and the business or operations of our research partners and other third parties with whom we conduct business have been and could continue to be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have business operations.

The COVID-19 pandemic has disrupted economic activity and business operations worldwide, including the San Francisco Bay Area, where our primary operations are located. The coronavirus pandemic continues to evolve, and multiple variants of the virus that causes COVID-19 are circulating globally, including the Delta and Omicron variants. To date the pandemic has led to the implementation of various responses, including government-imposed stay-at-home orders and quarantines, travel restrictions and other public health safety measures to mitigate the impact of the pandemic. We continue to monitor these changes and update our operations as necessary to comply with any state, county or local health orders.

In response to previous government-imposed stay-at-home orders and quarantines, we implemented work-from-home policies for employees and adjusted our operations to maximize employee safety and to comply with directives from health authorities. The effects of quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, in the United States and other countries, have negatively impacted and could continue to negatively impact our operations and the operations of third parties we rely on, such as our contract manufacturing sites in Colorado, Ohio, and Ontario, and have disrupted and could continue to disrupt or delay the enrollment of patients at our clinical sites. For example, at some of our contract manufacturing sites, COVID-19-related restrictions, including temporary shutdowns, and instances of COVID-19 cases impacting personnel have resulted in some delays. Some of our contract research organizations ("CROs") have also experienced employee turnover/attrition, delays, or disruptions during the pandemic. Some of our clinical trial sites have had to temporarily restrict enrollment into clinical protocols in order to prioritize hospital beds for COVID-19 patients, or because of loss of trial personnel to support research activities (mitigated by having the trial opened in multiple clinical sites simultaneously). In addition, we experienced some delays in construction of our cGMP manufacturing facility and in our internal research efforts. COVID-19 has also caused global supply shortages of certain materials, such as certain raw materials, cell culture media, disposable plastics, and equipment, that we and our contract development and manufacturing organizations ("CDMOs") use for research and GMP manufacturing. If we are not able to obtain sufficient quantities of cell culture media for our purposes due to the shortage, we may need to reduce the number of manufacturing runs we have planned. Supply chain and operational disruptions due to COVID-19 have contributed to certain enrollment delays in our NKX101 clinical trial. In addition, we have had minor delays in setting up clinical sites in our NKX019 clinical trial due to COVID-19 restrictions due to repurposing of healthcare personnel and facilities to support local pandemic efforts. We will continue to monitor the impact of COVID-19 and any additional waves of the pandemic on our operations, including continued enrollment in the NKX101 and NKX019 clinical trials, as well as on our collaboration partners, CROs, CDMOs, and clinical trial sites with respect to COVID-19 related shutdowns, restrictions on travel, and restrictions on hospital visits for clinical trial participants or clinical research staff. Although most COVID-19 restrictions have been lifted in the State of California and the County of San Mateo, restrictions similar to those previously imposed or new restrictions could be imposed again later.

In addition, the COVID-19 pandemic has significantly disrupted global financial markets and could continue to restrict the level of economic activity, and may limit our ability to access capital, which could in the future negatively affect our liquidity now or in the future. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The COVID-19 pandemic has also impacted, and may impact in the future, the regulatory authorities to which we are subject in our industry, which may, in turn, hamper or delay our clinical development efforts. We periodically interact with health authorities such as the FDA to obtain advice, or reach consensus, on our ongoing clinical trials, product development, and manufacturing activities. As FDA personnel prioritize pandemic related efforts, we may experience delays in obtaining periodic advice which may affect our ability to move our clinical programs forward into the next phase of development.

We cannot predict the potential future impacts of COVID-19, including its variants, on us, our research partners, including CRISPR, and other third parties with whom we conduct business. The extent of the impact of the COVID-19 pandemic on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, the development and spread of more contagious and/or vaccine-resistant variants, the effectiveness of actions taken in the U.S. and other countries to contain, vaccinate against, and treat the disease, and its impact on our current and planned preclinical studies and clinical trials, employees and vendors, all of which are uncertain. As a result of the COVID-19 pandemic or other pandemic, epidemic or outbreak of an infectious disease, we have experienced and/or may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials, including our ongoing NKX101 and NKX019 clinical trials;

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff and in training medical personnel on how to properly thaw and administer our product candidates;
- delays or difficulties in recruitment of key personnel;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines, including the review of IND or other regulatory submissions for our product candidates;
- interruption of, or delays in receiving, supplies of our product candidates, or materials necessary for production of our product candidates, from our vendors or contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery or supply systems;
- interruption of, or delays in manufacture of our product candidates, including at our in-house manufacturing facility and CDMOs, due to staffing shortages, production slowdowns and disruptions or inability to procure critical raw materials or other supplies in a timely fashion;
- delays or disruptions in the planning, construction or qualification of our cGMP facility for commercial-scale manufacture of our product candidates;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- interruptions, or delays in receiving supplies and materials necessary for our business operations, and research and development activities;
- increases in the cost of services or supplies necessary for our research and development activities;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our discovery and clinical activities.

The magnitude of these disruptions will depend, in part, on the length and severity of the COVID-19 restrictions and other limitations on our ability and the ability of others to conduct business in the ordinary course.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain. These impacts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak and the effectiveness of actions taken in the United States and other countries to contain, vaccinate against, and treat the disease. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole, but these delays could have a material impact on our business, financial condition, and/or results of operations.

Risks Related to Our Business and Industry

Our business depends upon the success of our CAR-NK cell technology platform.

Our success depends on our ability to utilize our chimeric antigen receptor-natural killer cell ("CAR-NK") technology platform to generate product candidates, to obtain regulatory approval for product candidates derived from it, and to then commercialize our product candidates addressing one or more indications. Phase 1 clinical trials to evaluate our first two CAR NK product candidates in humans have commenced. All of our product candidates developed from our technology platform will require significant additional clinical and non-clinical development, review and approval by the FDA or other regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. If any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, such problems could impact the development plans for our other product candidates because all of our product candidates are based on the same core CAR-NK engineering technology.

Utilizing CAR-NK cells represents a novel approach to the treatment of cancer, and we must overcome significant challenges in order to develop, commercialize and manufacture our product candidates.

We have concentrated our research and development efforts on utilizing CAR-NK cells as an immuno-oncology therapy. To date, the FDA has approved only a few cell-based therapies for commercialization and no NK-based cell therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for our product candidates. Because our CAR-NK platform product candidates are novel, and cell-based therapies are relatively new, regulatory agencies may lack precedents for evaluating product candidates like our CAR-NK product candidates. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent approval and commercialization of our CAR-NK platform product candidates. Additionally, advancing novel immuno-oncology therapies creates significant challenges for us, including:

- enrolling sufficient numbers of patients in clinical trials;
- training a sufficient number of medical personnel on how to properly thaw and administer our cells, especially in our planned solid tumor trial wherein the cells are given through a procedure by trained medical doctors;
- training a sufficient number of medical and clinical laboratory personnel in the proper collection and handling of clinical samples in our clinical trials to enable a sufficient understanding of CAR NK pharmacokinetics and pharmacodynamics for the design of an optimal dosing regimen;
- educating medical personnel regarding the potential side-effect profile of our cells and, as the clinical program progresses, on observed side effects with the therapy;
- developing a reliable and safe and an effective means of genetically modifying our cells;
- manufacturing and cryopreservation our cells on a large scale and in a cost-effective manner;
- sourcing starting material suitable for clinical and commercial manufacturing; 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 develop, commercialize and manufacture our product candidates utilizing CAR-NK cells.

Certain aspects of the function and production of CAR-NK cells are currently unknown or poorly understood, and may only become known through further preclinical testing and clinical trials. Any potential re-engineering required may result in delays and additional expenses.

Current clinical experience with NK cell therapy is predominantly based on cells from haplomatched donors, i.e., at least half of the major Human Leukocyte Antigen (“HLA”), types matched between donor and recipient. Our clinical development plan for NKX101 will seek to establish what degree of HLA matching, if any, is required for NKX101 to exhibit necessary levels of clinical activity and duration of response. Although the relationship between the degree of HLA matching and the clearance of donor allogeneic, off-the-shelf engineered natural killer ("NK") cells by the patient’s immune system has not been conclusively demonstrated, we intend to develop and commercialize products that do not require any HLA matching. While we believe that a high degree of HLA matching will not be required for clinically meaningful activity and durability of response, if it becomes apparent through preclinical testing or clinical trials that such matching is required, the production of NKX101, NKX019, and our other product candidates as standardized, off-the-shelf products for all patients will not be achievable. Instead, we would need to establish a bank of engineered CAR-NK cells for each of our product candidates where dozens of different donors will be required to achieve coverage of a large fraction of the addressable patient population.

Furthermore, the killer immunoglobulin-like receptor (“KIR”), is found on the surface of NK cells and recognizes certain HLA types. If there is a match between KIR and the HLA type, KIR acts as a natural inhibitor of NK activity, thereby serving to prevent immune reactions against an individual’s own cells. If we discover that a KIR mismatch is required to achieve clinically meaningful activity and durability of response, we will need to factor KIR mismatch into the donor and product selection process for patients enrolled in our clinical trials.

In addition, tumors are sometimes able to evade detection by naturally occurring NK cells by shedding the NKG2D ligands found on malignant cells. While NKX101 has been engineered to overcome this shedding mechanism, there can be no guarantee that tumor cells will not retain or regain the ability to shed NKG2D ligand completely despite the presence of NKX101, which would give such tumors a degree of resistance against NKX101. If we discover that tumors develop a resistance to NKX101 as a result of such NKG2D ligand shedding, we will need to reengineer NKX101 to counteract this effect, or we may need to change or abandon our development efforts for NKX101.

Finally, there is limited history of CAR-NK cells manufacturing for clinical use, and our understanding of NK cell biology is continuously expanding. If we find that our current manufacturing processes are inadequate, or should we identify opportunities for material improvement, adaptation of process improvements may require significant periods of time. Process improvements might also necessitate new pre-clinical studies and clinical protocols to establish product comparability. If we are unable to show comparability after a process change, further changes to our manufacturing process and/or clinical trials will be required.

The foregoing processes would require us to redesign the clinical protocols and clinical trials for our product candidates and could require significant additional time and resources to complete and the participation of a significant number of additional clinical trial participants and donors, any of which would delay the clinical development of our product candidates and their eventual commercialization.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.

Clinical trials are expensive, time consuming and subject to substantial uncertainty. Failure can occur at any time during the clinical trial process, due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA, or other applicable regulatory authorities may suspend or terminate clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. The FDA, or other applicable regulatory authorities may also require us to conduct additional preclinical studies or clinical trials due to negative or inconclusive results or other reasons, fail to approve the raw materials, manufacturing processes or facilities of third-party manufacturers upon which we rely, find deficiencies in the manufacturing processes or facilities upon which we rely, and change their approval policies or regulations or their prior guidance to us during clinical development in a manner rendering our clinical data insufficient for approval. In addition, data collected from clinical trials may not be sufficient to support the submission of a BLA, MAA or other applicable regulatory filings. We cannot guarantee that any clinical trials that we may plan or initiate will be conducted as planned or completed on schedule, if at all.

A failure of one or more of our clinical trials could occur at any stage, and any failure could prevent us from obtaining the FDA and other regulatory approvals necessary to commercialize our product candidates. Events that may prevent successful initiation, timely completion, or positive outcomes of our clinical development include, but are not limited to:

- delays in obtaining regulatory approval to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites and CROs;
- our inability to recruit sufficient patients for our clinical trials in a timely manner or at all;
- delays in achieving a sufficient number of clinical trial sites or obtaining the required institutional review board ("IRB"), approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by us or by the FDA or other regulatory agencies based on emerging data;
- clinical sites deviating from trial protocol or dropping out of a trial;
- our inability to obtain long-term follow-up data due to patient drop out or in cases where patients elect to receive post-protocol treatment for their disease before it progresses;
- suspension or termination of a clinical trial by the IRB of the institutions in which such trials are being conducted or by the Data Safety Monitoring Board ("DSMB") (where applicable);
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials, or production delays, shutdowns or setbacks at any of our contract manufacturers;
- delays due to additional regulatory, site and clinical trial participant approvals required if a product candidate, especially a product candidate custom manufactured for a specific patient, does not meet the required specifications;
- delays in reaching a consensus with regulatory agencies on the design or implementation of our clinical trials;
- changes in regulatory requirements or guidance that may require us to amend or submit new clinical protocols, or such requirements may not be as we anticipate;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- insufficient quantities or inadequate quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, or additional administrative burdens associated with foreign regulatory schemes; or
- failure of ourselves or any third-party manufacturers, contractors or suppliers to comply with regulatory requirements, maintain adequate quality controls, or be able to provide sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable. For example, we periodically interact with health authorities such as the FDA to obtain advice, or reach consensus, on our ongoing clinical trials, product development, and manufacturing activities. As FDA personnel prioritize pandemic related efforts, we may experience delays in obtaining periodic advice which may affect our ability to move our clinical programs forward into the next phase of development. Also, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities in response to the COVID-19 pandemic, and in July 2020, it began to work toward resuming prioritized domestic inspections of mission-critical inspections on a case-by-case basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Over the past year, FDA has periodically announced temporary changes to its inspection activities to ensure the safety of its employees and those of the firms it regulates as the FDA adapts to the evolving COVID-19 pandemic. As of February 7, 2022, the FDA resumed conducting domestic surveillance inspections. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions.

Multiple factors have impacted the rate of enrollment of patients in our ongoing Phase 1 clinical trials, including the use of haplomatched donor derived cells and requirement for a staggered enrollment of patients that was longer than originally expected in the original NKX101 study design and COVID-19 related disruptions. As previously announced, the NKX101 clinical trial protocol was later amended in consultation with the FDA to be able to dose patients with either off-the-shelf or haplomatched cells, shorten the stagger between certain patients, and introduce a second parallel dosing regimen. COVID-19 restrictions at certain sites have also resulted and may continue to result in minor disruptions in enrollment in our NKX019 clinical trial.

In October 2021, a company developing allogeneic CAR-T therapies (“the CAR-T Company”) reported that the FDA had placed a clinical hold on the CAR-T Company’s clinical trials following a report of a chromosomal abnormality in the gene-edited CAR-T cells recovered from a single patient in one of the CAR-T Company’s clinical trials. The technology reportedly used by the CAR-T Company to edit the CAR-T cells in which the abnormality was found is different from the gene-editing technology from CRISPR that we are using for our gene-edited product candidates, and the applicability of the CAR-T Company’s reported chromosomal abnormality issue to other gene-editing technologies or other cell types such as our NK cells has not been established. Nevertheless, if the FDA increases its scrutiny regarding the gene editing of cellular therapies more generally as a result of current or future data regarding chromosomal abnormalities from the CAR-T Company or other sources, our pipeline programs that involve gene-edited cells, including an allogeneic, off-the-shelf CAR-NK product candidate targeting the CD70 tumor antigen ("CD70 CAR-NK") and an allogeneic, off-the-shelf product candidate that comprises both engineered NK cells and engineered T cells ("NK+T") programs on which we are collaborating with CRISPR, may be delayed or we may be forced to incur additional costs for those programs. For example, the FDA may require additional or new release assays for manufactured lots of any product candidates that have been gene edited, which could slow development of our gene-edited product candidates and increase expenses.

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

Our business is highly dependent on the success of our product candidates, and on the success of NKX101 and NKX019 in particular, and we may fail to develop NKX101, NKX019 and/or our other product candidates successfully or be unable to obtain regulatory approval for them.

We cannot guarantee that NKX101 and NKX019, or any of our other product candidates, will be safe and effective, or will be approved for commercialization, on a timely basis or at all. Although certain of our employees have prior experience with clinical trials, regulatory approvals, and cGMP manufacturing, we have not previously completed any clinical trials or submitted a BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that NKX101 and NKX019 will be successful in clinical trials or receive regulatory approval. The FDA, and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. For further details about such reasons, see “—Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control.” Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize NKX101 and NKX019 and materially adversely affect our business, financial condition, results of operations and growth prospects.

NKX101 is in an early-stage clinical trial and is subject to the risks inherent in drug development. In November 2020, the first patient in the first-in-human Phase 1 clinical trial of NKX101 for the treatment of relapsed/refractory acute myeloid leukemia ("AML") or higher risk myelodysplastic syndromes ("MDS") was treated. If our Phase 1 or our later clinical trials of NKX101 encounter safety, efficacy, manufacturing problems, enrollment issues, development delays, regulatory issues, or other problems, our development plans for NKX101 could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects. Furthermore, because NKX101 and NKX019 are our most advanced product candidates, and because our other product candidates are based on similar technology, if our clinical trials of NKX101 or NKX019 experience any of the foregoing issues, our development plans for our other product candidates in our pipeline could also be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We also plan to develop NKX101 for additional indications if we are able to obtain clinical proof-of-concept from our NKX101 Phase 1 trials for blood cancers including AML and MDS, as well as hepatocellular carcinomas and other cancers localized to the liver. We may not be able to advance any of these indications through the development process. Even if we receive regulatory approval to market NKX101 for the treatment of any of these additional indications, any such additional indications may not be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize NKX101 for these additional indications, our commercial opportunity will be limited.

Furthermore, the development of NKX101 for treating solid tumors is subject to a number of risks related to use of cell therapies in general including a hostile tumor micro-environment and trafficking to tumor site. Additional risks from direct liver delivery using a catheter through the hepatic artery generally include potential damage to arteries from the catheter placement itself, from use of imaging contrast, radiation exposure, and differences between catheter models potentially introducing variability into the observed clinical effects. The development of treatments to treat solid tumors often requires larger and more expensive clinical trials than for treating blood cancers.

In October 2021, we announced that we had dosed the first patients with NKX019 in a multi-center Phase 1 clinical trial for the treatment of B-cell malignancies. Due to the availability of at least seven commercially available agents that target CD19 including four autologous CAR-T products, two monoclonal antibody products, and one antibody-drug conjugate, we may have difficulty enrolling subjects into trials with NKX019 who have not previously been exposed to a CD19 directed agent. This could impact the ability to obtain data about NKX019 activity and slow enrollment. For these reasons, the Phase 1 clinical trial of NKX019 includes clinical trial sites outside the United States. If our Phase 1 or later clinical trials of NKX019 encounter safety, efficacy, manufacturing problems, enrollment issues, development delays, regulatory issues, or other problems, our development plans for NKX019 could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We intend to develop our product candidates both as monotherapy and potentially as combination therapy, a common form of cancer treatment, with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the combination therapy used with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

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

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease that the product candidate is intended to treat and who meet other eligibility criteria. The rates of patient enrollment, a significant component in the timing of clinical trials, are affected by many factors, including:

- our ability to open clinical trial sites;
- the size and nature of the patient population;
- the design and eligibility criteria of the clinical trial;

- the proximity of subjects to clinical sites;
- the patient referral practices of physicians;
- changing medical practice patterns or guidelines related to the indications we are investigating;
- competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians;
- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- our ability to obtain and maintain patient consents due to various reasons, including but not limited to, patients' unwillingness to participate due to the ongoing COVID-19 pandemic;
- the risk that enrolled subjects will drop out or die before completion of the trial;
- patients failing to complete a clinical trial or returning for post-treatment follow-up; and
- our ability to manufacture the requisite materials for a patient and clinical trial, including to custom manufacture haplomatched clinical trial material.

In addition, we need to compete with many ongoing clinical trials to recruit patients into our expected clinical trials. Our clinical trials may also compete with other clinical trials of product candidates that are in a similar cellular immunotherapy area as our product candidates, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. If we are unable to enroll a sufficient number of patients in our clinical trials in a timely manner, our completion of clinical trials may be delayed or may not be achieved, which would prevent us from commercializing our product candidates.

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

In order to obtain FDA or other regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity, potency and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We began clinical development for our first product candidate, NKX101, in 2020 and our second product candidate, NKX019, in 2021, and the rest of our programs are in preclinical development. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

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

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

The results of preclinical studies and early-stage clinical trials may not be predictive of future results. Initial success in any clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. For example, preclinical models as applied to cell therapy in oncology do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks, and may not provide adequate guidance as to appropriate dose or administration regimen of a given therapy. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Interim or top line data from clinical trials that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data such as interim or top line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. Negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

If any of our product candidates, or any competing product candidates, demonstrate relevant, serious adverse events, we may be required to halt or delay further clinical development.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

As of the date of this Annual Report on Form 10-K, only two of our product candidates (NKX101 and NKX019) have been tested in cancer patients. The first patient was dosed with NKX101 in 2020, and the first patient was dosed with NKX019 in 2021. Prior to initiation of the NKX101 clinical trial, we had only evaluated our product candidates in preclinical mouse models and had observed fatalities in mice as a result of lung toxicity when NKX101 was administered in extremely high doses that were significantly higher than those we would expect to use in humans. We therefore do not yet know if NKX101, NKX019, or our other product candidates will have an acceptable safety profile in humans. As such, there can be no guarantee that any toxicity, or other adverse events, will not occur in human subjects during clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

While studies indicate that NK cell-based therapies may be better-tolerated as compared to T cell-based therapies due to biologic differences between these cell types, there can be no assurance that patients will not experience cytokine release syndrome ("CRS"), neurotoxicity, graft-versus-host disease ("GVHD"), or other serious adverse events. Severe adverse events associated with our product candidates NKX101 or NKX019 or lymphodepleting chemotherapy may also develop. NKX101 targets NKG2D ligands, which is not yet a well-characterized modality. NKG2D targets multiple ligands, and the landscape of ligand expression is currently not fully understood. For example, there are risks that ligands may be expressed on either known or an as-yet-underappreciated population of healthy cells. Therefore, such cells may also be targeted by NKX101 and lead to adverse events of unknown frequency and severity. Such adverse events may cause delays in completion of our clinical programs. If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit-risk profile, we, the FDA, the IRBs at the institutions in which our trials are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process.

We may seek various expedited programs available through regulatory authority such as Regenerative Medicine Advanced Therapy ("RMAT") designation, Breakthrough Therapy designation, Fast Track designation, or PRIority MEdicine ("PRIME"), from regulatory authorities, for any product candidate that we develop. A product candidate may receive RMAT designation from the FDA if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life threatening condition, and preliminary clinical evidence on a clinically meaningful endpoint, indicates that the product candidate has the potential to address an unmet medical need for such condition. A breakthrough therapy is defined by the FDA as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation by the FDA. PRIME is a voluntary scheme launched by the European Medicines Agency ("EMA"), to strengthen support for the development of medicines that target an unmet medical need through enhanced interaction and early dialogue with developers of promising medicines in order to optimize development plans and speed up evaluation to help such medicines reach patients earlier.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, we cannot assure you that the applicable regulatory authority would decide to grant it. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EMA, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program.

We may seek and obtain orphan drug designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively low prevalence populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. On December 16, 2021, we announced that the FDA granted orphan drug designation to NKX101 for the treatment of AML.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances (“sameness”). The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for our product candidates, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, 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. Moreover, orphan drug exclusive marketing rights in the United States 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 quantity of the drug to meet the needs of patients with the rare disease or condition. orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our product candidates, we may never

receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Public opinion and scrutiny of cell-based immuno-oncology therapies for treating cancer may impact public perception of our company and product candidates, or impair our ability to conduct our business.

Our platform utilizes a relatively novel technology involving the genetic modification of human NK 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. 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.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our NK cell engineering platform. We are seeking to do so through our internal research programs and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different cancers may require changes to our NK manufacturing platform, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may choose to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

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 we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

If third parties that we rely on to conduct clinical trials do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates.

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs to conduct or otherwise support clinical trials for our product candidates. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including GCPs for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the European Union member states, and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials not deviate from GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. The COVID-19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption, which may affect our ability to initiate and complete our preclinical studies and clinical trials. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, we plan to rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If we are not able to establish pharmaceutical or biotechnology collaborations on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may seek to collaborate with pharmaceutical and biotechnology companies to develop and commercialize such product candidates, such as our recent collaboration with CRISPR. Any of these relationships, including our relationship with CRISPR, may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, relinquish valuable rights to our product candidates, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for new collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations.

We have entered into a research collaboration with CRISPR Therapeutics regarding certain product candidates, and we may enter into additional collaborations with third parties to develop or commercialize other product

candidates. Our prospects with respect to those product candidates will depend in significant part on the success of those collaborations, and we may not realize the benefits of such collaborations.

We may form strategic alliances or create joint ventures or collaborations with respect to our product candidates that we believe will complement or augment our existing business. We routinely engage, and are engaged, in partnering discussions with a range of pharmaceutical and biotechnology companies and could enter into new collaborations at any time. If we enter into a collaboration, strategic alliance or license arrangement, there is no guarantee that the collaboration will be successful, or that any future partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

On May 5, 2021, we entered into the CRISPR Agreement to establish research plans for the purpose of collaboratively designing and advancing allogeneic, gene-edited NK cell therapies and an allogeneic, gene-edited NK+T cell therapy for use in the treatment of oncology, autoimmune disease, or infectious disease up to the filing of an application to a regulatory authority to request the ability to start a clinical trial. See Item 1, Business for additional information. If CRISPR, or any potential future collaboration partner, does not perform in the manner that we expect or fulfill their responsibilities in a timely manner or at all, the research, clinical development, regulatory approval and commercialization efforts related to the product candidates that are the subject of the collaboration with CRISPR, or that potential future collaboration partner, could be delayed or terminated.

If we terminate the CRISPR Agreement in its entirety or with respect to a particular product candidate under the research collaboration with CRISPR, due to a material breach by CRISPR or CRISPR's insolvency, then we have the right to negotiate a license from CRISPR to continue research, development, and commercialization of the terminated product candidate(s) on our own at our sole expense. We would need to pay CRISPR milestones and royalties for the terminated product candidate(s), and we may not be able to negotiate terms to the license that are favorable to us. Furthermore, assumption of sole responsibility for further development would greatly increase our expenditures and may mean we would need to limit the size and scope of one or more of our programs, seek additional funding and/or choose to stop work altogether on one or more of the affected product candidates. This could result in a limited potential to generate future revenue from such product candidates, and our business could be materially and adversely affected.

Whenever we enter into collaborations with third parties, we could face the following risks:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators could independently develop, or develop with third parties, products and processes that compete directly or indirectly with our products or product candidates;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If conflicts arise between our collaborators and us, including CRISPR, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. CRISPR or future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

As a result, we may not be able to realize the benefit of new or existing collaboration agreements and strategic partnerships if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

If we fail to compete effectively with academic institutions and other biopharmaceutical companies that develop similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected.

The development and commercialization of new cellular immunotherapy products is highly competitive. We face competition from existing and future competitors with respect to each of our product candidates currently in development, and will face competition with respect to other product candidates that we may seek to develop or commercialize in the future. For example, the autologous cell therapies Kymriah®, Yescarta®, Tecartus™ and Breyanzi®, which have been commercially approved, are direct competitors to our product candidate NKX019. In addition, other competitors, including biopharmaceutical companies, have clinical-stage or earlier stage allogenic programs, and a number of other companies are seeking to harness NK biology through engagers that seek to direct a patient's own NK cells to the site of a tumor or are investigating other types of immune cells. Numerous academic institutions are also conducting preclinical and clinical research in these areas, as well as with other white blood cell types including NKT cells and gamma-delta T cells. It is also possible that new competitors, including those developing similar or alternatives to cellular immunotherapy product candidates, may emerge and acquire significant market share. Such competitors may have an advantage over us due to their greater size, resources or institutional experience, or may develop product candidates that are safer, more effective, more widely accepted, more cost-effective or enable higher patient quality of life than ours. More established biopharmaceutical companies may also develop and commercialize their product candidates at a faster rate, which could render our product candidates obsolete or non-competitive before they are fully developed or commercialized. If we are not able to compete effectively against our existing and potential competitors, our business, financial condition, results of operations and growth prospects may be materially adversely affected.

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

As of December 31, 2021, we had 136 full-time employees. We will need to continue to expand our managerial, operational, clinical, quality, human resources, legal, manufacturing, finance, commercial and other resources in order to manage our operations and clinical trials, continue our development activities and eventually commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- discover new product candidates, develop the process and analytical methods for IND-enabling studies and FDA submissions, complete the required IND-enabling studies for each, and receive approval from the FDA and other regulatory authorities to initiate clinical trials for such product candidates;
- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- expand into additional office and laboratory space as we grow our employee base;
- complete the qualification of our in-house clinical GMP manufacturing facility and establish and validate a commercial GMP manufacturing facility; and

- continue to improve our operational, financial and management controls, reports systems and procedures.

If we are unable to attract skilled employees, increase the size of our organization or manage our future growth effectively, it will impair our ability to execute our business strategy and our business, financial condition, results of operations and growth prospects will be materially adversely affected.

If we fail to attract and retain senior management, clinical, and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our chief executive officer, as well as other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our future product candidates. We do not have employment agreements with our senior management team.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and manufacturing activities, or if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. If we are unable to hire and retain the qualified personnel we need to operate our business, our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Although we maintain product liability insurance coverage that also covers our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

In addition, although we are dependent on certain key personnel, we do not have any key man life insurance policies on any such individuals. Therefore, if any of our chief executive officer or other executive officers die or become disabled, we will not receive any compensation to assist with such individual's absence. The loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal.

We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore materially adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Manufacturing

Our manufacturing process is novel and complex, and we may encounter difficulties in production, or difficulties with internal manufacturing, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved.

Our product candidates are genetically engineered human cells, and the process of manufacturing such product candidates, as well as engineered K562 cells and viral vectors, is complex, highly regulated and subject to numerous risks. Manufacturing our product candidates involves harvesting white blood cells from a donor, isolating the NK cells, activating and expanding the NK cells, introducing a gamma-retrovirus with genes encoding the proteins we wish to express, cryopreservation, storage and eventually shipment. As a result of these complexities, the cost to manufacture our cellular product candidates, engineered K562 cells and viral vector is generally higher than traditional small-molecule chemical compounds or biologics, and the manufacturing process is presently less reliable and more difficult to reproduce. Furthermore, for certain patients in the early portion of our Phase 1 study of NKX101, we dosed patients with haplomatched NKX101. This requires custom manufacturing for each patient, which is especially complex, and we may continue to dose haplomatched patients through dose escalation.

Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product to the clinical trial recipient, preparing the product for administration, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth and variability in product characteristics.

Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing facility, through the manufacturing process and to the clinical trial recipient. Maintaining a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product or regulatory action, including withdrawal of our products from the market, if licensed. Any failure in the foregoing processes could render a batch of product unusable, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties or could harm our reputation and that of our product candidates.

Our manufactured product candidates may fail to meet the required specifications for any of a variety of reasons, including variability in starting material, deviations from normal manufacturing process, or insufficient optimization of specific process steps. This failure to meet specifications could result in delays related to obtaining additional regulatory, site and patient approvals to continue dosing the patient in the clinical trial. If the required additional approvals cannot be obtained, additional delays may occur as manufacturing would need to be restarted and/or the patient may be unable to remain in the study. We may lose the starting material for a manufactured product for one of our clinical trial patients at any point in the process, the manufacturing process for that patient would need to be restarted and the resulting delay could require restarting the manufacturing process or could result in such patient no longer participating in our clinical trial. Any delay in the clinical development or commercialization of NKX101, NKX019, or our other product candidates could materially adversely affect our business, financial condition, results of operations and growth prospects.

We may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as to control costs, achieve scale, decrease processing time, increase manufacturing success rate or for other reasons. Changes to our manufacturing process carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials, or the performance of the product once commercialized. Changes to our process made during the course of clinical development could require us to show the comparability of the product candidate used in earlier clinical phases or at earlier portions of a trial to the product candidate used in later clinical phases or later portions of the trial. It is difficult to establish comparability of cell therapy products, and this may complicate efforts to verify process changes during scale up. Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, or if regulatory authorities do not agree that comparability has been established, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Although we are manufacturing NKX019 in our own internal manufacturing facility for the NKX019 Phase 1 clinical trial, and plan to manufacture other product candidates in our internal manufacturing facilities in the future, we may encounter problems with the internal production of our product candidates. We believe this clinical cGMP facility will supply our anticipated non-pivotal clinical trial needs, but if the dose and number of cycles needed increases, our current manufacturing process may not be able to support the enrollment of trials which could lead to delays until we scale up the manufacturing. We have completed the construction of a cGMP facility for the production of certain of our product candidates for our early-stage clinical trials, but we do not yet have a cGMP facility for the commercial-scale manufacture of our product candidates. Our manufacturing facilities will be subject to compliance with regulatory requirements, which we may struggle to meet. Building a commercial-scale facility and manufacturing product candidates in our own facilities will require an increase in staff and significant internal resources. We may encounter problems with properly staffing our internal manufacturing facilities due to hiring challenges or other issues. For example, factors such as the COVID-19 pandemic and COVID-19-related restrictions could impact our ability to properly staff production of our product candidates. We may also encounter problems with training the staff we have to effectively manage and control the complex manufacturing process required to produce our product candidates and comply with all necessary regulations. In addition, we may find it difficult to properly manage supply chain issues critical to the manufacturing process. If we are unable to build, maintain, and properly staff our manufacturing facilities, manage and control the manufacturing process, and comply with regulations, the clinical development or commercialization of our product candidates could be significantly delayed, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We rely on third parties to manufacture certain of our product candidates, and certain materials for use in the production of our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or materials, or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

Although we are building a commercial-scale manufacturing facility, we do not yet operate our own cGMP facility for the production of commercial supplies of the product candidates that we are developing or evaluating in our development programs or supplies of such product candidates for pivotal clinical trials. We have limited personnel with experience in drug manufacturing and currently lack the resources and the capabilities to manufacture any of our product candidates on a commercial scale. If we are unable to successfully build, maintain and staff our own commercial-scale cGMP facility, we will need to rely on third parties for commercial-scale manufacture of our product candidates. We also currently rely on a third-party manufacturer for our clinical supply of NKX101. We expect to continue to outsource NKX101 manufacturing even though we have an internal cGMP facility for clinical supply, at least for a certain amount of time. We compete with other companies for access to third party cGMP facilities and cannot assure continued access.

In addition, we currently outsource manufacturing of certain critical materials necessary for production of our product candidates, including K562 cells and viral vectors. Even though we have established our own internal cGMP facility for clinical supply of certain product candidates, and even if we successfully establish our own cGMP manufacturing facility for manufacture of our product candidates on a commercial scale, we will continue to outsource manufacturing of certain materials necessary for production of our product candidates, at least for a certain amount of time.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to increase the manufacturing capacity for any of our product candidates or other necessary materials in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If these third-party manufacturers are unable to, or do not, scale up the manufacture of our product candidates or other necessary materials in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. We may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate or any material necessary for production of a product candidate that we develop, or may be unable to do so on acceptable terms. Even if we establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers for either clinical or commercial supply entails risks, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third-party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

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

If the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of the COVID-19 pandemic and the actions undertaken by governments and private enterprises to contain COVID-19, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. At some of our contract manufacturing sites, COVID-19-related restrictions, including temporary shutdowns, and instances of COVID-19 cases impacting personnel have resulted in some delays.

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

We are reliant on a sole supplier for certain steps of our manufacturing process.

Our manufacturing process for NKX101 and for NKX019 depends on the use of the Miltenyi CliniMACS Plus system, and related reagents, all of which are only available from Miltenyi as the sole supplier. In addition, some of these reagents, at the time of procurement, typically expire after approximately four to six months. This short expiration period means that stocking the reagents in large quantities for future needs would not be an effective strategy to mitigate against the risk of shortage due to disruption of the supply chain.

Furthermore, while many of the reagents and consumables used in our manufacturing process are available from more than one commercial supplier, we have not confirmed the suitability of the use of all such reagents and consumables in our manufacturing process. Even if we are able to replace any raw materials or consumables with an alternative, such alternatives may cost more, result in lower yields or not be as suitable for our purposes. In addition, some of the raw materials that we use are complex materials, which may be more difficult to substitute. Therefore, supply disruptions could result in delays and additional regulatory submissions and prevent us from being able to manufacture our product candidates due to the unsuitability of the substituted reagent or consumable that we are able to procure.

Any disruption in supply of these instruments and reagents could result in delays in our clinical trials, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

Delays in commissioning and receiving regulatory approvals for our manufacturing facilities could delay our development plans and thereby limit our ability to develop our product candidates and generate revenues.

We believe that internal cGMP manufacturing is important to facilitate clinical product supply, lower the risk of manufacturing disruptions and enable more cost-effective manufacturing. We have a cGMP facility in South San Francisco, California that allows us to supply the product candidates needed for our early-stage clinical trials. We have also leased a property where we are building a facility for the commercial-scale manufacture of our product candidates. The design, construction, qualification, regulatory approvals and maintenance for such facilities require substantial capital and technical expertise and any delay would limit our development activities and our opportunities for growth.

Furthermore, our manufacturing facilities will be subject to ongoing, periodic inspection by the FDA and other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of product candidates for clinical use or may result in the termination of or a hold on a clinical study. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

We also may encounter problems with the following:

- complying with regulations regarding evolving donor infectious disease testing, traceability, manufacturing, release of product candidates and other requirements from regulatory authorities outside the United States;
- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- bacterial, fungal or viral contamination in our manufacturing facilities;
- disruptions due to natural disasters or supply chain interruptions; and
- shortages of qualified personnel, raw materials or key contractors.

Our product candidates, if approved by applicable regulatory authorities, may require significant commercial supply to meet market demand. In these cases, we may need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we fail to develop sufficient manufacturing capacity and experience, whether internally or with a third party, are delayed in doing so, or fail to manufacture our product candidates economically or on reasonable scale or volumes, or in accordance with cGMP, or if the cost of this scale-up is not economically feasible, our development programs and commercialization of any approved products will be materially adversely affected and we may not be able to produce our product candidates in a sufficient quantity to meet future demand and our business, financial condition, results of operations and growth prospects may be materially adversely affected.

The optimal donor and manufacturing parameters for our product candidates have not been definitively established, which may hinder our ability to optimize our product candidates or to address any safety or efficacy issues that may arise.

If any of our clinical trials reveal issues with the safety or efficacy of any of our product candidates, modification of the donor selection criteria or the manufacturing process may be necessary to address such issues. Alternatively, we may choose to modify the manufacturing process in an effort to improve the efficiency of the process or efficacy of the product candidates. However, we have not, at present, fully characterized or identified how donor characteristics and manufacturing process parameters affect the optimal cancer cell killing ability for our engineered NK cell product candidates for in vitro and animal efficacy studies or how such potency differences may translate into efficacy to be seen in human clinical trials, including both the proportion of patients who achieve a meaningful clinical response, and the duration of any such clinical responses. As a result, our ability to improve our manufacturing process or product potency, safety, or efficacy according to such parameters is limited and may require significant trial and error, which may cause us to incur significant costs or could result in significant delays to the clinical development and eventual commercialization of our product candidates.

We are dependent on third parties to store our CAR-NK cells, viral vector, master and working cell banks of the engineered K562 cells, and any damage or loss would cause delays in replacement, and our business could suffer.

The CAR-NK cells, the viral vector, and the master and working cell banks of the engineered K562 cells are stored in freezers at third-party biorepositories and will also be stored in our freezers at our production facility. If these materials are damaged at these 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 CAR-NK cells, viral vector, and master and working cell banks of the engineered K562 cells, which would impact clinical supply and delay our patients' treatments. If we are unable to establish replacement materials, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer.

We have not yet developed a validated methodology for freezing and thawing commercial-scale quantities of CAR-NK cells, which we believe will be required for the storage and distribution of our CAR-NK product candidates.

We have not yet demonstrated that CAR-NK cells, which can be frozen and thawed in smaller quantities, can also be frozen and thawed in commercial scale 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 for large scale use, 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 CAR-NK cells for shipping purposes, our ability to promote adoption and standardization of our product candidates, 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 CAR-NK 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.

Furthermore, we have not yet demonstrated long-term stability of cryopreserved CAR-NK cells and therefore do not know if we will be able to store the cryopreserved cells for extended periods of time. If we are unable to demonstrate long-term stability, we will need to reduce the manufacturing batch size to ensure that the material we produce will be used before it expires. In that case, the scaling of our production processes will not deliver the efficiencies we expect, and the cost per dose of our product candidates will be substantially higher.

For these and other reasons, we have not yet established the long-term stability of our cryopreserved CAR-NK cells and we may not be able to commercialize CAR-NK cells on a large scale or in a cost-effective manner. If such product candidate is found to be instable, we would be required to conduct more frequent manufacturing runs, which could cause us to incur significant additional expenses.

Risks Related to Our Intellectual Property

If our license agreement with National University of Singapore and St. Jude's Children's Research Hospital, Inc. is terminated, we could lose our rights to key components enabling our NK cell engineering platform.

In August 2016, we entered into a license agreement with the National University of Singapore and St. Jude Children's Research Hospital, Inc., (the "Licensors"). Pursuant to this license, the Licensors granted to us an exclusive, worldwide, royalty-bearing, sublicensable license under specified patents and patent applications related to NK cell technology in the field of therapeutics. We make single-digit royalty payments, patent expenses, license maintenance fees and milestone payments to the Licensors. The term of the license agreement extends until expiration of the last of the patent rights licensed to us by the Licensors, which is currently expected to occur in approximately 2039. The Licensors may terminate the license agreement upon the occurrence of certain events, such as an uncured material breach by us, the cessation of our business or our insolvency, liquidation or receivership. If the Licensors terminate or narrow the license agreement, we could lose the use of intellectual property rights that may be material or necessary to the development or production of our product candidates, which could impede or prevent our successful commercialization of such product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects.

Furthermore, our patent license agreement with the Licensors is field-specific and has been granted to us in the field of therapeutics. This license agreement permits to Licensors to practice the licensed rights, and to allow non-profit academic third parties to practice the licensed rights for certain academic purposes. As such, certain patents in a patent family that is licensed to us by the Licensors have been licensed to at least one other third party. Although these patents should not be overlapping with our licensed patents, there is a risk that inadvertent overlap may occur, and thus resources may have to be expended to resolve any such overlap and to prevent other licensees from practicing under our licensed patents rights. If any of the foregoing were to occur, it could delay our development and commercialization of our product candidates, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our development and commercialization rights to our current and future product candidates and technology are subject, in part, to the terms and conditions of licenses granted to us by others.

Our patent portfolio consists of a combination of issued patents and pending patent applications licensed from third parties, jointly owned with third parties and assigned solely to us based on our ongoing development activities. We are reliant upon certain of these rights and proprietary technology from third parties for the engineering and development of our current and future product candidates. However, these and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

We also engage in collaborations with scientists at academic and non-profit institutions to access technologies and materials that are not otherwise available to us. Although the agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution's rights in any inventions that are created in the course of these collaborations, we may not be able to come to a final agreement for an exclusive license with an institution.

We also may in some instances enter into collaboration or license agreements with commercial entities to access technologies and materials that are not otherwise available to us. Our agreements with such entities may provide licenses to technology useful for the discovery, development, or commercialization of our product candidates. These licenses may in some instances, be non-exclusive. For example, we have entered into an agreement with CRISPR, which grants us a non-exclusive license on up to five gene-editing targets to enable us to independently research, develop and commercialize NK cell therapies that have been gene-edited using CRISPR's gene-editing technology.

Such licenses and other contracts may be the subject of disagreements with the grantors and/or various third parties regarding the interpretation of such licenses and contracts. The resolution of any such disagreements that may arise could affect the scope of our rights to the relevant technology, or affect financial or other obligations under the relevant agreement, either of which could inhibit our ability to utilize the underlying technology in a cost-effective manner to develop and commercialize our product candidates, which in turn could have materially adversely affect our business, financial condition, results of operations and growth prospects.

Under certain circumstances such as a material breach of terms, our licensors could terminate our license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with our best interests. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be impaired. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them.

Furthermore, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could harm our competitive position, and our business.

Duration of patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and the expiration of our patents may subject us to increased competition.

As of December 31, 2021, the patent portfolio that is assigned to us, jointly owned with others or licensed to us includes issued patents in the United States, Europe, Japan, and other jurisdictions outside the United States, and pending patent applications in the United States, Europe, Japan, and other jurisdictions outside the United States across our platform, NKX101, NKX019, and CD70 CAR-NK patent families. Our portfolio of issued patents, excluding pending patent applications, has expiration dates between 2024 and 2040. Our portfolio, including issued patents, and including pending applications if they issue, has expiration dates between 2024 and 2043. We plan to file additional patent applications that could potentially allow for further increase of the exclusive market protection for use of NKX101, NKX019, and the product candidate from our CD70 CAR-NK program. However, we can provide no assurance that we will be able to file or receive additional patent protection for these or other product candidates.

Patent expiration dates may be shortened or lengthened by a number of factors, including terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Our patent protection could also be reduced or eliminated for noncompliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies. In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights.

Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent; provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims directed to the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the United States Patent and Trademark Office, or USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, we could be exposed to liability to the applicable patent owner. If we or our licensors fail to maintain the patents and patent applications covering our product candidates and technologies, we may not be able to prevent a competitor from marketing products that are the same as or similar to our product candidates. Further, others commercializing products similar or identical to ours, and our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, which could increase competition for our product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects.

If any patent protection we obtain is not sufficiently robust, our competitors could develop and commercialize products and technology similar or identical to ours.

The market for cell therapy is highly competitive and subject to rapid technological change. Our success depends, in large part, on our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. If we are unable to protect our intellectual property, our competitive position could be materially adversely affected, as third parties may be able to make, use or sell products and technologies that are substantially the same as ours without incurring the sizeable development

and licensing costs that we have incurred. This, in turn, would materially adversely affect our ability to compete in the market.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates or effectively prevent others from commercializing competitive technologies and product candidates.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Claim scope in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

Even after issuance, our owned and in-licensed patents may be subject to challenge, which if successful could require us to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the use of the underlying technology, which could materially adversely affect our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, even after issuance, may be challenged in the courts or patent offices in the United States and abroad. Third-party challenges may result in a loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to prevent others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and product candidates.

Even if our patents are determined to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents.

Ex parte reexaminations have been filed by one or more third parties against certain licensed patents in our portfolio. Third party requests for ex parte reexamination of U.S. Patent Nos. 10,774,309 and 10,829,737, which relate to our NKX101 product candidate, were recently filed. Also, one ex parte reexamination of U.S. Patent No. 9,511,092, which does not relate to any of our current product candidates, is pending and another is on appeal. Although we plan to vigorously protect our intellectual property rights, as with all legal proceedings, there can be no guarantee as to the outcome, and, regardless of the merits of third-party challenges, such proceedings are time-consuming and costly. As a result of such reexaminations, our rights under the relevant patents could be narrowed or lost, and in the course of such proceedings, we may incur substantial costs, and the time and attention of our management may be diverted from the development and commercialization of our product candidates.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which could materially adversely affect our ability to develop, manufacture and market our product candidates.

There are many patents issued or applied for in the biotechnology industry, and we may not be aware of patents or patent applications held by others that relate to our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and elsewhere that is relevant to or necessary for the development and commercialization of our product candidates in any jurisdiction.

For example, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications directed to our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to patents directed to such technologies. If third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter recited by the patent claims of our applications.

Furthermore, after issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, and we may incorrectly determine that our product candidates are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or elsewhere that we consider relevant may also be incorrect. If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We may also be forced to attempt to redesign our product candidates in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to the development and commercialization of our product candidates.

Claims brought against us for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, would be costly and time-consuming and could prevent or delay us from successfully developing or commercializing our product candidates.

Our success depends in part on our ability to develop, manufacture and market our technology and use our technology without infringing the proprietary rights of third parties. As the relevant product industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated. As a result, our technology and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our product candidates.

We may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Accordingly, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether any such claims that we are infringing patents or other intellectual property rights have merit, such claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend.

Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our product candidates while we develop non-infringing substitutes, or may result in significant settlement costs. Litigation can involve substantial damages for infringement (and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees), and the court could prohibit us from selling or require us to take a license from a third party, which the third party is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees, milestone fees, or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale.

We may not be able to effectively monitor unauthorized use of our intellectual property and enforce our intellectual property rights against infringement, and may incur substantial costs as a result of bringing litigation or other proceedings relating to our intellectual property rights.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products for potential infringement of our rights. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully monitor unauthorized use of our intellectual property could result in competitors offering products that incorporate our product or service features, which could in turn reduce demand for our products.

We may also, from time to time, seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property.

If we choose to enforce our patent rights against a party, that party could counterclaim that our patent is invalid and/or unenforceable. The defendant may challenge our patents through proceedings before the Patent Trial and Appeal Board ("PTAB"), including inter partes and post-grant review. Proceedings to challenge patents are also available internationally, including, for example, opposition proceedings and nullity actions. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability and PTAB challenges are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the PTAB, even outside the context of litigation. 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. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our product candidates.

In addition, such lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. Litigation is inherently unpredictable, and there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. Furthermore, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights.

There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could materially adversely affect the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We have a number of international patents and patent applications and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. However, filing, prosecuting and defending patents relating to our product candidates, including all of our in-licensed patent rights, in all countries throughout the world would be prohibitively expensive. We must ultimately seek patent protection on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Furthermore, the protection offered by intellectual property rights in certain countries outside of the United States may be less extensive than those in the United States. Consequently, we may not be able to prevent third parties from utilizing proprietary technology in all countries outside of the United States, even if we pursue and obtain issued patents in particular foreign jurisdictions, or from selling or importing products made using our proprietary technology in and into the United States or other jurisdictions. Such products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. If such competing products arise in jurisdictions where we are unable to exercise intellectual property rights to combat them, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Changes in U.S. patent law or the patent law of other jurisdictions could decrease the certainty of our ability to obtain patents and diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. For example, in recent years the U.S. Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Those changes may materially adversely affect our patent rights and our ability to obtain issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Under the Leahy-Smith America Invents Act, or the America Invents Act, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product candidates could be materially diminished.

Trade secrets are difficult to protect. We rely on trade secrets to protect our proprietary information and technologies, especially where we do not believe patent protection is appropriate or obtainable, or where such patents would be difficult to enforce. We rely in part on confidentiality agreements with our employees, consultants, contractors, collaboration partners, scientific collaborators, and other advisors to protect our trade secrets and other proprietary information. We cannot guarantee that we have entered into such agreements with each party that may have had access to our proprietary information or technologies, or that such agreements, even if in place, will not be circumvented. These agreements may not effectively prevent disclosure of proprietary information or technology and may not provide an adequate remedy in the event of unauthorized disclosure of such information or technology. In addition, others may independently discover our trade secrets and proprietary information, in which case we may have no right to prevent them from using such trade secrets or proprietary information to compete with us. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business, financial condition, results of operations and growth prospects.

The U.S. government could choose to exercise certain rights in technology developed under government-funded research, which could eliminate our exclusive use of such technology or require us to commercialize our product candidates in a way we consider sub-optimal.

The U.S. government has certain rights in some of our licensed patents (including U.S. Patent Nos. 7,435,596, 8,026,097 and certain related U.S. patent applications) in accordance with the Bayh-Dole Act of 1980. These rights in certain technology developed under government-funded research include, for example, a nonexclusive, nontransferable, irrevocable, paid-up license to use those inventions for governmental purposes. In addition, the U.S. government has the right to require us to grant exclusive licenses to such inventions to a third party if the U.S. government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations.

The U.S. government also has the right to take title to such technology if we fail to disclose the invention of such technology to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to patent rights in any country in which a patent application is not filed within specified time limits. To the extent any of our owned or future in-licensed intellectual property is generated through the use of U.S. government funding, these provisions of the Bayh-Dole Act may apply.

Intellectual property generated under a government-funded program is also subject to certain reporting requirements. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. If we are unable to obtain a waiver from the government agency that provided the underlying research funding, we may be limited in our ability to contract with non-U.S. product manufacturers for products related to such intellectual property.

The exercise of any of the foregoing rights of the U.S. government over technology that we own or use in the development and commercialization of our product candidates could prevent us from enjoying the exclusive use of such technology, or could cause us to incur additional expenses in the commercialization of our product candidates. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Commercialization

If any of our product candidates are approved for marketing and commercialization and we have not developed or secured marketing, sales and distribution capabilities, either internally or from third parties, we will be unable to successfully commercialize such products and may not be able to generate product revenue.

We currently have no sales, marketing or distribution organizational infrastructure. We will need to develop internal sales, marketing and distribution capabilities to commercialize any product candidate that gains FDA or other regulatory authority approval, which would be expensive and time-consuming, or enter into partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties to market products or decide to co-promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any product revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, if any, either on our own or through third parties, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Our product candidates, including NKX101 and NKX019, could be subject to regulatory limitations following approval, if and when such approval is granted.

Following approval of a product candidate, if any, we must comply with comprehensive government regulations regarding the manufacture, labeling, marketing, distribution and promotion of biologic products. We must comply with the FDA's labeling protocols, which prohibits promoting "off-label uses." We may not be able to obtain the labeling claims necessary or desirable to successfully commercialize our products, including NKX101 and NKX019 or other product candidates in development.

The FDA and foreign regulatory authorities could impose significant restrictions on use of an approved product including potentially restricting its use to limited clinical centers as well as through the product label, as well as on advertising, promotional and distribution activities associated with such approved product. The FDA or a foreign regulatory authority could also condition their approval on the performance of post-approval clinical trials, patient monitoring or testing, which could be time-consuming and expensive. If the results of such post-marketing trials are not satisfactory, the FDA or such foreign regulatory authority could withdraw marketing authorization or may condition continued marketing on commitments from us or our partners that may be expensive and/or time-consuming to fulfill.

In addition, if we or others identify side-effects after any of our products are on the market, if our products fail to maintain a continued acceptable safety profile after approval, if manufacturing problems occur subsequent to regulatory approval, or if we, our manufacturers or our partners fail to comply with regulatory requirements, including those mentioned above, we or our partners could be subject to the following:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned clinical trials;
- restrictions on such products' manufacturing processes;
- changes to the product label;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- Untitled or Warning Letters from the FDA;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; or
- imposition of civil or criminal penalties.

Any one or a combination of these penalties could prevent us from achieving or maintaining market acceptance of the affected product, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating any revenue or profit from the sale of such product and could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, third-party payors may impose limitations on centers and personnel that may administer our products, including but not limited to requiring third-party accreditation to be obtained before the use of our products is reimbursed in such a center, which could materially adversely affect our potential commercial success and lead to slower market acceptance.

The market opportunities for our product candidates, if and when approved, may be limited, and if such market opportunities are smaller than we expect, our revenues could be materially adversely affected and our business could suffer.

Our initial clinical trials evaluate NKX101 and NKX019 in relapsed/refractory patients who have been previously treated with other anti-cancer therapies. We do not know at this time whether either NKX101 or NKX019 or any of our product candidates will be safe for use in humans or whether they will demonstrate any anti-cancer activity. If the activity is sufficient, we may initially seek approval of any product candidates we develop as a therapy for patients who have received one or more prior treatments. Depending on the activity we note in the initial clinical trials, we plan to conduct additional clinical trials in less heavily pretreated populations in order to expand use of our product candidates in a broader group of patients and increase market opportunities. However, there is no guarantee that product candidates we develop, even if approved for later lines of therapy, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates may be limited. Potentially addressable patient populations for of our product candidates are only estimates. These estimates could prove to be incorrect, and the estimated number of potential patients in the United States and elsewhere could be lower than expected. It may also be that such patients may not be otherwise amenable to treatment with our product candidates, or patients could become increasingly difficult to identify and access for a variety of reasons including other drugs being approved, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The commercial success of any of our product candidates will depend upon such product candidate's degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Our product candidates may not be commercially successful. Even if requisite approvals are obtained from the FDA in the United States and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance by physicians, patients and healthcare payors of cell therapy products in general, and our product candidates in particular, as medically necessary, cost-effective and safe. Physicians, patients, healthcare payors and others in the medical community may not accept any product that we commercialize. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of cell therapy products and, in particular, our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA;
- the willingness of physicians to refer patients and prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the nature, prevalence and severity of any side effects;
- product labeling or product insert requirements imposed by the FDA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the timing of market introduction of competitive products;
- adverse publicity concerning our product candidates or favorable publicity about competing products and treatments;

- sufficient third-party payor coverage, any limitations in terms of center or personnel training requirement imposed by third parties and adequate reimbursement;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts; and
- potential product liability claims.

Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after such product is launched. Our product candidates may not achieve broad market acceptance.

Furthermore, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market such products and to generate product revenue.

We expect the cost of a single administration of one of our cell therapy product candidates to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our products, if approved, will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be reimbursed by government authorities, private health coverage insurers and other third- party payors. Coverage and reimbursement by a third-party payor could depend upon several factors, including the third-party payor's determination that use of a product is (i) a covered benefit under its health plan, (ii) safe, effective and medically necessary, (iii) appropriate for the specific patient, (iv) cost-effective and (v) neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved drug products. In the United States, third-party payors, including government payors such as Medicare and Medicaid, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. Medicare and Medicaid are increasingly used as models for the development of private payors' and government payors' coverage and reimbursement policies. Currently, few cell therapy products have been approved for coverage and reimbursement by the CMS the agency responsible for administering Medicare. It is difficult to predict what third payors, including CMS, will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, since there is no body of established protocols and precedents for these types of drug products. Moreover, reimbursement agencies in other countries, such as those in Europe, may be more conservative than CMS.

Outside the United States, international operations vary significantly by country and are subject to extensive government price controls and other market regulations, and increasing emphasis on cost-containment initiatives in the European countries, Canada and other countries could place pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It can also take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs could limit coverage and the level of reimbursement for our product candidates. Payors are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. Furthermore, most third-party payors currently require additional accreditation for approved cell therapy drugs, which limits the centers that can administer the drugs, and similar limitations may also be imposed on the product candidates that we are developing. We expect to experience pricing pressures in connection with the sale of our product candidates, if any, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and on prescription drugs and surgical procedures in particular, has become intense. As a result, increasingly high barriers to entry are developing for new drug products such as ours.

Healthcare reform initiatives and other administrative and legislative proposals may harm our business.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, ("the ACA"), was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- 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;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow-on biologic products;
- 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
- establishment of the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA. For example, the Tax Cuts and Jobs Act of 2017 (the "Tax Act") was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Further, the 2020 federal spending package eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is an inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. The case was appealed to the U.S. Court of Appeals for the Fifth Circuit. On December 18, 2019, a three-judge panel of the U.S. Court of Appeals for the Fifth Circuit declared the ACA's individual mandate unconstitutional and remanded the case back to the Texas Federal District Court to determine whether the remainder of the ACA also is unconstitutional. On March 2, 2020, the U.S. Supreme Court agreed to hear two consolidated cases, filed by the State of California and the United States House of Representatives, asking the U.S. Supreme Court to review the severability issue. On June 17, 2021, the U.S. Supreme Court dismissed the case, finding that the plaintiffs lacked standing. Additionally, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. There can be no assurances that opponents to the ACA and other healthcare reform measures will not continue attempts to repeal and/or replace the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. However, the Medicare sequester reductions under the Budget Control Act of 2011 have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic; however, the reductions are expected to continue through 2030. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers 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 or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

There have also been a number of proposals in the United States to control the escalating cost of healthcare, including the cost of drug treatments, patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and we expect that coverage and reimbursement for new therapies will be increasingly restricted. Recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Congress and the administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Furthermore, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs could restrict the amount that we are able to charge for our drug products, which could render our product candidates, if approved, commercially unviable and materially adversely affect our ability to raise additional capital on acceptable terms. On July 24, 2020 and September 13, 2020, former President Trump signed several executive orders aimed at lowering drug prices. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. Congress and the Biden administration have indicated that they will continue to pursue measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot predict what initiatives may be adopted in the future. Further federal, state, and regional developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. These changes may adversely impact the prices we or our future collaborators may charge for our products candidates, if commercialized.

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

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including:

- different regulatory requirements for approval of therapies in foreign countries;

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and 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 currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, and other public health crises, illnesses, epidemics or pandemics, such as the potential impact of the COVID-19 outbreak.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Any of the foregoing difficulties, if encountered, could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our business operations and relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to penalties.

These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, the Health Information Technology for Economic and Clinical Health Act, the U.S. Physician Payments Sunshine Act and its implementing regulations, U.S. state laws and regulations, including, state anti-kickback and false claims laws, laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, laws requiring the registration of pharmaceutical sales representatives, laws governing the privacy and security of health information in certain circumstances, and similar healthcare laws and regulations in other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will also involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Any of the foregoing could significantly harm our business, financial condition, results of operations and growth prospects.

We may fail to comply with evolving global privacy laws.

If we conduct clinical trials in the European Economic Area, ("EEA"), we may be subject to additional privacy laws. The General Data Protection Regulation, (EU) 2016/679, ("GDPR"), imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing privacy and data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

In the event we conduct clinical trials in the EEA, we must also ensure that we implement and maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current and, in particular, future data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the "CCPA"), which went into effect on January 1, 2020, is creating similar risks and obligations as those created by the GDPR, though the California Consumer Privacy Act does exempt certain clinical trial data. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Risks Related to Our Common Stock

The market price for our common stock may be volatile, which could contribute to the loss of all or part of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control.

Factors affecting the trading price of our common stock may include, but are not limited to:

- our decision to initiate a clinical study, not to initiate a clinical study or to terminate an existing clinical study;
- delays in the announcement of initial data or clinical results from our clinical trials or expectations that such delays may occur;
- adverse regulatory decisions, including failure to receive regulatory approval for our products;
- success or failure of competitive products, immunotherapy drugs or cellular therapies more generally;
- adverse developments concerning our manufacturers or our strategic partnerships;
- adverse safety or other clinical results, such as those that have occurred in the past or that may occur in the future, related to cellular therapies being developed by other companies that are or may be perceived to be similar to our cellular therapies;
- operating and stock price performance of other companies that investors deem comparable to us;
- sales of substantial amounts of common stock by our directors, executive officers or significant stockholders or the perception that such sales could occur;
- general economic and political conditions such as recessions, interest rates, fuel prices, elections, drug pricing policies, international currency fluctuations, acts of war or terrorism, and other public health crises, illnesses, epidemics or pandemics, such as the potential impact of the COVID-19 outbreak; and
- other factors discussed in these risk factors.

Any of the factors listed above could materially adversely affect your investment in our common stock, and our common stock may trade at prices significantly below the initial public offering price or the price at which you purchased the stock, which could contribute to a loss of all or part of your investment. In such circumstances the trading price of our common stock may not recover and may experience a further decline.

In addition, broad market and industry factors could materially adversely affect the market price of our common stock, irrespective of our operating performance. The stock market in general, and Nasdaq and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of ours, may not be predictable. For instance, technical factors in the public trading market for our common stock may produce price movements that may or may not comport with macro, industry or company-specific fundamentals, including, without limitation, the sentiment of retail investors (including as may be expressed on financial trading and other social media sites), the amount and status of short interest in our common stock, access to margin debt, and trading in options and other derivatives on our common stock. In addition, the trading prices for common stock of other biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The full extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence. A loss of investor confidence in the market for biotechnology or pharmaceutical stocks or the stocks of other companies which investors perceive to be similar to us, the opportunities in the biotechnology and pharmaceutical market or the stock market in general, could depress our stock price regardless of our business, financial condition, results of operations or growth prospects.

Concentration of ownership of our shares of common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of March 14, 2022, our directors and executive officers, and entities affiliated with them, as well as holders of more than 5% of our outstanding shares of common stock, in the aggregate beneficially own 63% of our common stock. These stockholders, acting together, are able to control or significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

Some of these persons or entities may have interests different from yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in the IPO and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of stockholders intend to sell shares of our common stock, could reduce the market price of our common stock. As of March 14, 2022, we had 33,000,863 shares of common stock outstanding.

Holders of an aggregate of 14,689,215 shares of common stock, including with respect to shares of our convertible preferred stock that converted into shares of our common stock upon the completion of the IPO, have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act, or until the rights terminate pursuant to the terms of the stockholders agreement between us and such holders. We have also registered all shares of common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on registration statements on Form S-8, and these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a negative impact on the trading price of our common stock.

We are an "emerging growth company" under the JOBS Act and a "smaller reporting company" and we rely on exemptions from certain disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, as a result of which our common stock may be less attractive to investors.

We take advantage and may continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including: not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company" as defined by applicable rules of the SEC. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company and would be permitted to continue to take advantage of many of the same reporting exemptions, including exemption from compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act as long as we do not otherwise also qualify as an "accelerated filer" or "large accelerated filer" for SEC reporting purposes and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive if we rely on emerging growth company or smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our severance and change in control agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated, which could materially adversely affect our financial condition or results of operations.

Our executive officers are parties to agreements that contain certain change in control and severance provisions. The agreements provide for cash payments for severance and other benefits in the event of a termination of employment that is not in connection with a change in control of us. They also provide for cash payments for severance and other benefits and acceleration of stock options vesting in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and could materially adversely affect the market price of our common stock. The payment of these severance benefits could materially adversely affect our financial condition and results of operations. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Our ability to use our net operating loss carryovers and certain other tax attributes may be limited.

As described above under "We have incurred significant losses since our inception, and we expect to continue to incur significant losses for the foreseeable future," we have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. Under the Internal Revenue Code of 1986 ("the Code"), a corporation is generally allowed a deduction for net operating losses ("NOLs") carried over from a prior taxable year. Under that provision, we can carry forward our NOLs to offset our future taxable income, if any, until such NOLs are used or expire, in the case of NOLs generated prior to 2018. The same is true of other unused tax attributes, such as tax credits. The amounts of our unused carryovers of NOLs and tax credits as of December 31, 2017, and a description of the valuation allowance we have recorded with respect to those items, are set forth below under "Management's Discussion and Analysis of Financial Condition and Results of Operations." In addition, under the Tax Act, the amount of post-2017 NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The Tax Act generally eliminates the ability to carry back any NOL to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely. Recently enacted legislation, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") temporarily reverses the limitations imposed by the Tax Act by suspending the 80% taxable income limitation to permit a corporation to offset without limitation its taxable income in 2019 or 2020 with NOL carryforwards generated in prior years. The CARES Act also allows NOLs generated in tax years 2018-2020 to be carried back up to five years.

Furthermore, 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, Sections 382 and 383 of the Code limit the corporation's ability to use carryovers of its pre-change NOLs, credits and certain other tax attributes to reduce its tax liability for periods after the ownership change. Our issuance of common stock pursuant to our IPO may result in a limitation under Sections 382 and 383 of the Code, either separately or in combination with certain prior or subsequent shifts in the ownership of our common stock. As a result, our ability to use carryovers of our pre-change NOLs and credits to reduce our future U.S. federal income tax liability may be subject to limitations. This could result in increased U.S. federal income tax liability for us if we generate taxable income in a future period. Limitations on the use of NOLs and other tax attributes could also increase our state tax liability. The use of our tax attributes will also be limited to the extent that we do not generate positive taxable income in future tax periods. To the extent our ability to utilize our NOLs and other tax assets going forward is limited, in part or altogether, our tax liability for future periods may be greater than expected, and our business, financial condition, results of operations and growth prospects may be materially adversely affected.

We do not expect to pay any cash dividends to the holders of our common stock for the foreseeable future.

We currently intend to invest our future earnings, if any, to fund our growth. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our stockholders have purchased our common stock. Investors seeking cash dividends should not purchase our common stock.

Provisions in our certificate of incorporation, our bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation, bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;

- establish a classified board of directors such that not all members of the board are elected at one time, which may delay the ability of our stockholders to change the membership of a majority of our board of directors;

- specify that only our board of directors, the Chairperson of our board of directors, our Chief Executive Officer or the President, or holders of greater than 10% of our common stock can call special meetings of our stockholders;

- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that a majority of directors then in office, even though less than a quorum, may fill vacancies on our board of directors;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our Certificate of Incorporation and bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit your opportunity to receive a premium for your shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our certificate of incorporation includes a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our Certificate of Incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for any:

- derivative action or proceeding brought on our behalf;
- action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
- action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or
- other action asserting a claim against us that is governed by the internal affairs doctrine.

This exclusive forum provision is intended to apply to claims arising under Delaware state law and is not intended to apply to claims brought pursuant to the Exchange Act or the Securities Act, or any other claim for which the federal courts have exclusive jurisdiction. This exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. The Delaware Supreme Court recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is permissible and enforceable under Delaware law, reversing an earlier decision from the Court of Chancery of the State of Delaware that had ruled that such provisions were not enforceable. Nevertheless, there is uncertainty as to whether a federal district court would enforce any exclusive forum provision with respect to claims under the Securities Act.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Certificate of Incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect our business, financial condition, results of operation and growth prospects.

General Risk Factors

Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent or unknown liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- adequately prosecuting and maintaining protection of any acquired intellectual property rights;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties about our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired drugs, intellectual property rights, technologies, and/or businesses sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a period of volatility or decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition, results of operation and growth prospects.

If securities analysts do not publish research or reports about our business or if they publish negative reports or downgrade our stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may materially adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules of the SEC and those of Nasdaq have imposed various requirements on public companies including that we establish and maintain effective disclosure and financial controls. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures following an initial transition period available to public companies. In particular, we must evaluate our systems and procedures, and test our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting in the later of our second Annual Report on Form 10-K or the first Annual Report on Form 10-K following the date on which we are no longer an emerging growth company unless we are a smaller reporting company and do not otherwise also qualify as an "accelerated filer" or "large accelerated filer" for SEC reporting purposes. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we do not comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

To successfully implement our business plan and comply with Section 404, we must prepare timely and accurate financial statements. We expect that we will need to continue to improve existing procedures and controls, and implement new operational and financial systems, to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer, and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could materially adversely affect the trading prices for our common stock and our ability to access the capital markets.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would materially adversely affect our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10-K. When we lose our status both as an emerging growth company and a smaller reporting company, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could materially adversely affect the trading price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Changes to, or interpretations of, financial accounting standards may affect our results of operations and could cause us to change our business practices.

We prepare our financial statements in accordance with U.S. GAAP. These accounting principles are subject to interpretation by the Financial Accounting Standards Board, the SEC and various bodies formed to interpret and create accounting rules and regulations. Changes in accounting rules can have a significant effect on our reported financial results and may affect our reporting of transactions completed before a change is announced. Changes to those rules or the questioning of current practices may materially adversely affect our financial results, including those contained in this filing, or the way we conduct our business.

Computer system interruptions or security breaches could significantly disrupt our product development programs and our ability to operate our business.

Our internal computer systems, cloud-based computing services and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage or interruption from computer viruses, ransomware, malware, data corruption, cyber-based attacks, phishing attacks, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have taken steps to protect the security of our information systems and the data maintained in those systems, we have, from time to time, experienced cyber incidents of varying degrees, although none of these cyber incidents have had a material adverse impact on our business, financial condition or results of operations. It is possible that in the future our safety and security measures will not prevent the improper functioning or damaging of our systems, or the improper access or disclosure of personally identifiable information, and any such event could materially and adversely impact our business, financial condition or results of operations. In addition, if a significant system failure, accident, security breach or other cyber incident were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, the disclosure of protected personally identifiable patient information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, federal, state and international laws and regulations, such as the GDPR, which took effect in May 2018, and the CCPA which took effect on January 1, 2020, as well as the California Consumer Privacy Act, which was passed in November 2020 and makes a number of significant amendments to the CCPA, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail or if our privacy practices do not meet the requirements of such laws. Other states are considering similar laws that could impact our use of research data with respect to individuals in those states. There are extensive documentation obligations and transparency requirements, which may impose significant costs on us. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. To the extent that any disruption, security breach or other cyber incident 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, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our facilities are located at two adjacent leased sites. The first site, located at 6000 Shoreline Court, Suites 102, 201, 203, 204 and 325, South San Francisco, California, consists of approximately 34,070 square feet of office and laboratory space and is primarily used for research, clinical, manufacturing and corporate activities. Our lease for Suite 325 commenced in January 2021. Our lease covering Suites 102, 204, and 325 expires in January 2029, with an option to extend this lease for an additional seven years. Our sublease covering Suites 201 and 203 expires in March 2021, after which our lease covering Suites 201 and 203 will be in effect, which expires in March 2024. The second site, located at 7000 Shoreline Court, South San Francisco, California, consists of 340 square feet of vivarium space and an additional 215 square feet of shared laboratory space, and is primarily used for preclinical research. Our agreement that provides for our use of these vivarium and laboratory spaces expires in June 2023. Our lease for an 88,000 square foot facility in South San Francisco to support research and development and future manufacturing of Nkarta's cell therapy products and product candidates commences in 2022 and expires in 2034. This new facility will also serve as our future headquarters with office space and research facilities.

We believe that these facilities are sufficient to meet our current needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business, results of operations, financial condition or growth prospects.

Ex parte reexaminations have been filed by one or more third parties against certain licensed patents in our portfolio. Third party requests for ex parte reexamination of U.S. Patent Nos. 10,774,309 and 10,829,737, which relate to our NKX101 product candidate, were recently filed. Also, one ex parte reexamination of U.S. Patent No. 9,511,092, which does not relate to any of our current product candidates, is pending and another is on appeal. Although we plan to vigorously protect our intellectual property rights, as with all legal proceedings, there can be no guarantee as to the outcome, and, regardless of the merits of third-party challenges, such proceedings are time-consuming and costly. As a result of such reexaminations, our rights under the relevant patents could be narrowed or lost, and in the course of such proceedings, we may incur substantial costs and the time and attention of our management may be diverted from the development and commercialization of our product candidates.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock has been listed on The Nasdaq Global Select Market under the symbol "NKTX" and has been publicly traded since July 10, 2020. Prior to that date, there was no public trading market for our common stock.

Holders of Common Stock

As of March 14, 2022, there were approximately 34 holders of record of our common stock. The actual number of stockholders is greater than this 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 by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, we may enter into agreements in the future that could contain restrictions on payments of cash dividends.

Use of Proceeds

On July 14, 2020, we completed our IPO. Our registration statement on Form S-1 (File No. 333-239301) relating to the IPO was declared effective by the SEC on July 9, 2020.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on July 13, 2020 pursuant to Rule 424(b)(4) under the Securities Act. As of December 31, 2021, we estimate that we have used $20.9 million from the net proceeds from the IPO primarily to advance our product candidates through preclinical studies and clinical trial programs, the construction of our manufacturing facility, and for working capital and general corporate purposes. We invested the remaining funds received in cash equivalents and other marketable securities in accordance with our investment policy.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities during the period covered by this report.

Issuer Purchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III, Item 12 of this Annual Report on Form 10 K.

Item 6. [Reserved]

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 in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs, and involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those discussed in the section titled "Risk Factors" included under Part I, Item 1A and elsewhere in this Annual Report. See "Cautionary Note Regarding Forward-Looking Statements" in this Annual Report.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of allogeneic, off-the-shelf engineered natural killer ("NK"), cell therapies to treat cancer. Our NK cell engineering platform builds on prior experience and success with engineering T cells and includes proprietary technologies that enable us to generate an abundant supply of NK cells, improve the persistence of these cells for sustained activity in the body, engineer enhanced NK cell recognition of tumor targets and to freeze, store and thaw our engineered NK cells for off-the-shelf use for the treatment of cancer. All of our product candidates are designed to be allogeneic, meaning they are produced using cells from a different person than the patient treated, as well as off-the-shelf, meaning they are produced in quantity, then frozen and therefore available for treating patients without delay, unlike existing autologous cell therapies, or cell therapies derived from a patient's own cells. Based on recently published data and data presented at medical conferences from a number of clinical trials of certain NK cell therapies, we believe that engineered NK cells have the potential to be an effective cancer therapy, be well tolerated, and avoid some of the toxicities observed with other cell therapies. Our two co-lead product candidates are NKX101 and NKX019.

Our NK cell engineering platform is designed to address the limitations and challenges of current technologies for engineering T cells and NK cells and is a result of our internal expertise and deep understanding of NK cell biology. Our platform includes proprietary technologies for NK cell expansion, persistence, targeting and cryopreservation. All of our product candidates incorporate each of the four components of our technology platform, which we believe provides the best opportunity for achieving clinically meaningful results in our development program.

We currently have two ongoing Phase 1 clinical trials. In November 2020, we announced that the first patient was treated in the multi-center Phase 1 clinical trial of NKX101 for the treatment of relapsed/refractory acute AML or higher risk MDS. This first-in-human multi-center study evaluates the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX101.

In October 2021, we announced that we had dosed the first patients with NKX019 in the Phase 1 clinical trial for the treatment of B-cell malignancies. This multi-center first-in-human study evaluates the safety, pharmacokinetics, and preliminary anti-tumor activity of NKX019, administered in a cycle of three weekly infusions following lymphodepletion.

Under the Company's collaboration with CRISPR, we are collaboratively designing and advancing up to two (2) allogeneic, gene-edited NK cell therapies, one of which is the CD70 CAR-NK program, and one (1) allogeneic, gene-edited NK+T cell therapy.

Since the commencement of our operations in 2015, we have devoted substantially all of our resources in support of our product development efforts, hiring personnel, raising capital to support and expand such activities and providing general and administrative support for these operations. We have not generated any revenue from product sales and have funded our operations primarily from our initial public offering, the issuance of convertible promissory notes, private placements of our preferred stock and with proceeds from our previous collaboration. We have incurred a net loss of $86.1 million and $91.4 million during the years ended December 31, 2021 and 2020, respectively, and we expect to continue to incur significant losses for the foreseeable future. As of December 31, 2021, we had an accumulated deficit of $204.1 million. At December 31, 2021, we had cash, cash equivalents, restricted cash and short-term investments of $240.2 million.

We expect our operating expenses to significantly increase as we continue to develop and seek regulatory approvals for our product candidates, engage in other research and development activities to expand our pipeline of product candidates, maintain and expand our intellectual property portfolio, and ultimately establish a commercial organization. We have also incurred increased operating expenses since becoming a public company, which we expect will further increase when we are no longer able to rely on certain "emerging growth company" exemptions we are afforded under the Jumpstart Our Business Startups Act (the "Jobs Act") as further described under "—Jobs Act" below. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, and our expenditures on other research and development activities.

We will need substantial additional funding to support our continuing operations and pursue our long-term development strategy. We may seek additional funding through the issuance of our common stock, including through our ATM Offering Program (as defined below), other equity or debt financing or collaborations or partnerships with other companies. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts for our product candidates and other research, development and manufacturing activities. We may not be able to raise additional capital on terms acceptable to us, or at all. Any failure to raise capital as and when needed would compromise our ability to execute on our business plan and may cause us to significantly delay, scale back or discontinue the development of some of our programs or curtail any efforts to expand our product pipeline.

We issued shares of our Series B convertible preferred stock for aggregate gross proceeds of $64.4 million on July 1, 2020 in connection with the exercise by the holders of at least one-third of our Series B convertible preferred stock prior to the completion of our IPO (the "Series B Milestone Closing"). On July 14, 2020, we completed our IPO. In connection with the IPO, we issued and sold 16,100,000 shares of our common stock, including 2,100,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $18.00 per share. We received approximately $265.1 million in net proceeds, after deducting underwriting discounts and commissions and other offering costs of $24.7 million. The shares began trading on the Nasdaq Global Select Market on July 10, 2020. Upon completion of the IPO, all of our outstanding shares of convertible preferred stock converted into 14,689,215 shares of our common stock.

The COVID-19 pandemic has affected and may continue to affect our business and operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct and enrollment of current and future clinical trials. We have taken certain precautionary measures to minimize exposure of our employees to the virus and to comply with directives from public health officials. This includes work from home policies for our employees as well as enhanced safety measures for our employees and other personnel working in our offices, labs and manufacturing facility. We have mandated vaccination for our employees working on site and have encouraged vaccination of our employees working remotely. Some of the third-party vendors that we use, including some of our contract manufacturing sites, and our contract research organizations ("CROs"), have experienced employee turnover/attrition, delays or other disruptions during this pandemic and the accompanying flexible work options and, in some instances, costs have increased. We have incorporated remote monitoring of clinical trial sites, where feasible, for our ongoing NKX101 Phase 1 trial in the U.S. and ongoing NKX019 Phase 1 trial with sites in both the U.S. and Australia. In addition, we have experienced some internal delays due to COVID-19, including some delays in construction of our GMP manufacturing facility and in our internal research efforts. COVID-19 has also caused global supply shortages of certain materials that we and our contract development and manufacturing organization ("CDMO") partners use for research and cGMP manufacturing, such as certain raw materials, cell culture media, disposable plastics, and equipment. Supply chain and operational disruptions due to COVID-19 have contributed to certain enrollment delays in our NKX101 clinical trial. In addition, we have had minor delays in setting up clinical sites in our NKX019 clinical trial due to repurposing of healthcare personnel and facilities to support local pandemic efforts. We will continue to monitor the impact of COVID-19 and any additional waves of the pandemic on the Company's operations including continued enrollment in the NKX101 and NKX019 clinical trials, as well as on our CROs, CDMOs, and clinical trial sites with respect to COVID-19 related shutdowns, restrictions on travel, and restrictions on hospital visits for clinical trial participants or clinical research staff. Our clinical programs may also be impacted by delays at the FDA or other regulatory authorities due to COVID-19. In response to the pandemic, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. We continue to evaluate the impact of the CARES Act on our financial position, results of operations and cash flows. We currently do not believe the CARES Act will have a material impact on our financial condition, results of operations, or liquidity.

Financial Operations Overview

Operating Expenses

Research and Development

Research and development costs consist primarily of costs incurred for the discovery and clinical development of our drug candidates, which include:

- employee-related expenses, including salaries, related benefits, travel and share-based compensation expenses for employees engaged in research and development functions;
- expenses incurred in connection with research, laboratory consumables, sponsored research, and preclinical studies;
- expenses incurred in connection with conducting clinical trials including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with CROs, other vendors or central laboratories and service providers engaged to conduct our trials;
- the cost of consultants engaged in research and development related services and the cost to manufacture drug product candidates for use in our preclinical studies and clinical trials;
- facilities, depreciation and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs related to regulatory compliance; and
- the cost of annual license fees.

We typically have various early-stage research and drug discovery projects as well as various product candidates undergoing clinical trials. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding the costs incurred for these early-stage research and drug discovery programs on a project-specific basis.

We expense research and development costs as they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

The following table summarizes our research and development expenses for the years ended December 31, 2021 and 2020. The direct external development program expenses reflect external costs attributable to our clinical development candidates and preclinical candidates selected for further development. Such expenses include third-party contract costs relating to manufacturing, clinical trial activities, translational medicine and toxicology activities. The partner cost sharing represents reimbursable research and development expenses from the CRISPR Agreement. The unallocated internal research and development costs include personnel, facility costs, laboratory consumables and discovery and research related activities associated with our pipeline.

	Year Ended December 31,	
	2021	2020
Direct external development program expenses:		
NKX101	$ 12,456	$ 8,145
NKX019	7,466	1,141
CD70	645	589
NK+T	520	—
Partner cost sharing	(2,310)	—
Unallocated internal research and development costs:		
Personnel related (including share-based compensation)	29,919	16,989
Others	14,716	9,356
Total research and development costs	$ 63,412	$ 36,220

Research and development activities are central to our business model. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our drug candidates. However, we expect that our research and development expenses will increase substantially in connection with our planned preclinical and clinical development activities in the near term and in the future.

The successful development of our drug candidates is highly uncertain. A change in the outcome of any of a number of variables with respect to the development of our drug candidates may significantly impact the costs and timing associated with the development of our drug candidates. A discussion of the risks and uncertainties that we face in the development and commercialization of our drug candidates can be found under Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K. We may never succeed in obtaining regulatory approval for any of our drug candidates.

General and Administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including share-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and facility-related costs.

We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities and to reflect increased costs associated with operating as a public company. These increased costs will likely include increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income (Expense)

Change in Fair Value of Preferred Stock Purchase Right Liability

In August 2019, we entered into a Series B Preferred Stock Purchase Agreement that contained future purchase rights that were required to be accounted for as liabilities and remeasured to fair value at each reporting date, with any change in the fair value reported as a component of other expense, net. We recorded periodic adjustments to the estimated fair value of the preferred stock purchase rights until they were exercised in July 2020, in connection with our IPO. Upon the exercise of the preferred stock purchase right, the final remeasurement adjustment of the convertible preferred stock purchase right liability was recorded and was reclassified to additional paid-in capital on the balance sheets.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and short-term investments and adjustments related to amortization of purchase premiums and accretion of discounts of short-term investments.

Income Taxes

We are subject to corporate U.S. federal and state income taxation. As of December 31, 2021, we had federal and state net operating loss carryforwards of approximately $139.0 million and $65.4 million, respectively. Of the $139.0 million federal net operating loss carryforwards, $3.2 million will begin expiring in 2035, if not utilized, while $135.8 million can be carried forward indefinitely. The state tax loss carryforwards will begin expiring in 2036, if not utilized. As of December 31, 2021, we had federal and state research and development tax credits of approximately $5.4 million and $3.6 million, respectively. If not utilized, the federal research tax credit will begin to expire in 2035. The California research tax credit can be carried forward indefinitely.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of net operating losses and credits before utilization. We have not performed an analysis to determine the limitation of our net operating loss carryforwards.

We estimate our income tax provision, including deferred tax assets and liabilities, based on management's judgment. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. As of December 31, 2021 and 2020, we had gross unrecognized tax benefits of $1.4 million and $0.8 million, respectively, all of which would affect our income tax expense if recognized, before consideration of our valuation allowance. As of December 31, 2021, we do not expect our unrecognized tax benefits will significantly change over the next 12 months.

Results of Operations

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year Ended December 31,		
	2021	2020	Change
Operating expenses:			
Research and development	63,412	36,220	27,192
General and administrative	23,017	15,288	7,729
Total operating expenses	86,429	51,508	34,921
Loss from operations	(86,429)	(51,508)	(34,921)
Other income (expense), net:			
Change in fair value of purchase right liability	—	(40,163)	40,163
Interest income	370	313	57
Other expense, net	(16)	(3)	(13)
Total other income (expense), net	354	(39,853)	40,207
Net loss	$ (86,075)	$ (91,361)	$ 5,286

Research and development expenses

Research and development expenses were $63.4 million and $36.2 million for the years ended December 31, 2021 and 2020, respectively. The increase of $27.2 million was primarily due to increases of $12.9 million in personnel costs, including an increase in share-based compensation expense of $4.8 million as a result of continued growth in headcount, and increases of $11.2 million in our external program costs related to NKX101 and NKX019, and $5.4 million in other internal research costs, primarily consisting of research and laboratory supplies and facilities expenses, offset by $2.3 million in partner cost sharing reimbursable expenses. The increase in program costs relating to NKX101 and NKX019 is primarily due to additional clinical development activities compared to the prior year period. We expect our research and development expenses will continue to increase in future periods as we progress our product candidates and conduct our clinical trials and development activities.

General and administrative expenses

General and administrative expenses were $23.0 million and $15.3 million for the years ended December 31, 2021 and 2020, respectively. The increase of $7.7 million was primarily due to an increase in personnel costs of $4.7 million, including an increase of $2.9 million in share-based compensation expense as a result of continued growth in headcount. The increases in general and administrative expense were also due to a $0.9 million increase in professional services related to accounting services, corporate legal fees, other consulting and patent legal fees, and a $2.1 million increase in other general and administrative expenses that included insurance, rent, depreciation expense and other facilities expense. We have incurred and expect to continue to incur additional expenses as a result of being a public company following the completion of our IPO in July 2020, which we expect will further increase when we no longer qualify as an "emerging growth company" under the JOBS Act. In addition, we have incurred and expect to continue to incur increased expenses related to additional insurance, investor relations and other increases related to needs for additional human resources and professional services associated with being a public company.

Change in fair value of preferred stock purchase right liability

We recognized a remeasurement adjustment for the change in fair value of preferred stock purchase right liability of $40.2 million in other expense for the year ended December 31, 2020. This remeasurement adjustment was related to the Series B Preferred Stock Purchase Agreement entered into in August 2019, which contained future purchase rights that were required to be accounted for as liabilities and remeasured to fair value at each reporting date, with any change in the fair value reported as a component of other expense, net. Upon the exercise of the preferred stock purchase right with the completion of the Series B Milestone Closing in July 2020, that resulted in the issuance of 27,066,206 shares of our Series B convertible preferred stock for an aggregate gross proceeds of $64.4 million, the final remeasurement adjustment of the preferred stock purchase right liability was recorded and reclassified to additional paid-in capital on the balance sheet.

Interest income

Interest income was $0.4 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively. The increase in interest income was due to interest earned from short-term investments, partially offset by amortization of purchase premiums and accretion of discounts of short-term investments.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2021, we had cash, cash equivalents, restricted cash and short-term investments of $240.2 million. In connection with our IPO which closed on July 14, 2020, we received $265.1 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses. We issued and sold 16,100,000 shares of our common stock, including 2,100,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $18.00 per share. On July 1, 2020, we issued 27,066,206 shares of our Series B convertible preferred stock at a price of $2.37935 per share for gross proceeds of $64.4 million in connection with the Series B Milestone Closing.

Prior to our IPO, we funded our operations primarily through the issuance of convertible promissory notes and private placements of our convertible preferred stock with total gross proceeds of $126.0 million, and $7.9 million from our previous collaboration agreement with GlaxoSmithKline, which terminated in December 2018.

On August 12, 2021, we filed a Registration Statement on Form S-3 (the "Shelf Registration Statement"), covering the offer and sale from time to time, pursuant to Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), of up to $500.0 million in aggregate offering price of shares of our common stock, shares of our preferred stock, debt securities, warrants, and rights and units. The Shelf Registration Statement was declared effective by the SEC on September 2, 2021. The Shelf Registration Statement included a prospectus covering the

offer and sale from time to time of up to $150.0 million in aggregate offering price of shares of the Company's common stock through an "at-the-market" equity offering program under the Securities Act (the "ATM Offering Program") with Cowen and Company, LLC, as sales agent. As of December 31, 2021, no sales of our common stock had been made pursuant to the ATM Offering Program.

We have incurred net losses and negative cash flows from operations since our inception and anticipate that we will continue to incur net losses for the foreseeable future. We expect to incur substantial expenditures as we develop our product pipeline and advance our drug candidates through clinical development, undergo the regulatory approval process and, if approved, launch commercial activities. Specifically, in the near term we expect to incur substantial expenses relating to initiating and completing our clinical trials, the development and validation of our manufacturing processes, and other development activities. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of our drug candidates, if ever, we expect to finance our operations through the sale of equity, including pursuant to our ATM Offering Program, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of our drug candidates or delay our efforts to expand our product pipeline. We may also be required to sell or license to other parties' rights to develop or commercialize our drug candidates that we would prefer to retain.

We believe that our current cash, cash equivalents, restricted cash and short-term investments as of December 31, 2021 will be sufficient to meet our cash needs for at least 12 months following the issuance date of this Annual Report on Form 10-K.

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (67,927)	$ (43,506)
Net cash provided by (used in) investing activities	32,534	(210,081)
Net cash provided by financing activities	1,202	329,817
Net (decrease) increase in cash and cash equivalents	$ (34,191)	$ 76,230

Operating Activities

The net cash used in operating activities for the year ended December 31, 2021 was $67.9 million was primarily due to our net loss of $86.1 million, adjusted for net non-cash charges of $19.8 million and a change in operating assets and liabilities of $1.6 million. The net non-cash charges of $19.8 million consisted primarily of share-based compensation of $14.5 million, depreciation and amortization of $1.8 million, investment accretion and amortization of $3.2 million and non-lease lease expense of $0.4 million. The net change in operating assets and liabilities of $1.6 million was related to the increase in prepaid and other current assets of $4.4 million primarily due to the cost sharing receivable, higher manufacturing and clinical deposits and other current assets, offset by an increase in accounts payable and accrued and other liabilities of $2.8 million as we continued to increase our research and development related activities.

The net cash used in operating activities for the year ended December 31, 2020 was $43.5 million was primarily due to our net loss of $91.4 million, adjusted for net non-cash charges of $48.7 million and a change in operating assets and liabilities of $0.8 million. The net non-cash charges of $48.7 million consisted primarily of change in fair value of our preferred stock purchase right liability of $40.2 million related to the remeasurement

adjustment of the Series B convertible preferred stock purchase right liability, share-based compensation of $6.7 million, depreciation and amortization of $0.8 million, investment accretion and amortization of $0.7 million and non-lease lease expense of $0.3 million. The net change in operating assets and liabilities of $0.8 million was related to the increase in prepaid and other current assets of $3.6 million primarily due to higher prepayments for director and officer insurance premiums and other current assets, offset by an increase in accounts payable and accrued and other liabilities of $2.8 million as we continued to increase our research and development related activities.

Investing Activities

The net cash provided by investing activities for the year ended December 31, 2021 of $32.5 million was comprised of proceeds from maturities of short-term investments of $264.8 million, partially offset by purchases of property and equipment of $5.0 million primarily related to the construction of our manufacturing facility and purchases of short-term investments of $227.3 million.

The net cash used by investing activities for the years ended December 31, 2020 of $210.1 million was comprised of purchases of short-term investments of $222.6 million using the proceeds from Series B preferred stock upon the closing of Series B Preferred Stock Milestone Closing and proceeds from our initial public offering in July 2020, offset by proceeds from maturities of short-term investments of $20.0 million, and purchases of property and equipment of $7.5 million primarily related to the construction of our manufacturing facility.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 of $1.2 million was mainly due to proceeds from the exercise of stock options, partially offset by payment of deferred offering costs of $0.3 million associated with the filing of our Shelf Registration Statement and the establishment of our ATM Offering Program.

Net cash provided by financing activities for the year ended December 31, 2020 of $329.8 million, was mainly due to the net proceeds of $265.1 million from initial public offering, after deducting underwriting discounts and commissions and other offering costs of $24.7 million, net proceeds of $64.3 million from the issuance of our Series B convertible preferred stock, after deducting issuance costs of $0.1 million, and proceeds of $0.4 million from the exercise of stock options.

Funding Requirements

Based upon our current operating plans, we believe that our existing cash, cash equivalents, restricted cash and short-term investments will be sufficient to fund our operations for at least the next 12 months from the date of issuing this Annual Report on Form 10-K. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing therapeutic product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

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

- the type, number, scope, progress, expansions, results, costs and timing of, our clinical trials and preclinical studies for our product candidates or other potential product candidates or indications which we are pursuing or may choose to pursue in the future;
- the outcome, timing and costs of regulatory review of our product candidates;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing and the costs associated with building our manufacturing facility;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;

- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- patients' willingness or ability to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements, including payments required for meeting regulatory and commercial milestones or sales based royalties;
- the costs of obtaining, maintaining and enforcing our patent and other intellectual property rights; and
- costs associated with any product candidates, products or technologies that we may in-license or acquire.

Until such time as we can generate significant revenue from sales of our therapeutic product candidates, if ever, we expect to finance our cash needs through public or private equity, including pursuant to our ATM Offering Program, or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. 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 or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity 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 funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and may reduce the value of our common stock. 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 even if we would otherwise prefer to develop and market such product candidates ourselves.

Contractual Obligations and Commitments

In May 2018, we entered into a lease agreement for our corporate office and laboratory space located in South San Francisco, California with an expiration date in May 2025 (the "Initial Lease Agreement"). In April 2019, we executed the first amendment to the Initial Lease Agreement for additional corporate space, laboratory space and manufacturing capabilities and an extension to the lease term through April 2026. The terms of the lease amendment contain a rent abatement for the first month and rent escalation provisions. In addition to the base rent payments, we will be obligated to pay certain customary amounts for our share of operating expenses and tax obligations related to the facilities.

In May 2020, we executed the second amendment to the Initial Lease Agreement for an eight-year non-cancelable lease for additional office and laboratory space in the same building. The lease amendment for the additional space provided for abatement of rent during the first three months of the lease and contained rent escalations during the term of the lease. The lease amendment for this additional space commenced in January 2021 and expires in January 2029. The lease amendment also included an extension of the lease term of our existing office and laboratory space through January 2029, with an option to extend the lease for an additional seven-year term.

In January 2021, we executed the third amendment to the Initial Lease Agreement for a three-year non-cancelable lease for additional office space in the same building. The lease amendment for this additional space commenced in the second quarter of 2021 and expires in March 2024.

In October 2021, we executed the fourth amendment to the Initial Lease Agreement for a seven-year non-cancelable lease for additional office and laboratory space in the same building. The lease amendment for additional space provided for abatement of rent during the first two months of the lease and contained rent escalations during the term of the lease. The lease amendment for this additional space is anticipated to commence in April 2022 and expires in January 2029. The Company expects to pay base rent of approximately $4.6 million over the lease term. The lease amendment also includes this additional space in our option to extend the lease for an additional seven-year term. The other terms of the Initial Lease Agreement, as amended, remain unchanged.

In July 2021, we entered into a lease agreement for corporate office, manufacturing and laboratory space located in South San Francisco, California with an expiration date approximately twelve years after the lease's legal commencement date (the "Additional Lease Agreement"). We will become responsible for paying rent on the lease's legal commencement date. The Company expects to pay base rent of approximately $99.6 million over the lease term. In addition to the base rent payments, we will be obligated to pay certain customary amounts for our share of operating expenses and tax obligations related to the facilities. The Additional Lease Agreement also provides for certain tenant improvement allowances for tenant improvements and certain infrastructure upgrades in connection with the initial buildout of the premises, a portion of which, if utilized, would need to be repaid by us over the lease term.

In November 2021, we executed an amendment to the Additional Lease Agreement for our corporate office, manufacturing and laboratory space. The amendment expressly includes manufacturing as a permitted use at the facility, clarifies that Silicon Valley Bank is an acceptable bank for purposes of issuing a letter of credit under the lease, revises the letter of credit transferability terms and replaces the form of letter of credit attached to the lease. The other terms of the Additional Lease Agreement remain unchanged.

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 the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and judgments, including those related to preclinical studies and clinical trial accruals, and share-based compensation. We base our estimates and assumptions on historical experience, known trends and events, and various other factors that are believed to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. See Note 2 to our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for a summary of significant accounting policies and the effect on our financial statements.

Recently Issued Accounting Pronouncements

See Recent Accounting Pronouncements in Note 2 to our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also a party to indemnification agreements with our officers and directors. We believe the fair value of the indemnification rights

and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of December 31, 2021 and 2020.

Segment Information

We have one business activity and operate in one reportable segment.

JOBS Act

We are an "emerging growth company" as described under the JOBS Act, and we could have taken advantage of an extended transition period for complying with new or revised accounting standards. This would have allowed us to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have chosen irrevocably to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act").

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of our IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company or a non-accelerated filer, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our prospectuses and in our periodic reports and proxy statements.

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

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in money market funds, commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For marketable investment securities with short-term maturities, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the statements of operations and comprehensive loss. As such, we believe that if a 10.0% change in interest rates were to have occurred on December 31, 2021, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

We are exposed to market risk related to changes in foreign currency exchange rates. We contract with vendors that are located outside the United States and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with such arrangements. We do not currently hedge our foreign currency exchange risk. Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

We do not believe that inflation, interest rate changes, or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

Nkarta, Inc.
Index to Financial Statements
For the years ended December 31, 2021 and 2020

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Nkarta, Inc. (the Company) as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows, for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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 2019.

Redwood City, California
March 17, 2022

NKARTA, INC.
Balance Sheets
(In thousands, except share and per share data)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 60,816	$ 96,692
Short-term investments, available-for-sale	177,272	218,221
Prepaid expenses and other current assets	7,692	3,922
Total current assets	245,780	318,835
Restricted cash	2,098	413
Property and equipment, net	12,856	9,350
Operating lease right-of-use assets	11,678	8,505
Other long-term assets	1,491	547
Total assets	$ 273,903	$ 337,650
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,112	$ 1,176
Operating lease liabilities, current portion	2,484	1,402
Accrued and other current liabilities	9,347	6,253
Total current liabilities	12,943	8,831
Operating lease liabilities, net of current portion	9,975	7,517
Other long-term liabilities	18	82
Total liabilities	22,936	16,430
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 54,350,179 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2021 and 2020; 32,971,107 and 32,627,963 shares issued and outstanding at December 31, 2021 and 2020, respectively	3	3
Additional paid-in capital	455,210	439,235
Accumulated other comprehensive income (loss)	(150)	3
Accumulated deficit	(204,096)	(118,021)
Total stockholders' equity	250,967	321,220
Total liabilities and stockholders' equity	$ 273,903	$ 337,650

See accompanying notes to the financial statements.

NKARTA, INC.
Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	63,412	36,220
General and administrative	23,017	15,288
Total operating expenses	86,429	51,508
Loss from operations	(86,429)	(51,508)
Other income (expense), net:		
Change in fair value of preferred stock purchase right liability	—	(40,163)
Interest income	370	313
Other expense, net	(16)	(3)
Total other income (expense), net	354	(39,853)
Net loss	$ (86,075)	$ (91,361)
Comprehensive loss:		
Net loss	(86,075)	(91,361)
Other comprehensive (loss) gain:		
Unrealized (loss) gain on securities	(153)	5
Comprehensive loss	$ (86,228)	$ (91,356)
Net loss per share, basic and diluted	$ (2.62)	$ (5.44)
Weighted-average number of common shares used in net loss per share, basic and diluted	32,856,883	16,806,262

See accompanying notes to the financial statements.

NKARTA, INC.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2020	27,283,973	$ 59,815	1,600,601	$ 1	$ 1,179	$ (26,660)	$ (2)	$ (25,482)
Issuance of Series B second tranche convertible preferred stock, net of issuance costs	27,066,206	64,321	—	—	—	—	—	—
Reclassification of preferred stock purchase right liability to equity upon issuance of convertible preferred stock	—	41,641	—	—	—	—	—	—
Conversion of convertible preferred stock to common stock	(54,350,179)	(165,777)	14,689,215	1	165,776	—	—	165,777
Issuance of common stock upon initial public offering, net of issuance costs	—	—	16,100,000	1	265,095	—	—	265,096
Vesting of shares of common stock subject to repurchase	—	—	85,304	—	50	—	—	50
Issuance of common stock upon exercise of stock option	—	—	152,843	—	387	—	—	387
Share-based compensation expense	—	—	—	—	6,748	—	—	6,748
Unrealized gain on short-term investments	—	—	—	—	—	—	5	5
Net loss	—	—	—	—	—	(91,361)	—	(91,361)
Balance at December 31, 2020	—	$ —	32,627,963	$ 3	$ 439,235	$ (118,021)	$ 3	$ 321,220
Vesting of shares of common stock subject to repurchase	—	—	62,045	—	35	—	—	35
Issuance of common stock upon exercise of stock option	—	—	281,099	—	1,479	—	—	1,479
Share-based compensation expense	—	—	—	—	14,461	—	—	14,461
Unrealized loss on short-term investments	—	—	—	—	—	—	(153)	(153)
Net loss	—	—	—	—	—	(86,075)	—	(86,075)
Balance at December 31, 2021	—	$ —	32,971,107	$ 3	$ 455,210	$ (204,096)	$ (150)	$ 250,967

See accompanying notes to the financial statements.

NKARTA, INC.
Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (86,075)	$ (91,361)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	14,461	6,748
Depreciation and amortization expense	1,756	786
Accretion of discount and amortization of premium on investments, net	3,237	738
Non-cash lease expense	367	262
Change in fair value of preferred stock purchase right liability	—	40,163
Others	(30)	(14)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,435)	(3,645)
Accounts payable and accrued and other liabilities	2,792	2,817
Net cash used in operating activities	(67,927)	(43,506)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(227,282)	(222,570)
Proceeds from maturities of available-for-sale securities	264,841	20,000
Purchase of property and equipment	(5,025)	(7,511)
Net cash provided by (used in) investing activities	32,534	(210,081)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	64,321
Proceeds from initial public offering, net of issuance costs	—	265,096
Proceeds from stock option exercises	1,479	387
Proceeds from early exercise of stock options	—	13
Payments of deferred offering costs	(277)	—
Net cash provided by financing activities	1,202	329,817
Net (decrease) increase in cash and cash equivalents	(34,191)	76,230
Cash, cash equivalents and restricted cash at beginning of year	97,105	20,875
Cash, cash equivalents and restricted cash at end of year	$ 62,914	$ 97,105
Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:		
Cash and cash equivalents	$ 60,816	$ 96,692
Restricted cash	2,098	413
Total cash, cash equivalents and restricted cash	$ 62,914	$ 97,105
Supplemental disclosures of non-cash investing and financing activities:		
Acquisitions of property and equipment	$ 238	$ 455

See accompanying notes to the financial statements.

1. Description of Business

Description of the Business

Nkarta, Inc. ("Nkarta" or the "Company") was incorporated in the State of Delaware in July 2015. The Company is a biopharmaceutical company developing engineered natural killer ("NK") cells to treat cancer. The Company is focused on leveraging the natural potent power of NK cells to identify and kill abnormal cells and recruit adaptive immune effectors to generate responses that are specific and durable. Nkarta is combining its NK expansion platform technology with proprietary cell engineering technologies to generate an abundant supply of NK cells, engineer enhanced NK cell recognition of tumor targets, and improve persistence for sustained activity in the body for the treatment of cancer. Nkarta's goal is to develop off-the-shelf NK cell therapy product candidates to improve outcomes for patients. The Company's operations are based in South San Francisco, California and it operates in one segment.

Initial Public Offering

On July 14, 2020, the Company completed its initial public offering ("IPO"). The Company's Registration Statement on Form S-1 (File No. 333-239301) relating to the IPO was declared effective by the Securities and Exchange Commission ("SEC") on July 9, 2020. The shares began trading on the Nasdaq Global Select Market on July 10, 2020. The Company issued 16,100,000 shares of its common stock, including 2,100,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at an offering price of $18.00 per share. Immediately prior to the closing of the Company's IPO on July 14, 2020, all outstanding shares of the Company's convertible preferred stock were converted into 14,689,215 shares of the Company's common stock. In aggregate, the shares issued in the IPO generated approximately $265.1 million in net proceeds after deducting underwriting discounts and commissions and other offering costs.

Liquidity and Management Plans

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. Since inception, the Company has devoted substantially all of its efforts to organizing and staffing, business planning, raising capital, conducting preclinical studies and initiating clinical studies, and has not realized substantial revenues from its planned principal operations. In addition, the Company has a limited operating history, has incurred operating losses since inception and expects that it will continue to incur net losses into the foreseeable future as it continues its research and development activities. As of December 31, 2021, the Company had an accumulated deficit of $204.1 million and cash, cash equivalents, restricted cash and short-term investments of $240.2 million.

On August 12, 2021, the Company filed a Registration Statement on Form S-3 (the "Shelf Registration Statement"), covering the offer and sale from time to time, pursuant to Rule 415 of the Securities Act of 1933, as amended (the "Securities Act"), of up to $500.0 million in aggregate offering price of shares of the Company's common stock, shares of the Company's preferred stock, debt securities, warrants, and rights and units. The Shelf Registration Statement was declared effective by the Securities and Exchange Commission (the "SEC") on September 2, 2021. The Shelf Registration Statement included a prospectus covering the offer and sale from time to time of up to $150.0 million in aggregate offering price of shares of the Company's common stock through an "at-the-market" equity offering program (the "ATM Offering Program") with Cowen and Company, LLC, as sales agent. As of December 31, 2021, no sales of the Company's common stock had been made pursuant to the ATM Offering Program.

Management plans to continue to incur substantial costs in order to conduct research and development activities and additional capital will be needed to undertake these activities. The Company intends to raise such capital through debt or equity financings or other arrangements to fund operations. Management believes that the Company's current cash, cash equivalents, restricted cash and short-term investments will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the filing date of this report.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principle ("U.S. GAAP").

Reverse Stock Split

On July 1, 2020, the Company effected a 1-for-3.7 reverse stock split (the "Reverse Stock Split") of its issued and outstanding common stock. Accordingly, the conversion ratio for the Company's outstanding convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. The par value of the common stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, options to purchase common stock, early exercised options, share data, per share data, convertible preferred stock (to the extent presented on an as-converted to common stock basis) and related information contained in these financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

COVID-19 Pandemic

The COVID-19 pandemic has caused disruptions in the global economy and has affected and may continue to affect the Company's business and operations. The extent of the impact of the COVID-19 pandemic on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, the development and spread of more contagious and/or vaccine-resistant variants, the effectiveness of actions taken in the United States and other countries to contain, vaccinate against, and treat the disease, and the pandemic's impact on the Company's current and planned preclinical studies and clinical trials, employees and vendors, all of which are uncertain and cannot be predicted. The extent to which the COVID-19 pandemic may impact the Company's financial condition or results of operations is uncertain. In response to the pandemic, CARES Act was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no impact on the Company's income tax provision for the year ended December 31, 2021. The Company continues to evaluate the impact of the CARES Act on its financial position, results of operations and cash flows. The Company currently does not expect to apply for loans or grants under the CARES Act.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the Company's financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to preclinical studies, fair value of assets and liabilities, share-based compensation and income taxes. Management bases its estimates on historical experience, knowledge of current events and actions it may undertake in the future that management believes to be reasonable under the circumstances. Actual results may differ from these estimates and assumptions.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash, cash equivalents and short-term investments. The Company maintains cash, cash equivalents and short-term investments with various high credit quality and are invested through banks and other financial institutions in the United States. Such deposits may be in excess of federally insured limits. Management believes that 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 deposits since inception.

Comprehensive Loss

Comprehensive loss consists of net loss and unrealized gains or losses on available-for-sale investments. The Company displays comprehensive loss and its components as part of the statements of operations and comprehensive loss.

Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of prepaid expenses and other current assets, accounts payable, accrued liabilities and other current liabilities are reasonable estimates of their fair value due to the short-term nature of these accounts.

Cash, Cash Equivalents, Short-term Investments and Restricted Cash

Cash and Cash Equivalents

The Company considers all highly liquid investments with insignificant interest rate risk and an original maturity of three months or less at the date of purchase to be cash equivalents. Cash includes demand deposits held in readily available checking accounts at a federally insured financial institution. Cash equivalents consist of money market funds.

Short-term Investments

Short-term investments consist of commercial debt securities, commercial paper and U.S. Government securities, classified as available-for-sale securities and have maturities of greater than three months but less than one year. The Company has classified all of its available-for-sale investment securities as current assets on the balance sheets because these are considered highly liquid securities and are available for use in current operations. The Company carries these securities at fair value, and reports unrealized gains and losses as a separate component of accumulated other comprehensive loss. The cost of debt securities is adjusted for amortization of purchase premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income in the statements of operations and comprehensive loss. Realized gains and losses on sales of securities are determined using the specific identification method and recorded in other income (expense), net in the statement of operations and comprehensive loss.

Restricted Cash

The Company is required to maintain letters of credit related to its office and lab space lease and the additional facility in South San Francisco that the Company plans to use for corporate offices, laboratories and manufacturing. This cash is the collateral for those letters of credit and per the terms of the leases must remain in place until one to two months after the termination of the leases. As the remaining terms of the leases as of December 31, 2021 is greater than one year, the related restricted cash has been classified as non-current.

Property and Equipment, Net

Property and equipment, which consist of leasehold improvements, furniture and fixtures, research equipment, computers and software and construction-in-progress are stated at cost less accumulated depreciation. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the assets, which ranges from three to five years. Leasehold improvements are amortized over the remaining life of the lease for leasehold improvements at the time the asset is placed into service.

Impairment of Long-Lived Assets

The carrying value of long-lived assets, including property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. Through December 31, 2021, there has been no such impairment losses recorded by the Company.

Deferred Offering Costs

Deferred offering costs that consisted of legal, accounting, printing and other fees and costs directly attributable to the IPO were capitalized. Upon the completion of the IPO in July 2020, the total deferred offering costs of $4.4 million were offset against the proceeds from the IPO and reclassified to additional paid-in capital on the balance sheet.

Preferred Stock Purchase Right Liability

The Company at times enters into convertible preferred stock financings where, in addition to the initial closing, investors agree to buy, and the Company agrees to sell, additional shares of that convertible preferred stock at a fixed price in the event that certain agreed upon milestones are achieved or at the election of investors. The Company evaluates this purchase right and assesses whether it meets the definition of a freestanding instrument and, if so, determines the fair value of the purchase right liability and records it on the balance sheets with the remainder of the proceeds raised being allocated to convertible preferred stock. The preferred stock purchase right liability is revalued at each reporting period with changes in the fair value of the liability recorded as change in fair value of preferred stock purchase right in the statements of operations and comprehensive loss. A final revaluation adjustment of preferred stock purchase right liability was recorded at settlement in July 2020 and the resultant fair value was then reclassified to convertible preferred stock at that time.

Convertible Preferred Stock

The Company recorded all shares of convertible preferred stock at their respective issuance price less issuance costs on the dates of issuance. Convertible preferred stock was previously classified outside of stockholders' equity (deficit) on the balance sheets as events triggering redemption were not solely within the Company's control because the preferred stockholders had the ability to effect a liquidation event, as they have majority of the Company's Board seats.

Immediately prior to the closing of the Company's IPO in July 2020, all outstanding shares of the Company's convertible preferred stock converted into the Company's common stock. There were no outstanding shares of the Company's convertible preferred stock as of December 31, 2021.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and other benefits of research and development personnel, including associated share-based compensation, costs related to research activities, preclinical studies, clinical trial, drug manufacturing and allocated overhead and facility-related expenses. The Company accounts for non-refundable advance payments for goods or

services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made.

Clinical trial costs are a component of research and development expenses. The Company expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company uses information it receives from internal personnel and outside service providers to estimate the clinical trial costs incurred.

Commitments

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has occurred and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range. There has been no such liabilities recorded by the Company as of December 31, 2021.

Leases

At the commencement date of a lease, the Company recognizes lease liabilities which represent its obligation to make lease payments, and right-of-use assets ("ROU assets") which represent its right to use the underlying asset during the lease term. The lease liability is measured at the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the lease commencement date. The ROU asset is measured at cost, which includes the initial measurement of the lease liability and initial direct costs incurred by the Company and excludes lease incentives. ROU assets are recorded in operating lease ROU assets and lease liabilities are recorded in operating lease liabilities, current and noncurrent in the balance sheets.

Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. Lease agreements that contain both lease and non-lease components are generally accounted for separately. The Company does not recognize lease liabilities and ROU assets for short-term leases with terms of twelve months or less.

Share-Based Compensation

Share-based compensation expense represents the cost of the grant-date fair value of employee, officer, director, and non-employee stock option grants, estimated in accordance with the applicable accounting guidance, recognized using the straight-line method over the vesting period for service-based options and using the graded vesting method for performance-based options. The vesting period generally approximates the expected service period of the awards. Forfeitures are recognized and accounted for as they occur.

The fair value of stock options is estimated using a Black-Scholes option pricing model on the date of grant. This method requires certain assumptions be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, expected dividend yield, and a risk-free interest rate. Options granted during the year have a maximum contractual term of ten years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the average of the contractual term of the stock option and its weighted-average vesting period. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future. The risk-free interest rates used are based on the U.S. Department of Treasury ("U.S. Treasury") yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the stock options.

Income Taxes

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Segment Reporting

The Company's chief operating decision maker, its President and Chief Executive Officer, manages its operations and business as one operating segment for the purposes of allocating resources, makes operating decisions and evaluates financial performance. No product revenue has been generated since inception and all assets are held in the United States.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of common shares plus the potential dilutive effects of potential dilutive securities outstanding during the period. Potential dilutive securities are excluded from diluted earnings or loss per share if the effect of such inclusion is antidilutive. The Company's potentially dilutive securities, which include convertible preferred stock prior to the conversion of such shares to common stock, unvested common stock, and outstanding stock options under the Company's equity incentive plan, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Recent Accounting Pronouncements

Adopted Accounting Pronouncements

Income Taxes. In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12—Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in Topic 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates. This standard is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. The Company adopted this standard in the first quarter of 2021 using the prospective method, and the adoption did not have a material impact on the Company's financial statements.

There were no other significant updates to the recently issued accounting standards other than as disclosed herewith. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

3. Net Loss Per Share

The following tables summarize the computation of the basic and diluted net loss per share (in thousands except share and per share data):

	Year Ended December 31,	
	2021	2020
Numerator:		
Net loss	$ (86,075)	$ (91,361)
Denominator:		
Weighted average common shares outstanding	32,901,002	16,918,664
Less: weighted average unvested common stock issued upon early exercise of common stock options	(44,119)	(112,402)
Weighted average shares used to compute net loss per share, basic and diluted	32,856,883	16,806,262
Net loss per share, basic and diluted	$ (2.62)	$ (5.44)

The following table summarizes the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	December 31,	
	2021	2020
Common stock options	4,204,686	3,640,715
Unvested common stock upon early exercise of common stock options	16,181	77,393
	4,220,867	3,718,108

4. Fair Value of Financial Instruments

The following tables summarize the fair value of the Company's financial instruments (in thousands):

		Fair Value Measurements Using		
	December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 57,018	$ 57,018	$ —	$ —
Short-term investments:				
Corporate debt securities	$ 111,466	$ —	$ 111,466	$ —
Commercial paper	21,272	—	21,272	—
U.S. Government securities	44,534	—	44,534	—
Total short-term investments	$ 177,272	$ —	$ 177,272	$ —
Total	$ 234,290	$ 57,018	$ 177,272	$ —

	December 31, 2020	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 94,631	$ 94,631	$ —	$ —
Short-term investments:				
Corporate debt securities	$ 48,614	$ —	$ 48,614	$ —
Commercial paper	63,445	—	63,445	
U.S. Government securities	106,162	—	106,162	—
Total short-term investments	$ 218,221	$ —	$ 218,221	$ —
Total	$ 312,852	$ 94,631	$ 218,221	$ —

Cash Equivalents and Short-Term Investments

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and short-term investments. Cash equivalents consisted of money market funds and short-term investments consisted of commercial paper, corporate debt securities and U.S. Government securities. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers.

Investments are classified as Level 1 within the fair value hierarchy if their quoted prices are available in active markets for identical securities. Investments in money market funds of $57.0 million and $94.6 million included in cash equivalents as of December 31, 2021 and 2020, respectively, were classified as Level 1 instruments.

Investments in corporate debt securities, commercial paper and U.S. Government securities included in short-term investments are valued using Level 2 inputs. Level 2 securities are initially valued at the transaction price and subsequently valued and reported upon utilizing inputs other than quoted prices that are observable either directly or indirectly, such as quotes from third-party pricing vendors. Fair values determined by Level 2 inputs, which utilize data points that are observable such as quoted prices, interest rates and yield curves, require the exercise of judgment and use of estimates, that if changed, could significantly affect the Company's financial position and results of operations.

The following tables summarize the Company's short-term investments as of December 31, 2021 and 2020 (in thousands):

	Maturity (in years)	December 31, 2021			
		Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
Corporate debt securities	1 year or less	$ 111,548	$ (89)	$ 7	$ 111,466
Commercial paper	1 year or less	21,272	—	—	21,272
U.S. Government securities	1 year or less	44,602	(68)	—	44,534
Total		$ 177,422	$ (157)	$ 7	$ 177,272

	Maturity (in years)	December 31, 2020			
		Amortized Cost	Unrealized Losses	Unrealized Gains	Estimated Fair Value
Corporate debt securities	1 year or less	$ 48,616	$ (6)	$ 4	$ 48,614
Commercial paper	1 year or less	63,445	—	—	63,445
U.S. Government securities	1 year or less	106,157	(7)	12	106,162
Total		$ 218,218	$ (13)	$ 16	$ 218,221

The Company considers whether unrealized losses have resulted from a credit loss or other factors. The unrealized losses on the Company's available-for-sale securities as of December 31, 2021 and 2020 were caused by fluctuations in market value and interest rates as a result of the economic environment and not credit risk. The Company concluded that an allowance for credit losses was unnecessary as of December 31, 2021 and 2020. It is neither management's intention to sell nor is it more likely than not that the Company will be required to sell these investments prior to recovery of their cost basis or recovery of fair value. Unrealized gains and losses are included in accumulated other comprehensive loss.

The Company excludes accrued interest from both the fair value and the amortized cost basis of the available-for-sale debt securities for the purposes of identifying and measuring an impairment and to not measure an allowance for expected credit losses for accrued interest receivables. Accrued interest receivable is written off through net realized investment gains (losses) at the time the issuer of the bond defaults or is expected to default on payment. It is the Company's policy to present the accrued interest receivable balance as part of prepaid expenses and other current assets in the balance sheets. Accrued interest receivable related to short-term investments was $1.0 million and $1.1 million as of December 31, 2021 and 2020, respectively.

Preferred Stock Purchase Right Liability

In August 2019, the Company entered into a Series B Preferred Stock Purchase Agreement (see Note 10) that contained future purchase rights that were required to be accounted for as liabilities, remeasured to fair value at each reporting date, and classified as a Level 3 instrument within the fair value hierarchy. Upon the exercise of the preferred stock purchase right on July 1, 2020, the preferred stock purchase right liability was revalued at an estimated fair value of $41.6 million and was reclassified to additional paid-in capital in the balance sheets.

The estimated fair value of the preferred stock purchase right liability at July 1, 2020 was determined using a valuation model that incorporated the probability of the occurrences of the Series B Milestone Closing in addition to the factors considered at issuance. An intrinsic value model was used to determine the fair value of preferred stock purchase right as of July 1, 2020.

The following table provides the change in preferred stock purchase right liability for the year ended December 31, 2020 (in thousands):

	Preferred Stock Purchase Right Liability
Balance, January 1, 2020	$ 1,478
Change in fair value of preferred stock purchase right	40,163
Reclassification of preferred stock purchase right liability to equity upon issuance of convertible preferred stock	(41,641)
Balance, December 31, 2020	$ —

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are comprised of the following (in thousands):

	December 31,	
	2021	2020
Prepaid expenses	$ 4,538	$ 2,586
Other current assets	3,154	1,336
Total prepaid expenses and other current assets	$ 7,692	$ 3,922

Property and Equipment, Net

Property and equipment, net is comprised of the following (in thousands):

	December 31,	
	2021	2020
Leasehold improvements	$ 3,462	$ 1,984
Furniture and fixtures	544	322
Research equipment	9,633	4,892
Computers and software	130	124
Construction-in-progress	2,274	3,459
Total property and equipment	16,043	10,781
Less accumulated depreciation and amortization	(3,187)	(1,431)
Total property and equipment, net	$ 12,856	$ 9,350

Depreciation and amortization expense were $1.8 million and $0.8 million for the years ended December 31, 2021 and 2020, respectively.

Accrued and Other Current Liabilities

Accrued and other current liabilities are comprised of the following (in thousands):

	December 31,	
	2021	2020
Accrued compensation	$ 5,453	$ 3,534
Accrued research and development costs	2,280	1,675
Accrued property and equipment	96	117
Other accrued and current liabilities	1,518	927
Total accrued and other liabilities	$ 9,347	$ 6,253

6. Leases

The Company has operating leases for its current corporate offices, laboratory space, manufacturing facility, and dedicated space in a vivarium in South San Francisco, California, as well as for an additional facility in South San Francisco that the Company plans to use for corporate offices, laboratories and manufacturing.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Operating lease expense	$ 2,581	$ 1,856
Variable lease expense [(1)]	302	178
Short-term lease expense	92	14
Total lease expense	$ 2,975	$ 2,048

[(1)] Variable lease expense for the periods presented primarily included common area maintenance charges.

Supplemental information related to operating leases were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows used for operating leases	$ 2,239	$ 1,705

The weighted-average remaining lease term was 6.7 years for the corporate office and laboratory space leases as of December 31, 2021. The corporate office lease includes an option to renew for an additional seven years. However, the renewal option was not included in the lease term for calculating the lease liability, as the renewal option allow the Company to maintain operational flexibility, and the Company was not reasonably certain that it

would exercise the renewal option at the time of the lease commencement. The weighted-average discount rate was 9.2% as of December 31, 2021.

Maturities of operating lease liabilities under existing operating leases as of December 31, 2021 were as follows (in thousands):

Year ending December 31,	Amount
2022	$ 2,579
2023	2,432
2024	2,184
2025	2,200
2026	2,288
2027 and thereafter	5,035
Total future minimum lease payments	16,718
Less imputed interest	(4,259)
Present value of net minimum lease payments	$ 12,459
Operating lease liabilities:	
Current	2,484
Non-current	9,975
Total lease liability	$ 12,459

In May 2018, the Company entered into a lease agreement for its corporate office and laboratory space located in South San Francisco, California with an expiration date in May 2025 (the “Initial Lease Agreement”). In April 2019, the Company executed the first amendment to the Initial Lease Agreement for additional corporate space, laboratory space and manufacturing capabilities and an extension to the lease term through April 2026.

In May 2020, the Company signed a second amendment to the Initial Lease Agreement. The amended lease provides for an eight-year non-cancelable lease of additional office and laboratory space in the same building. The lease amendment for additional office and laboratory space provided for abatement of rent during the first three months of the lease and contains rent escalations during the term of the lease. The lease for this additional space commenced in January 2021 and expires in January 2029. The lease amendment also includes an extension of the lease term for the existing office and laboratory space beginning on May 1, 2020 and expiring in January 2029. The amendment to the Initial Lease Agreement also includes an option to extend the lease for an additional seven-year term.

In January 2021, the Company signed a third amendment to the Initial Lease Agreement which provides for the lease of additional space in the same building. The lease amendment for this additional space commenced in April 2021 and expires in March 2024.

In October 2021, the Company signed a fourth amendment to the Initial Lease Agreement which provides for the lease of additional space in the same building. The lease for additional office and laboratory space provides for abatement of rent during the first two months of the lease and contains rent escalations during the term of the lease. The lease amendment of this additional space is anticipated to commence in April 2022 and expires in January 2029. The Company expects to pay base rent of approximately $4.6 million over the lease term. The lease amendment also includes this additional space in the Company’s option to extend the amended Initial Lease Agreement for an additional seven-year term. The other terms of the Initial Lease Agreement, as amended, remain unchanged.

In July 2021, the Company entered into a lease agreement for corporate office, manufacturing and laboratory space located in South San Francisco, California with an expiration date approximately twelve years after the lease's legal commencement date (the “Additional Lease Agreement”). The Company will become responsible for paying rent on the lease's legal commencement date. The Company’s monthly installment of base rent for the new premises will start at approximately $0.6 million commencing on the lease commencement date and will increase on an annual basis up to a maximum monthly base rent of approximately $0.8 million. The Company expects to pay base rent of approximately $99.6 million over the lease term. In addition to base rent, the Company is responsible for

payment of direct expenses, which include operating, insurance and tax expenses. The lease also provides for certain tenant improvement allowances of up to approximately $25.2 million for tenant improvements and certain infrastructure upgrades in connection with the initial buildout of the premises, approximately $4.4 million of which, if utilized, would need to be repaid by the Company over the lease term. As of December 31, 2021, we recorded a receivable of $0.8 million in other current assets related to costs incurred in 2021 that are reimbursable under the agreement. In 2021, the Company delivered a security deposit in the form of a letter of credit of $1.6 million to the Landlord in connection with the Additional Lease Agreement. For accounting purposes, the lease commencement date was determined to be in January 2022, which was the date at which the Company was deemed to have obtained control over the property. We expect to record lease liabilities of approximately $49 - $62 million based on the present value of the remaining minimum rental payments using discount rates as of the effective date. We also expect to record corresponding right-of-use assets of approximately $49 - 62 million. The Company, however, does not expect a material impact to its consolidated statements of operations and consolidated statements of cash flow.

In November 2021, the Company entered into an amendment to Additional Lease Agreement. The lease amendment expressly includes manufacturing as a permitted use at the facility, clarifies that Silicon Valley Bank is an acceptable bank for purposes of issuing a letter of credit under the lease, revises the letter of credit transferability terms and replaces the form of letter of credit attached to the lease.

Total minimum lease payments of $4.6 million and $99.6 million related to the lease of additional space under the fourth amendment to the Initial Lease Agreement and the Additional Lease Agreement, respectively, were excluded from the table above as the lease agreement had not yet commenced as of December 31, 2021.

7. Commitments and Contingencies

Guarantee Agreement

The Company has agreements whereby it indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company has a director and officer insurance policy that limits its exposure and enables the Company to recover a portion of any future amounts under certain circumstances and subject to deductibles and exclusions. The Company had no liabilities recorded for these agreements as of December 31, 2021 and 2020.

Letters of Credit

The Company has $2.1 million in letter of credit agreements with a financial institution that are used as collateral for the Company's corporate headquarters' operating lease and the additional facility in South San Francisco that the Company plans to use for corporate offices, laboratories and manufacturing. The letters of credit automatically renew annually without amendment unless cancelled by the financial institutions within 30 to 60 days of the annual expiration date.

8. Collaboration and License Agreements

CRISPR Collaboration Agreement

On May 5, 2021, the Company entered into the CRISPR Agreement with CRISPR to co-develop and co-commercialize an engineered CAR-NK product candidate targeting the CD70 tumor antigen and a NK+T product candidate. In addition, the Company will receive a license from CRISPR for up to five CRISPR-Cas9 gene editing targets that can be engineered into an unlimited number of its own NK cell products. CRISPR also has an option to co-develop and co-commercialize a future CAR-NK program.

Under the terms of the CRISPR Agreement, the Company and CRISPR share equally in all research and development costs and potential profits worldwide related to the CD70 CAR-NK product candidate, NK+T product candidate, and the potential future CAR-NK program (collectively, "Collaboration Products"). For the NK+T program, CRISPR is responsible for gene-editing activities and T cell related activities, and Nkarta is responsible for NK cell related activities. The related impact of the cost sharing associated with the research and development

activities is included in research and development expense on the condensed statements of operations. Expenses related to services performed by the Company are classified as research and development expense. Payments received from CRISPR for partial reimbursement of expenses are recorded as a reduction of research and development expense. As of December 31, 2021, the Company had a $1.1 million receivable under the research cost sharing provision, which is included as part of prepaid expenses and other current assets in the condensed balance sheet.

For each non-collaboration product candidate incorporating a gene editing target licensed from CRISPR, the Company would retain worldwide rights and may be required to make potential future payments based on the achievement of development and regulatory approval milestones totaling less than mid-twenty million dollars for each non-collaboration product, as well as tiered royalties up to the mid-single digits on net product sales of such product. As of December 31, 2021, the Company has not paid any amounts nor are any amounts owed by the Company under the CRISPR Agreement, and no milestones have been achieved.

MaxCyte License Agreement

On October 26, 2021, the Company entered into a license agreement (the “MaxCyte Agreement”) with MaxCyte, Inc. ("MaxCyte") to obtain non-exclusive clinical and commercial rights to use MaxCyte's cell loading technology to develop and commercialize in up to ten licensed products.

In connection with the MaxCyte Agreement, the Company must pay to MaxCyte annual research license fees and commercialization license fees, ranging from $0.1 million to $0.3 million, for each instrument licensed by the Company. Further, the Company could be required to make milestone payments to MaxCyte upon completion of certain regulatory and commercial milestones related to the clinical development and commercialization of certain of the Company’s licensed products. The aggregate potential milestone payments range from $10 million to $13 million per licensed product. Additionally, the Company may be required to make net sales milestone payments totaling between $61.9 million to $116.8 million per licensed product. As of December 31, 2021, the Company has not paid any amounts nor are any amounts owed by the Company under the MaxCyte Agreement, and no milestones have been achieved.

University of Singapore and St. Jude Children’s License Agreement

In August 2016, the National University of Singapore (“NUS”) and St. Jude Children’s Research Hospital (“St. Jude”) and the Company entered into a license agreement under which NUS and St. Jude (the “Licensors”) granted the Company an exclusive, royalty-bearing, worldwide license to its patent rights related to a method for expanding natural killer cells; a chimeric receptor with NKG2D specificity; and a method for supporting autonomous natural killer cell function (“NUS and St. Jude License Agreement”). The NUS and St. Jude License Agreement provides the Company with the rights to grant and authorize sublicenses to make, have made, use, sell, offer for sale and import products and otherwise exploit the patent rights.

As consideration for the license, the Company made an upfront payment of $31,800 and issued NUS 250,000 shares of the Company’s common stock. The Company determined that the upfront payment (SGD 42,750) and value of the common stock issued ($2,500 based on fair value at time of issuance) as part of the license agreement would be expensed upon execution of the contract as the license was acquired for research and development purposes which does not have alternative future uses, and the underlying technology has not reached technological feasibility, hence the Company expensed these costs during 2016.

In addition, the Company is required to pay an annual license maintenance fee of SGD 25,000, increasing to SGD 50,000 after year two of the agreement. Further, the Company could be required to make milestone payments to the Licensors upon completion of certain regulatory and commercial milestones related to the clinical development and commercialization of certain of the Company’s product candidates. The aggregate potential milestone payments are approximately SGD 5 million. The Company has also agreed to pay the Licensors royalties of 2.5% of net sales of products sold by the Company or through a sublicense. Additionally, the Company agreed to pay the Licensors a tiered percentage of sublicensing income (ranging from 7.5% to 20%) based on the timing of capital raised and stage of clinical trials. The NUS and St. Jude License Agreement also includes certain performance objectives which obligate the Company to meet various milestones related to the clinical development

and commercialization of certain of the Company's product candidates over time for up to 120 months after the effective date of the NUS and St. Jude License Agreement.

The Company recorded $37,000 license maintenance fees included as part of research and development expenses for each of the years ended December 31, 2021 and 2020. In 2020, the Company also recorded a $0.1 million milestone payments upon completion of a regulatory milestone related to the clinical development of the Company's product candidate, included as part of research and development expenses.

9. Employee Benefits

On January 1, 2018, the Company adopted a defined contribution 401(k) plan that is available to eligible employees. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, limited to the maximum amount allowable under federal tax regulations. As part of the plan, the Company elected to make non-matching contributions via mandatory 3% of compensation safe harbor nonelective contributions. The Company recognized $0.6 million and $0.3 million for expense related to the nonelective 401(k) contributions for the years ended December 31, 2021 and 2020, respectively.

10. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Under the Amended and Restated Certificate of Incorporation dated August 26, 2019, the Company had a total of 126,270,161 shares of capital stock authorized for issuance, consisting of 71,919,982 shares of common stock, par value of $0.0001 per share, and 54,350,179 shares of convertible preferred stock, par value of $0.0001 per share. Of the 54,350,179 shares of convertible preferred stock, 6,170,349 were designated Series A convertible preferred stock and 48,179,830 were designated Series B convertible preferred stock.

In connection with the Reverse Stock Split on July 1, 2020, the Company filed a certificate of amendment to its certificate of incorporation, which provided 100,000,000 authorized shares of common stock with a par value of $0.0001 per share and 54,350,179 authorized shares of preferred stock with a par value of $0.0001 per share.

Series A Convertible Preferred Stock

In December 2017, the Company sold and issued in a private placement 3,866,602 shares of Series A convertible preferred stock at $2.07 per share (the "Series A Financing"). Upon the closing of the Series A Financing, the convertible notes outstanding at that date were converted into 2,011,114 shares of Series A convertible preferred stock at 80% of the $2.07 price per share (the "Series A Original Issue Price") paid by the Series A Financing investors. The GSK Convertible Note converted into 292,633 shares of Series A convertible preferred stock at 85% of the Series A Original Issue Price. In connection with the convertible notes, the Company recorded a beneficial conversion feature of $0.9 million which was recognized as a debt discount and accreted to interest expense over the term of the note using the effective interest method.

Series B Convertible Promissory Notes

In May 2019, the Company entered into Series B Convertible Promissory Notes (the "Convertible Notes") whereby the Company agreed to issue and certain existing Series A investors (the "Noteholders") agreed to purchase $6,000,000 in Convertible Notes. The Convertible Notes accrued interest at a contractual rate of 7.5% per year and had an original maturity date of one year from their issuance date. The Convertible Notes were to automatically convert into Series B convertible preferred stock at 85% or 80% of the price per share paid by other investors upon certain qualified financing events, with the percent discount based on the timing of the financing, or through a voluntary option to convert upon certain non-qualified financing events. In addition, if the maturity date were to occur prior to the conversion or repayment of the Convertible Notes, the Noteholders had the right to convert the outstanding principal amount of the Convertible Notes, and all accrued and unpaid interest, into Series A convertible preferred stock at the Series A original issuance price.

As the Convertible Notes contained various settlement outcomes, the Company evaluated each scenario for accounting purposes. The settlement into Series A convertible preferred stock scenario resulted in the Company

recording a beneficial conversion feature of $0.3 million upon the issuance of the Convertible Notes, as the fair value of the Series A convertible preferred stock on the date of issuance was greater than the original Series A issuance price. The conversion discounts were considered to be redemption features and were evaluated as an embedded derivative and bifurcated from the Convertible Notes, due to the substantial premium to be paid upon redemption. Upon bifurcating the redemption features, the Company recorded a derivative instrument of $1.3 million. The derivative instrument and beneficial conversion feature were recorded as a debt discount at inception and were being amortized to interest expense using the effective interest method over the one-year term of the debt.

In August 2019, in connection with the Series B convertible preferred stock financing, the Convertible Notes terms were modified so that the Noteholders received a conversion benefit equal to an annual effective interest rate of 7.5% on the outstanding principal on the Convertible Notes, rather than the originally stated 85% price. The change in the conversion benefit resulted in an adjustment to the derivative instrument of $0.9 million. In addition, as the Convertible Notes contained an embedded beneficial conversion feature and were extinguished before conversion, the Company allocated a portion of the settlement to the repurchase of the beneficial conversion feature, using the intrinsic value on the extinguishment date. This resulted in a reduction to the previously recorded beneficial conversion feature of $0.1 million. Additionally, the Company recorded a loss on extinguishment of debt of $0.8 million, representing the write-off on the unamortized debt issuance costs on the date the Convertible Notes converted into Series B convertible preferred stock.

Series B Convertible Preferred Stock

On August 27, 2019, the Company entered into a Series B Preferred Stock Purchase Agreement (the “Stock Purchase Agreement”). The Stock Purchase Agreement contained provisions that obligated the Company to sell, outside of its control, an additional 27,066,206 shares of Series B convertible preferred stock at the Series B Original Issue Price per share, for expected gross proceeds of $64.4 million, upon the achievement of a milestone, or by election of the holders of at least one-third of the Company’s Series B convertible preferred stock at any time prior to the completion of the Company’s initial public offering if the milestone was not achieved (the “Series B Milestone Closing”). If the shares were not purchased prior to the completion of the Company’s initial public offering, then the right to purchase these shares would have automatically expired. In the event that an Initial Series B Closing purchaser, or its affiliates or transferees, failed to purchase their required shares in the Series B Milestone Closing, then all the Series B convertible preferred stock held by such initial Series B purchaser would have been automatically converted into one share of common stock for each ten shares of Series B convertible preferred stock.

On July 1, 2020, the Company completed the Series B Milestone Closing pursuant to a milestone waiver by the holders of the Series B convertible preferred stock and issued 27,066,206 shares of Series B convertible preferred stock for gross proceeds of $64.4 million. On July 14, 2020, upon the closing of the Company’s IPO, all outstanding shares of the Company’s convertible preferred stock converted into 14,689,215 shares of the Company’s common stock. There were no outstanding shares of the Company’s convertible preferred stock as of December 31, 2021 and 2020.

The Company determined its obligation to issue additional shares of the Company’s Series B convertible preferred stock in the Series B Milestone Closing represented a freestanding financial instrument that required liability accounting. This freestanding preferred stock purchase right liability was initially recorded at fair value, with fair value changes recognized in the statements of operations and comprehensive loss. At the time the Stock Purchase Agreement was entered into in August 2019, the initial estimated fair value of the preferred stock purchase right liability was $2.8 million, and was revalued at $1.5 million as of December 31, 2019. On July 1, 2020, the preferred stock purchase right liability was revalued at an estimated fair value of $41.6 million and was reclassified to additional paid-in capital upon the exercise of the preferred stock purchase right. The Company recorded the change in the fair value of the Series B convertible preferred stock purchase right liability of $40.2 million as other expense for the year ended December 31, 2020, in the statement of operations and comprehensive loss.

Common Stock

In conjunction with the Company’s July 2020 IPO closing, the Company issued and sold 16,100,000 shares of its common stock, including 2,100,000 shares pursuant to the full exercise of the underwriters' option to purchase

additional shares, at a public offering price of $18.00 per share, for aggregate net proceeds of $265.1 million after deducting underwriting discounts and commissions and other offering costs. In connection with this offering, all outstanding shares of the Company's convertible preferred stock converted into 14,689,215 shares of common stock.

11. Share-Based Compensation

Equity Incentive Plan

2015 Equity Incentive Plan

The Company granted options under its 2015 Equity Incentive Plan (the "2015 Plan") until July 2020 when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2015 Plan. The 2015 Plan allows for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock unit awards and other stock awards. Awards can be made to officers, directors, employees, non-employee directors, and consultants of the Company. In connection with the Board of Directors' and stockholders' approval of the 2020 Plan, the 2015 Plan was terminated as to future awards and any options or awards outstanding under the 2015 Plan remain outstanding and effective. As of December 31, 2021, there were an aggregate of 1,798,614 shares of common stock issuable upon the exercise of outstanding options under the 2015 Plan.

2020 Performance Incentive Plan

The Company's 2020 Performance Incentive Plan (the "2020 Plan") which was adopted by the Company's board of directors in June 2020 and approved by the Company's stockholders in July 2020, became effective upon the consummation of the IPO in July 2020. Upon the effectiveness of the 2020 Plan, no further grants may be made under the Company's 2015 Plan. The Company's 2020 Plan allows for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, stock bonuses, restricted stock, stock units and other forms of awards including cash awards to its officers, directors, employees, consultants and advisors.

As of December 31, 2021, a total of 4,295,638 shares of the Company's common stock were authorized for issuance with respect to awards granted under the 2020 Plan. The share limit will automatically increase on the first trading day in January of each year (commencing in 2021) by an amount equal to the lesser of (1) 5% of the total number of outstanding shares of the Company's common stock on the last trading day in December in the prior year, or (2) such lesser number as determined by the Company's board of directors. Any shares subject to awards granted under the 2020 Plan or the 2015 Plan that are not paid, delivered or exercised before they expire or are canceled or terminated, or otherwise fail to vest, as well as shares used to pay the purchase or exercise price of such awards or related tax withholding obligations, will become available for new award grants under the 2020 Plan. A total of 2,179,766 shares was available for issuance under the 2020 Plan for the year ended December 31, 2021.

The following table summarizes the stock option activity during the year ended December 31, 2021 (in thousands, except number of shares, exercise prices and contractual term):

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	3,640,715	$ 11.00	9.0	$ 183,742
Granted	1,005,372	45.55		
Exercised	(281,932)	5.25		
Forfeited	(159,469)	23.09		
Outstanding at December 31, 2021	4,204,686	$ 19.19	8.2	$ 22,022
Exercisable at December 31, 2021	1,516,556	$ 14.53	7.7	$ 10,009
Vested and expected to vest at December 31, 2021	4,204,686	$ 19.19	8.2	$ 22,022

The aggregate intrinsic value represents the difference between the exercise price of stock options and the quoted market price of the Company's common stock for all in-the-money stock options.

Additional information related to the Company's stock options is summarized below (in thousands, except per share amounts):

	Year Ended December 31,	
	2021	2020
Weighted-average grant-date fair value of stock option grants per share	$ 30.87	$ 12.84
Intrinsic value of options exercised	$ 9,991	$ 1,444
Fair value of options vested	$ 13,638	$ 2,664

Employee Stock Purchase Plan

The Company's 2020 Employee Stock Purchase Plan (the "ESPP"), which was adopted by the Company's board of directors in June 2020 and approved by the Company's stockholders in July 2020, became effective upon the consummation of the IPO. A total of 622,652 shares of the Company's common stock is available for issuance under the ESPP. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides for six-month offering periods, and at the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last trading day of the offering period. As of December 31, 2021, no shares had been issued under the ESPP, and the full number of shares authorized under the ESPP Plan was available for issuance purposes.

Liability for Early Exercise of Restricted Stock Options

Certain individuals were granted the ability to early exercise their stock options. The shares of common stock issued from the early exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. The shares purchased by the employees and non-employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for exercised and unvested shares related to stock options granted is recorded as a liability for the early exercise of stock options on the accompanying balance sheets and will be transferred into common stock and additional paid-in capital as the shares vest. Shares subject to repurchase by the Company were 16,181 shares and 77,393 shares, with the related liability of $18 thousand and $0.1 million as of December 31, 2021 and 2020, respectively, recorded under other long-term liabilities in the balance sheets.

Common Stock Reserved for Future Issuance

As of December 31, 2021, the Company had reserved the following shares of common stock for future issuance:

	December 31, 2021
Common stock options granted and outstanding	4,204,686
Reserved for future equity award grants	2,179,766
Reserved for future ESPP issuances	622,652
	7,007,104

Share-Based Compensation Expense

Share-based compensation expense for the years ended December 31, 2021 and 2020 were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Research and development	$ 6,719	$ 1,871
General and administrative	7,742	4,877
Total share-based compensation expense	$ 14,461	$ 6,748

The total unrecognized compensation cost related to share-based awards was $36.4 million, which is expected to be recognized over a weighted-average remaining service period of 2.2 years as of December 31, 2021.

In October 2020, the Company recorded share-based compensation expense of $2.3 million related to the modification of certain stock option granted to its former Chief Financial Officer, Matthew Plunkett, under a Separation and Release Agreement that was executed on October 2, 2020 (the "Termination Date"). In addition, the Company recorded severance benefits expense of $0.3 million in October 2020 that was paid within the 6 months after the Termination Date.

Fair Value Disclosures

The fair value of stock options was estimated on the date of grant using the Black-Scholes option pricing model with the following range of assumptions:

	Year Ended December 31,	
	2021	2020
Common stock fair value	$15.35 - $54.89	$4.29 - $61.47
Risk-free interest rate	0.6% - 1.4%	0.4% - 0.5%
Expected volatility	77.3% - 79.9%	74.8% - 81.4%
Expected term (in years)	5.5 - 6.1	5.5 - 6.1
Expected dividend yield	—	—

The Company recognizes compensation costs related to stock options granted to employees and nonemployees based on the estimated fair value of the awards on the date of grant, net of forfeitures. The Company generally recognizes grant-date fair value of stock options granted to employees and non-employee service providers on a straight-line basis over the requisite service period, which is generally the vesting term of the respective awards. The Company determines the fair value of stock options with a service and performance condition, or performance-based options, based on the fair value of the Company's common stock on the date of grant. The Company accounts for the impact of forfeitures as they occur. For purposes of calculating share-based compensation, the Company estimates the fair value of stock options issued using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes option-pricing model is affected by the Company's stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends.

Expected term. The Company opted to use the "simplified method" for estimating the expected term of employee options, whereby the expected term equals the average of the vesting term and the original contractual term of the option (generally 10 years).

Expected volatility. Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company based its estimate of expected volatility on the historical volatilities of the common stock of comparable publicly traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, and financial leverage to the Company.

Risk-free interest rate. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the stock options.

Expected dividend yield. The Company has not issued any dividends and do not expect to issue dividends over the life of the options, as a result the estimated dividend yield is zero.

12. Income Taxes

Due to the Company's net losses for the years ended December 31, 2021 and 2020, and since the Company has a full valuation allowance against deferred tax assets, there was no tax provision or benefit for income taxes recorded in the years presented other than minimum amounts required for state tax purposes.

A reconciliation on income taxes to the amount computed by applying the statutory federal income tax rate to the net loss is summarized as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Income tax benefit at statutory rates	$ (18,076)	$ (19,186)
State income tax, net of federal benefit	(1,005)	(3,929)
Permanent items	592	749
Research and development credits	(1,661)	(1,264)
Other	(515)	231
Change in valuation allowance	20,665	14,965
Change in fair value of derivative liabilities		8,434
Income tax expense	$ —	$ —

Significant components of the Company's deferred tax assets are shown below (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carry forwards	$ 33,767	$ 17,674
Depreciation and amortization	268	265
Research and development credits	6,984	3,986
Share-based compensation	2,245	876
Accrued expenses	1,189	983
Lease liability	2,616	2,496
Other, net	34	15
Total deferred tax assets	47,103	26,295
Valuation allowance for deferred tax assets	(44,361)	(23,696)
Deferred tax assets, net of valuation allowance	2,742	2,599
Deferred tax liabilities:		
Right-of-use asset	(2,471)	(2,382)
Depreciation and amortization	(271)	(217)
Net deferred tax assets	$ —	$ —

The Company has a net operating loss and has provided a valuation allowance against net deferred tax assets due to uncertainties regarding the Company's ability to realize these assets. The valuation allowance increased by $20.7 million and $15.0 million as of December 31, 2021 and 2020, respectively.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its net deferred tax assets will not be realized, and therefore, the net deferred tax assets are substantially offset by a valuation allowance at

December 31, 2021 and 2020. The $2.7 million net deferred tax asset is realizable as a result of utilizing the deferred tax liabilities associated with the Company's leases as a source of income. The deferred tax assets were primarily comprised of federal and state tax net operating losses and tax credit carryforwards.

As of December 31, 2021, the Company had net operating loss ("NOL") carryforwards of approximately $139.0 million and $65.4 million, available to reduce future taxable income, if any, for federal and California state income tax purposes, respectively. Of the $139.0 million federal NOL carryforwards, $0.2 million and $3.0 will begin expiring in 2035 and 2036, respectively, if not utilized, while $135.8 million can be carried forward indefinitely. The state NOL carryforwards will begin expiring in 2036, if not utilized.

The Company also had federal and state research and development credit carry forwards of approximately $5.4 million and $3.6 million, respectively, at December 31, 2021. The federal credits will begin expiring in 2035 if not utilized. The California credits have no expiration date.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. The future utilization of the Company's NOL and tax credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of changes in ownership by stockholders that hold 5% or more of the Company's common stock. An assessment of such ownership changes under Section 382 was not completed through December 31, 2019. To the extent that an assessment is completed in the future, the Company's ability to utilize tax attributes could be restricted on a year-by-year basis and certain attributes could expire before they are utilized. The Company will examine the impact of any potential ownership changes in the future.

The Company has not been audited by the Internal Revenue Service or any state income or franchise tax agency. As of December 31, 2021, its federal and state returns for the years ended 2015 through the current period are still open to examination. In addition, all of the net operating losses and research and development credit carryforwards that may be used in future years are still subject to inquiry given that the statute of limitation for these items would begin in the year of the utilization. The balance of gross unrecognized tax benefits as of December 31, 2021 and 2020 was approximately $1.4 million and $0.8 million, respectively, all of which would affect the Company's income tax expense if recognized, before consideration of the Company's valuation allowance. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. There was no interest and penalties for the years ended December 31, 2021 and 2020. The Company files income tax returns in the United States federal jurisdiction and the State of California and is not currently under examination by any taxing authority for any open tax year. Due to net operating loss carryforwards, all years remain open for income tax examination. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

The following table summarizes the changes in the Company's gross unrecognized tax benefits (in thousands):

	December 31,	
	2021	2020
Balance at the beginning of the year	$ 777	$ 270
Increases (decreases) related to tax positions taken in prior years	(281)	14
Increases related to tax positions taken in current year	863	493
Balance at the end of the year	$ 1,359	$ 777

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

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, 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 SEC's rules and forms and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial and Business Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. Based on this evaluation, our Chief Executive Officer and Chief Financial and Business Officer concluded that, as of December 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. 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 that the transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial and Business Officer, regarding the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial and Business Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. 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, 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 the collusion of two or more people or by management override of controls. The design of any system of controls is also 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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

We have adopted a written code of business ethics that applies to our Chief Executive Officer and senior financial officers and a code of business conduct and ethics that applies to directors, executive officers, and employees. A current copy of each code is posted under “Corporate Governance” on our website at https://ir.nkartatx.com/. To the extent required by rules adopted by the Securities and Exchange Commission and The Nasdaq Stock Market LLC, we intend to promptly disclose future amendments to certain provisions of the code, or waivers of such provisions granted to executive officers and directors, on our website at www.nkartatx.com/.

The remaining information required by this Item will be set forth in the Company’s proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company’s fiscal year end and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item will be set forth in the Company’s proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company’s fiscal year end 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 set forth in the Company’s proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company’s fiscal year end and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be set forth in the Company’s proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company’s fiscal year end and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item will be set forth in the Company’s proxy statement to be filed with the Securities and Exchange Commission within 120 days after the Company’s fiscal year end and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements.* See Index to Financial Statements in Part II Item 8 of this Annual Report on Form 10-K.

2. *Financial Statement Schedules*. None. All financial statement schedules are omitted because they are not applicable, not required under the instructions or the requested information is included in the financial statements or notes thereto.

3. *Exhibits*. The following is a list of exhibits filed with this report or incorporated herein by reference:

Exhibit Index

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Nkarta, Inc.	8-K	001-39370	3.1	7/14/2020	
3.2	Amended and Restated Bylaws of Nkarta, Inc.	8-K	001-39370	3.2	7/14/2020	
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	333-239301	4.1	7/2/2020	
4.2	Amended and Restated Investors' Rights Agreement, dated as of August 27, 2019, by and among the registrant and certain of its stockholders.	S-1	333-239301	4.2	6/19/2020	
4.3	Description of Capital Stock	10-K	001-39370	4.3	3/25/2021	
10.1#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	333-239301	10.1	7/2/2020	
10.2(A)#	2015 Equity Incentive Plan.	S-1	333-239301	10.2	6/19/2020	
10.2(B)#	Form of Stock Option Agreement for 2015 Equity Incentive Plan.	S-1	333-239301	10.3	6/19/2020	
10.3(A)#	2020 Performance Incentive Plan.	S-1/A	333-239301	10.4	7/2/2020	
10.3(B)#	Form of Director Option Agreement between Registrant and certain of its directors.	10-Q	001-39370	10.5	8/20/2020	
10.3(C)#	Form of non-qualified Stock Option Agreement between Registrant and certain of its officers and employees.	10-Q	001-39370	10.6	8/20/2020	
10.4#	2020 Employee Stock Purchase Plan.	S-1/A	333-239301	10.5	7/2/2020	
10.5#	Nkarta, Inc. Non-Employee Director Compensation Policy, as amended on March 16, 2022.					X
10.6(A)#	Employment Offer Letter between the Registrant and Paul Hastings.	S-1	333-239301	10.6	6/19/2020	
10.6(B)#	Employment Offer Letter between the Registrant and Dr. Kanya Rajangam.	S-1	333-239301	10.7	6/19/2020	
10.6(C)#	Employment Offer Letter between the Registrant and Dr. Nadir Mahmood	10-Q	001-39370	10.2	5/13/2021	
10.6(D)#	First Amendment to Employment Offer Letter between the Registrant and Dr. Nadir Mahmood	10-Q	001-39370	10.3	5/13/2021	
10.6(E)#	Employment Offer Letter between the Registrant and Dr. Alicia Hager	10-Q	001-39370	10.4	5/13/2021	

10.7#	Separation and Release Agreement between Nkarta, Inc. and Matthew Plunkett, dated October 2, 2020.	8-K	001-39370	10.1	10/05/2020	
10.8#	Form of Severance Agreement	8-K	001-39370	10.1	01/13/2021	
10.9	Exclusive License Agreement between the Registrant, National University of Singapore and St. Jude Research Hospital, Inc.	S-1	333-239301	10.9	6/19/2020	
10.10(A)	Lease Agreement, dated May 29, 2018, by and between the Registrant and HCP Life Science REIT, Inc.	S-1	333-239301	10.10	6/19/2020	
10.10(B)	First Amendment to Lease Agreement, dated April 24, 2019, by and between the Registrant and HCP Life Science REIT, Inc.	S-1	333-239301	10.11	6/19/2020	
10.10(C)	Second Amendment to Lease Agreement, dated May 5, 2020, by and between the Registrant and HCP Life Science REIT, Inc.	S-1	333-239301	10.12	6/19/2020	
10.10(D)	Third Amendment to Lease Agreement, dated January 14, 2021, by and between the Registrant and HCP Life Science REIT, Inc.	10-K	001-39370	10.10(D)	3/25/2021	
10.10(E)	Fourth Amendment to Lease Agreement, dated October 19, 2021, by and between the Registrant and HCP Life Science REIT, Inc.	8-K	001-39370	10.1	10/22/2021	
10.11(A)	Lease, dated July 9, 2021, by and between the Registrant and HCP BTC, LLC	8-K	001-39370	10.1	7/14/2021	
10.11(B)	First Amendment to Lease, dated November 5, 2021, by and between the Registrant and HCP BTC, LLC	10-Q	001-39370	10.2	11/10/2021	
10.12**	Research Collaboration Agreement, dated May 5, 2021, by and between the Registrant and CRISPR Therapeutics AG	10-Q	001-39370	10.1	8/12/2021	
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

101.INS	Inline XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X

# Indicates management contract or compensatory plan

+ This certification is being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Portions of this exhibit have been omitted in accordance with Item 601(b)(10)(iv) of Regulation S-K. The Company undertakes to provide to the Securities and Exchange Commission or its staff, if requested and on a supplemental basis, an unredacted copy of this exhibit.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Nkarta, Inc.

Date: March 17, 2022

By: /s/ Paul J. Hastings
Paul J. Hastings
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Paul J. Hastings Paul J. Hastings	Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2022
/s/ Nadir Mahmood Nadir Mahmood, Ph.D.	Chief Financial and Business Officer (Principal Financial and Accounting Officer)	March 17, 2022
/s/ Tiba Aynechi Tiba Aynechi, Ph.D.	Director	March 17, 2022
/s/ Fouad Azzam Fouad Azzam, Ph.D., MBA	Director	March 17, 2022
/s/ Ali Behbahani Ali Behbahani, M.D., MBA	Director	March 17, 2022
/s/ Michael Dybbs Michael Dybbs, Ph.D.	Director	March 17, 2022
/s/ Simeon George Simeon George, M.D., MBA	Director	March 17, 2022
/s/ Leone Patterson Leone Patterson, MBA	Director	March 17, 2022
/s/ Zachary Scheiner Zachary Scheiner, Ph.D.	Director	March 17, 2022
/s/ Laura Shawver Laura Shawver, Ph.D.	Director	March 17, 2022

NKARTA, INC.
DIRECTOR COMPENSATION POLICY

(Last Amended March 16, 2022)

Directors of Nkarta, Inc., a Delaware corporation (the "Company"), who are not employed by the Company or one of its subsidiaries ("Non-Employee Directors") are entitled to the compensation set forth below for their service as a member of the Board of Directors (the "Board") of the Company. The Board (or any committee of the Board within the authority delegated to it) has the right to amend this policy from time to time.

Cash Compensation

Annual Retainer	$40,000
Additional Board Chair/Lead Independent Director Retainer	$30,000
Additional Committee Chair Retainers:	
Audit Committee Chair	$15,000
Compensation Committee Chair	$10,000
Nominating and Governance Committee Chair	$8,000
Additional Committee Retainers:	
Audit Committee	$7,500
Compensation Committee	$5,000
Nominating and Governance Committee	$4,000

The retainers set forth above are expressed as annualized amounts. These retainers will be paid on a quarterly basis, in arrears after the end of each fiscal quarter, to the Non-Employee Directors serving on the Board (or in the applicable position, in the case of the Additional Board Chair/Lead Independent Director Retainer or an Additional Committee or Committee Chair Retainer) during such fiscal quarter. Retainers for the fiscal quarter in which the Effective Date occurs will be paid on a pro-rated basis. If an individual serves as a Non-Employee Director, Chair of the Board or lead independent director, or Chair or member of a Board committee, as the case may be, for only a portion of a fiscal quarter, the Non-Employee Director will be paid a pro-rata portion of the applicable retainer for such quarter based on the time the individual served in the applicable position.

Equity Compensation

Annual Equity Awards for Continuing Board Members

On the date of each annual meeting of the Company's stockholders at which one or more directors are to be elected to the Board, each Non-Employee Director continuing in office after that date will be granted an award of Company stock options ("Options") to acquire a number of shares of Company common stock equal to the lesser of (a) 16,000[1] shares or (b) the number of shares that produce a grant date fair value for the award of approximately $231,000 as to any such award granted in 2022 or, as to any such award granted after 2022, approximately $270,000 (the lesser of (a) or (b), the "Share Number"); provided, however, that the Share Number will be multiplied by the Pro-Rata Fraction (as defined below) in the case of such an award to a Non-Employee Director whose initial appointment or election to the Board occurred after the date of the immediately preceding annual meeting of the Company's stockholders at which one or more

(1) This share limit to be proportionately adjusted for, and to mitigate the impact of, any stock split, reverse stock split, or stock dividend.

directors were elected to the Board (for example, in the case of such an award in connection with the Company's 2022 annual meeting of stockholders, as to a Non-Employee Director whose initial appointment or election to the Board occurred after the date of the Company's 2021 annual meeting of stockholders). The "Pro-Rata Fraction" is a fraction (not greater than one), the numerator of which is the total number of days in the period of time commencing with the date that the Non-Employee Director was first elected or appointed to the Board through and including the date of the annual meeting of the Company's stockholders at which the award in question is to be granted, and the denominator of which is the total number of days in the period of time commencing with the date of the immediately preceding annual meeting of the Company's stockholders at which one or more directors were elected to the Board through and including the date of the annual meeting of the Company's stockholders at which the award in question is to be granted.

Each such award of Options will be scheduled to vest on the first to occur of (i) the first anniversary of the date of grant of the award, or (ii) on the day immediately preceding the first annual meeting of the Company's stockholders to occur after the date of grant of the award.

Initial Equity Awards

Each new Non-Employee Director appointed or elected to the Board after the Effective Date will (unless otherwise provided by the Board) be granted, on the date that the new Non-Employee Director first becomes a member of the Board, an award of Options to acquire a number of shares of Company common stock equal to the lesser of (a) 32,000[2] shares or (b) the number of shares that produce a grant date fair value for the award of approximately $540,000. Each such award of Options will be scheduled to vest as to one-third of the Options subject to the award on each of the first, second and third anniversaries of the date of grant of the award.

Notwithstanding anything to the contrary herein, if a Non-Employee Director is first elected to the Board at an annual meeting of the Company's stockholders, the Non-Employee Director will be entitled to an initial equity award pursuant to the immediately preceding paragraph but will not (unless otherwise provided by the Board) be eligible for an annual equity award in connection with that annual meeting. Unless otherwise provided by the Board, an employee or former employee of the Company or one of its subsidiaries who ceases or has ceased to be so employed and becomes a Non-Employee Director will not be eligible for an initial equity award grant pursuant to the immediately preceding paragraph, but will be eligible for cash compensation and annual equity awards on the same basis as other Non-Employee Directors.

Provisions Applicable to All Non-Employee Director Equity Awards

Each Option granted to a Non-Employee Director will be granted under and subject to the terms and conditions of the Company's 2020 Performance Incentive Plan or any successor equity compensation plan approved by the Company's stockholders and in effect at the time of grant.

Unless otherwise provided by the Board in connection with a particular award, each award of Options granted to a Non-Employee Director will have a maximum term of 10 years, will vest (to the extent then outstanding and otherwise unvested) should a change in control of the Company occur (as defined in the applicable award agreement), and will be evidenced by and subject to the terms and conditions of the Company's standard form of stock option award agreement for Non-Employee Director stock option grants

(2) This share limit to be proportionately adjusted for, and to mitigate the impact of, any stock split, reverse stock split, or stock dividend.

as in effect on the date of grant of the award. The per share exercise price of each Option granted to a Non-Employee Director will equal the closing price of a share of Company common stock on the date of grant of the award (or, if such date of grant is not a trading day, the closing price of a share of Company common stock on the last trading day immediately preceding the date of grant of the Award), with such exercise price and the number of shares subject to the award subject to adjustment for stock splits and similar events as provided in the applicable stock option award agreement.

The Board (or any committee of the Board within the authority delegated to it) may approve other grants of equity-based awards to Non-Employee Directors from time to time, on such terms as the Board (or committee) may determine and subject to the applicable provisions of the Company's equity compensation plan then in effect.

Expense Reimbursement. All Non-Employee Directors will be entitled to reimbursement from the Company for their reasonable travel (including airfare and ground transportation), lodging and meal expenses incident to meetings of the Board or committees thereof or in connection with other Board-related business. The Company will make reimbursement to a non-employee director within a reasonable amount of time following submission by the non-employee director of reasonable written substantiation for the expenses.

Exhibit 23.1

Consent of Independent Registered Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-252134) pertaining to the Nkarta, Inc. 2020 Performance Incentive Plan and the Nkarta, Inc. Employee Stock Purchase Plan of Nkarta, Inc.;

(2) Registration Statement (Form S-8 No. 333-240309) pertaining to the Nkarta, Inc. 2020 Performance Incentive Plan, the Nkarta, Inc. Employee Stock Purchase Plan, and the Nkarta, Inc. 2015 Equity Incentive Plan of Nkarta, Inc.; and

(3) Registration Statement (Form S-3 No. 333-258766) of Nkarta, Inc. pertaining to the offer, issuance, and sale of a maximum aggregate offering of up to $500,000,000 of common stock, preferred stock, debt securities, warrants, rights and unit and at-the-market offering of common stock.

of our report dated March 17, 2022, with respect to the financial statements of Nkarta, Inc. included in this Annual Report (Form 10-K) of Nkarta, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Redwood City, California
March 17, 2022

Exhibit 31.1

NKARTA, INC.
CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Paul J. Hastings, certify that:

1. I have reviewed this Annual Report on Form 10-K (the “report”) of Nkarta, Inc. (the “registrant”);

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2022

By: /s/ Paul J. Hastings

Paul J. Hastings
Chief Executive Officer

Exhibit 31.2

NKARTA, INC.
CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Nadir Mahmood, certify that:

1. I have reviewed this Annual Report on Form 10-K (the “report”) of Nkarta, Inc. (the “registrant”);

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2022

By: /s/ Nadir Mahmood

Nadir Mahmood
Chief Financial and Business Officer

Exhibit 32

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

In connection with the Annual Report on Form 10-K for the year ended December 31, 2021 of Nkarta, Inc. (the “Company”) as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Paul J. Hastings, Chief Executive Officer of the Company, and Nadir Mahmood, Chief Financial and Business Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 17, 2022 By: /s/ Paul J. Hastings
Paul J. Hastings
Chief Executive Officer

Date: March 17, 2022 By: /s/ Nadir Mahmood
Nadir Mahmood
Chief Financial and Business Officer

This is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350. This certification shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Company specifically incorporates it by reference.