UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

or

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

For the transition period from to .

Commission File Number: 001-38905

NextCure, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**04-5231247** (I.R.S. Employer Identification No.)
9000 Virginia Manor Road, Suite 200 **Beltsville, Maryland** (Address of principal executive offices)	**20705** (Zip Code)

Registrant's telephone number, including area code: **(240) 399-4900**

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, $0.001 par value per share	NXTC	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 Section 15(d) of the Act.
Yes ☐ No ☒

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $236.4 million, as computed by reference to the closing price of the common stock on the Nasdaq Global Select Market on that date.

As of March 11, 2020, the registrant had 27,509,510 shares of common stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2020 Annual Meeting of Stockholders, which will be filed with the Commission within 120 days after December 31, 2019, are incorporated by reference into Part III of this Report.

NextCure, Inc.
Form 10-K
For the Year Ended December 31, 2019

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements, including with respect to our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “continue,” “could,” “due,” “estimate,” “expect,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or similar language. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the timing, progress and results of preclinical studies and clinical trials for NC318, NC410 and any other product candidates we develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing or likelihood of regulatory filings for NC318, NC410 and any other product candidates we develop and our ability to obtain and maintain regulatory approvals for such product candidates for any indication;
- the development of companion or complimentary diagnostics for NC318, NC410 or any other product candidates we develop;
- our manufacturing capabilities and strategy, including the scalability of our manufacturing methods and processes;
- our expectations regarding the potential benefits, activity, effectiveness and safety of NC318, NC410 and any other product candidates we develop;
- our intentions and ability to successfully commercialize our product candidates;
- our expectations regarding the nature of the biological pathways we are targeting;
- our expectations for our FIND-IO platform, including our ability to discover and advance product candidates using our FIND-IO platform;
- the potential benefits of and our ability to maintain our relationships and collaborations with Yale University and Dr. Lieping Chen;
- our estimates regarding our expenses, future revenues, capital requirements, our needs for or ability to obtain additional financing and the period over which we expect our current cash, cash equivalents and marketable securities to be sufficient to fund our operations;
- our intended reliance on and the performance of third parties, including collaborators, contract research organizations and third-party manufacturers;
- our ability to protect and enforce our intellectual property protection and the scope and duration of such protection;
- developments and projections relating to our competitors and our industry, including competing therapies; and
- the impact of current and future laws and regulations.

These statements, and other forward-looking statements, are based on management's current expectations, estimates, forecasts and projections about our business and industry, are not guarantees of future performance and involve known

and unknown risks, uncertainties and other factors that are in some cases beyond our control and that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. Forward-looking statements contained in this Annual Report should be considered in light of these factors and the factors described elsewhere in this Annual Report, including in in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” You should read these factors and the other cautionary statements made in this Annual Report as being applicable to all related forward-looking statements wherever they appear in this Annual Report. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, levels of activity, performance, or achievements may vary materially from any future results, activity, performance, or achievements expressed or implied by these forward-looking statements.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date of this Annual Report. We undertake no obligation to publicly update any forward-looking statements after the date of this Annual Report, whether as a result of new information, future events or otherwise, except as required by law. We qualify all of our forward-looking statements by the foregoing cautionary statements.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases by restoring normal immune function. We view the immune system holistically and, rather than target one specific immune cell type, we focus on understanding biological pathways, the interactions of cells and the role each interaction plays in an immune response. Through our proprietary Functional, Integrated, NextCure Discovery in Immuno-Oncology, or FIND-IO, platform, we study various immune cells to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. We are focused on patients who do not respond to current therapies, patients whose cancer progresses despite treatment and patients with cancer types not adequately addressed by available therapies. We are committed to discovering and developing first-in-class immunomedicines, which are immunomedicines that use new or unique mechanisms of action to treat a medical condition, for these patients.

Our lead product candidate, NC318, is a first-in-class immunomedicine targeting a novel immunomodulatory receptor called Siglec-15, or S15. In October 2018, we initiated a Phase 1/2 clinical trial of NC318 in patients with advanced or metastatic solid tumors. We completed enrollment of the Phase 1 portion of this trial in August 2019 and preliminary data from the Phase 1 portion was presented in November 2019 at the Society for Immunotherapy of Cancer, or SITC, annual meeting. As of November 9, 2019, NC318 had been well tolerated in the Phase 1 portion of the trial and only one dose-limiting toxicity had been observed. Most treatment-related adverse events were easily manageable, asymptomatic or mild or moderate. Data from the trial indicate activity in multiple tumor types, including a complete response and a partial response in patients with NSCLC and durable stable disease in patients with NSCLC, endometrial cell cancer, ovarian cancer, squamous cell carcinoma, Merkel cell cancer, and head and neck cancer. We began enrolling patients in the Phase 2 portion of the trial in October 2019 and expect to announce initial data from the Phase 2 portion by the end of 2020. In addition, in mid-2020, we intend to initiate a Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors.

Our second product candidate, NC410, is a novel immunomedicine designed to block immune suppression mediated by an immune modulator called Leukocyte-Associated Immunoglobulin-like Receptor 1, or LAIR-1. The U.S. Food and Drug Administration, or the FDA, accepted our investigational new drug application, or IND, for NC410 in the first quarter of 2020 and we intend to initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the second quarter of 2020.

Our approach to identifying targets for new immunomedicines is based on our FIND-IO platform. FIND-IO embodies a rational approach to the discovery of novel cell surface and secretory molecules that drive functional immune responses. We use our immunology knowledge, experience and capabilities and tools we have developed, including our FIND-IO platform, to support our discovery efforts. We are working to discover novel targets that play a key role in mediating immune dysfunctions that allow tumors to evade the immune system. We seek to identify and develop

immunomedicines that counteract these outcomes and to further validate and advance our product candidates. We have identified multiple novel targets using our FIND-IO platform, including those for which certain of our research programs are being designed to target. In addition, the immunosuppressive properties of S15, the target of NC318, were discovered using a predecessor of our FIND-IO platform.

NC318, our lead immunomedicine program, is a monoclonal antibody targeting S15, which is expressed on highly immunosuppressive cells called M2 macrophages and on tumor cells. The immunosuppressive properties of S15 were discovered in 2015 at Yale University, or Yale, by our scientific founder Dr. Lieping Chen. Dr. Chen was also the first to discover a molecule he called B7-H1, which is now more widely known as PD-L1, or programmed cell death protein ligand 1, which is the ligand for PD-1, or programmed cell death 1. In preclinical research, we and others have observed that S15 promotes suppression of T cell proliferation and negatively regulates T cell function. NC318 is designed to block this S15-mediated immune suppression and restore T cell function and anti-tumor immunity in the tumor microenvironment, or TME, which we believe will reduce and kill tumors. We believe NC318 has the potential to treat multiple cancer indications because S15 is expressed in multiple tumor types and has a unique ability to modulate immune responses in the TME. In addition, because S15 and PD-L1 expression in tumors generally appear to be non-overlapping, we believe NC318 may be well suited to treat patients who are not responding to PD-1/PD-L1 directed cancer therapies. We are initially evaluating NC318 for the treatment of advanced or metastatic solid tumors, including ovarian cancer, non-small cell lung cancer, or NSCLC, head and neck squamous cell carcinoma, or HNSCC, and triple-negative breast cancer, or TNBC.

NC410, our second immunomedicine program, is a fusion protein designed to block immune suppression mediated by LAIR-1. LAIR-1 is expressed on T cells and antigen-presenting cells, known as dendritic cells, that present tumor antigens to immune cells in order to generate immune responses. The binding of LAIR-1 to collagen or C1q results in loss of immune function in the TME and a reduction in T cell function and dendritic cell activity. By blocking the binding of LAIR-1, NC410 can promote T cell function and dendritic cell activity, which could result in anti-tumor immune responses that eliminate cancer cells. The FDA accepted our IND in the first quarter of 2020, and we intend to initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the second quarter of 2020. We are currently focused on opportunities for NC410 in ovarian cancer, NSCLC and pancreatic cancer.

We are using our FIND-IO platform as our discovery engine to identify targets and develop immunomedicines that restore normal immune function in the TME through novel mechanisms of action. Since our founding in 2015, we have developed, industrialized and optimized our FIND-IO platform based on the immunological expertise of our management team and the scientific leadership of our scientific founder, Dr. Lieping Chen. Our approach in creating the FIND-IO platform, and how we apply it, reflects our belief in the importance of understanding biological pathways of all cells in the immune system and restoring normal immune function. The platform uses our proprietary approaches to assess the suppressive or stimulatory function of immune pathways in T cells and other immune cells, as measured by effects on proliferation or induction of molecules known to impact immune responses, such as cytokines, which are signaling molecules secreted by cells in the immune system that mediate and regulate immunity and inflammation. We study primary immune cells from healthy donors and from patients with various diseases, as well as established cell lines from immune and non-immune cell lineages, including T cell subsets, monocytes, macrophage subpopulations and cancer cell lines. In oncology, we are using the FIND-IO platform to discover immunomedicines with the potential to intervene or modulate interactions of immune cells within the TME to restore anti-tumor activity. We are also expanding the functional screening approach of our FIND-IO platform for the identification of novel targets in other serious illnesses outside of oncology, including autoimmune, inflammatory and neuro-inflammatory diseases.

We have assembled an experienced management team to execute on our mission to create novel immunomedicines. Our scientific founder and members of our management team collectively have extensive experience in drug discovery and product development and are leaders in the immuno-oncology field. Members of our management team have experience discovering, developing, manufacturing and commercializing biologics, including some of the earliest approved monoclonal antibodies, such as Synagis, as well as some of the first immune checkpoint inhibitor monoclonal antibodies and fusion proteins targeting the PD-1/PD-L1 pathway and CTLA-4, including Yervoy. Within three years, we advanced our company from formation to antibody generation to the clinic, and constructed a manufacturing facility that complies with current good manufacturing practice, or cGMP, and that we have used to manufacture our preclinical and clinical drug supply.

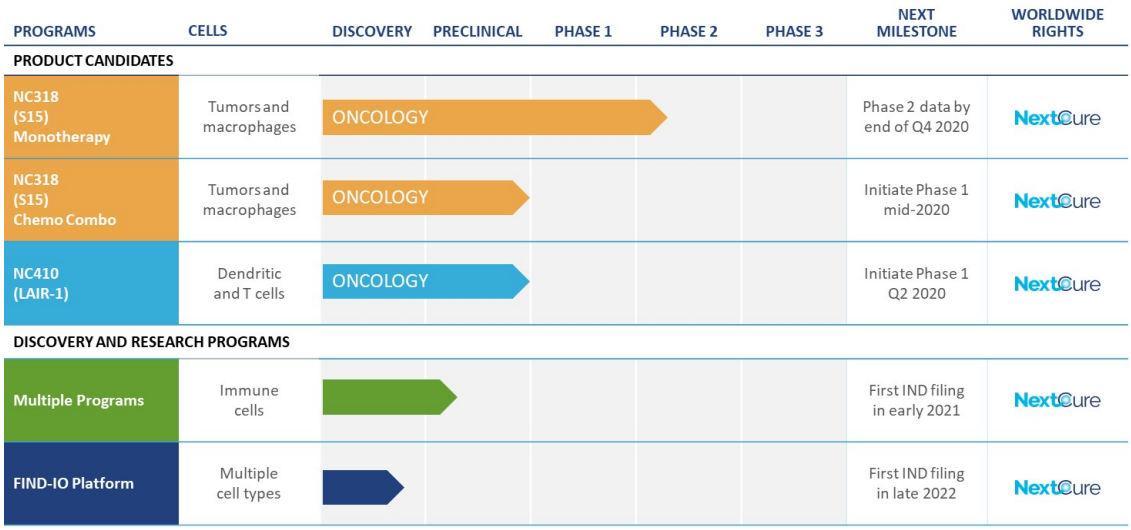
Members of our management team have a longstanding relationship with our scientific founder Dr. Chen, who is the United Technologies Corporation Professor in Cancer Research and Professor of Immunobiology, of Dermatology and

of Medicine (Medical Oncology) at Yale, and the Co-Director of the Cancer Immunology Program at Yale Cancer Center. Dr. Chen was the first to discover PD-L1, and to show that it is expressed by multiple tumor types and its activity can cause the death of T cells, preventing those T cells from eliminating cancer cells. He also showed that blocking the interaction between PD-1 and PD-L1 with monoclonal antibodies improved the immune system's ability to eliminate tumors. Dr. Chen's work provided an important foundation for the subsequent development of immunotherapies that enable more effective immune treatments against cancer. Since then, his laboratory has identified and characterized various molecules in two of the major families of immune modulating proteins, the B7-CD28 and the tumor necrosis factor, or TNF, receptor/ligand superfamilies, and elucidated their interactions and functions in controlling immune responses. The immunosuppressive properties of S15, the target of our lead product candidate, NC318, were discovered in Dr. Chen's lab using a predecessor of our FIND-IO platform. We continue to collaborate with Dr. Chen on discovering novel immunomedicines through an exclusive sponsored research agreement with Yale.

We believe the combination of our team's capabilities and focus on understanding the biological pathways of the immune system, our product development expertise and manufacturing infrastructure and our relationship with Dr. Chen and Yale positions us to build a sustainable portfolio of first-in-class immunomedicines.

Our Pipeline

We are leveraging our understanding of biological pathways and our FIND-IO platform to discover, validate and build a proprietary pipeline of immunomedicine candidates. The figure below details our pipeline of product candidates and principal discovery and research programs.



Our Strategy

Our strategy is to use our fully integrated discovery and product development infrastructure to build a sustainable pipeline of product candidates to treat cancer patients who are not adequately served by currently available therapies. The key elements of our strategy include:

- ***Advancing the clinical development of our lead product candidates, NC318 and NC410.*** In October 2018, we initiated a Phase 1/2 clinical trial evaluating NC318 in patients with advanced or metastatic solid tumors. We completed enrollment of the Phase 1 portion of this trial in August 2019 and preliminary data from the Phase 1 portion was presented at the SITC annual meeting in November 2019. We began enrolling patients in the Phase 2 portion of the trial in October 2019 and expect to announce initial data from the Phase 2 portion by the end of 2020. In mid-2020, we intend to initiate a Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors. For NC410, the FDA accepted our IND in the first quarter of 2020 and we intend to initiate a Phase 1/2 clinical trial in the second quarter of 2020.

- ***Building an oncology pipeline of novel targets for new immunomedicines focused on non-responders***. We are leveraging our immunological expertise and our FIND-IO platform to identify novel targets relevant to overcoming immune suppression. In addition to our internal discovery efforts, we also expect to leverage our relationship with Dr. Chen's laboratory at Yale for the discovery of additional targets for immunomedicines.

- ***Leveraging our fully integrated development, quality systems and cGMP manufacturing capabilities.*** Our approach is to integrate key aspects of product development within our organization. We have assembled a team with extensive experience in identifying, characterizing and developing novel immunomedicines. We seek to couple discovery of important targets with the capability to rapidly streamline target validation and conduct key IND-enabling studies, leading to clinical development of lead candidates. Our purpose-built, dedicated, state-of-the-art cGMP manufacturing facility utilizes single-use technology to support development of our pipeline and advancement of our product candidates into and through clinical development. The facility has an initial production capacity of 1,000 liters with additional room for expansion and is designed to operate as a multi-product facility. Compared to working with third-party manufacturers, we believe our facility provides better quality assurance, greater control in scheduling and prioritizing manufacturing activities and enhanced capital efficiency.

- ***Expanding our current focus and creating new opportunities outside of the oncology field***. While our primary focus is oncology, the functional screening approach and proprietary technology of our FIND-IO platform are broadly applicable to the identification of positive and negative immune modulators, and therefore can be used and expanded to discover novel targets in other inflammatory diseases. Our goal is to enable next-generation immunomedicines for other serious inflammatory diseases with significant unmet medical needs in fields beyond oncology. For example, we are developing our FIND-AI platform, a new platform focused on discovery efforts in autoimmunity and inflammation.

- ***Extending the reach of our product candidates through strategic partnerships and collaborations***. We have exclusive worldwide rights to our current product candidates and our FIND-IO platform. We expect to explore a variety of market opportunities for our current and future product candidates and our platforms, including through the pursuit of strategic partnerships or other collaborations with regard to selected indications or geographical areas such as Asia. We intend for our product candidates to be developed and commercialized globally, by us in key markets and in collaboration with other companies for other geographies.

Immuno-Oncology Background

The immune system has powerful biological mechanisms to defend and protect the body from pathogens, such as viruses, parasites and bacteria. It also provides surveillance against cancers by recognizing and responding to antigens that are uniquely or highly expressed on cancer cells. In cancer, complex interactions between immune cells and growing tumor cells can prevent an immune response by blocking cellular interactions, resulting in immunosuppression in the TME. This phenomenon, referred to as immune evasion, is a hallmark of cancer where the tumor can prevent tumor-specific immune cells called T cells from functioning within the TME or gaining access to the tumor site, which allows the tumor to continue to grow, leading to disease progression. Tumors in advanced cancer have multiple mechanisms of evasion in the TME that can differ from tumor to tumor.

The TME is the cellular environment in which the tumor exists and encompasses the surrounding blood vessels, a variety of immune cells, fibroblasts, bone marrow-derived inflammatory cells, lymphocytes, signaling molecules and the extracellular matrix, or ECM. Immune cell types in the TME include T cells, natural killer, or NK, cells, dendritic cells, macrophages, suppressive myeloid cells and neutrophils. The tumor and the surrounding microenvironment interact constantly. Tumors and immune cells can express co-inhibitory proteins known as checkpoints that lead to immune tolerance by the tumor and/or immune cells, allowing the tumor to grow by evading the host immune response. In addition to modulating immune function, immune cells in the TME can also promote a pro-tumorigenic environment that fosters the growth and evolution of cancer cells.

Remodeling the TME and overcoming its immunosuppressive properties is a major focus of cancer research and drug development. Checkpoint inhibitors are a drug class designed to counteract certain tumor defenses against the immune system. Currently approved checkpoint inhibitors were developed for the treatment of cancer based on the belief that inactivation of the immune system by checkpoints could be reversed to reactivate the immune system to recognize and

attack the tumor. Therapies against checkpoints, such as PD-L1, PD-1 and CTLA-4, have produced impressive results in the clinic across an array of cancers and have been approved for several malignancies. However, despite the recent success of these checkpoint inhibitors, efficacy has been limited. It is estimated that up to 60% to 70% of cancer patients, including those with melanoma, renal cell cancer, colorectal cancer, NSCLC, urothelial cancer and HNSCC, do not respond to single-agent therapy with checkpoint inhibitors. Many of the patients who are non-responders possess so called “cold” tumors that do not contain meaningful numbers of T cells that recognize their tumors. In addition, some patients develop resistance after initial treatment with these checkpoint inhibitors. This limited efficacy highlights the importance of our effort to identify novel targets and molecular pathways responsible for tumor immune evasion mechanisms that we believe will work independently from current targets for cancer immunotherapy.

Our Approach to Developing Immunomedicines for Cancer

Our approach to identifying targets for new immunomedicines in cancer is based on the combination of our FIND-IO platform, our immunological expertise and our belief in the importance of understanding biological pathways and the normal function of the immune system in the TME. Rather than focusing on a specific type of immune cell, we are targeting molecules that modulate the immune system in ways that we believe may provide new treatment opportunities for patients that are differentiated from currently marketed targeted therapies as well as those in development. Our primary goal is to develop immunomedicines that increase response rates, efficacy and durable overall survival among patients who do not respond to current therapies, patients whose cancer progresses despite treatment and patients with cancer types that are not adequately addressed by currently available therapies. We design our product candidates either to restore the normal effects of the immune system to promote elimination of the tumors or to counteract tumor immune evasion mechanisms.

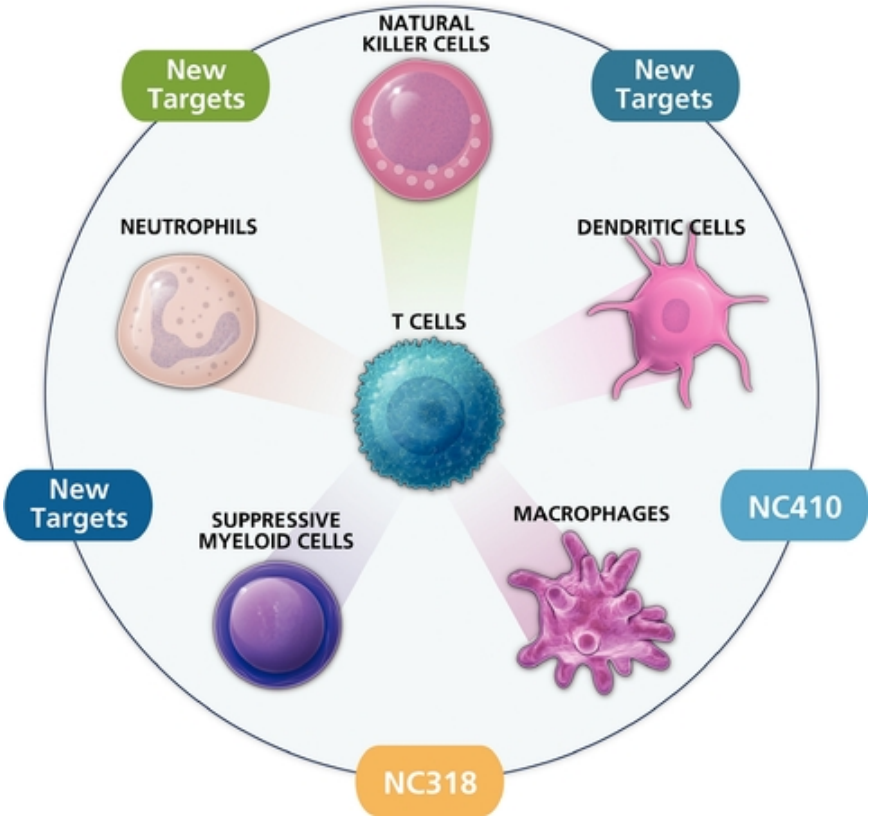
Our FIND-IO platform applies a function-based screening approach to identify human proteins and to determine whether those proteins alter or stop an immune response resulting in immune evasion. The platform is designed to identify novel cell surface molecular interactions that drive functional immune responses. Our FIND-IO platform broadly and quantitatively evaluates interactions between relevant protein components and different cellular types over time in order to identify novel targets that either increase or decrease immune-related functional responses associated with desired immune responses against tumors. By identifying novel immune modulators through the FIND-IO platform, we aim to develop next-generation immunomedicines that restore normal immune function in the TME.

To create our FIND-IO platform, we industrialized, expanded and optimized the T Cell Activity Array, or the TCAA, a predecessor of the FIND-IO platform that Dr. Chen used to discover the immunosuppressive properties of S15. Our work in developing the FIND-IO platform beyond the TCAA includes using different and expanded gene libraries, adding biological pathways and reporters, expanding immune cell types and, most importantly, increasing the repertoire of functional assay readouts. We also broadened the platform to look at signaling within both the immune cell and the cell expressing the library gene. By transfecting cells with library genes, which encode membrane-bound or soluble proteins, FIND-IO is designed to determine whether the genes have signaling functions when interacting with an immune cell.

Our FIND-IO technology includes proprietary approaches to functionally assess immune pathways in both primary immune cells and established cell lines from immune lineages, including T cell subsets, monocytes, macrophage subpopulations, dendritic cells, cancer cell lines and cells isolated from diseased patients. This platform allows us to identify proteins that can be targeted with novel immunomedicines to repair and maintain anti-tumor immunity. By focusing on understanding the TME in oncology, we believe we can identify multiple new positive and negative modulators of immune cells, including T cells, NK cells, macrophages and myeloid-derived suppressor cells.

As shown in the figure below, our product candidates target a variety of cell types in the immune system. For example, NC318 targets macrophages and tumor cells and prevents suppressive myeloid cells from negatively regulating T cells, and NC410 targets the negative signaling from dendritic cells, macrophages and T cells mediated by the binding of LAIR-1 to its ligands collagen and C1q. We also have earlier stage discovery programs that are investigating the negative effects of NK cells and other immune cells in the TME on T cells.

Expanding Targets Beyond T Cells



Our Programs

NC318

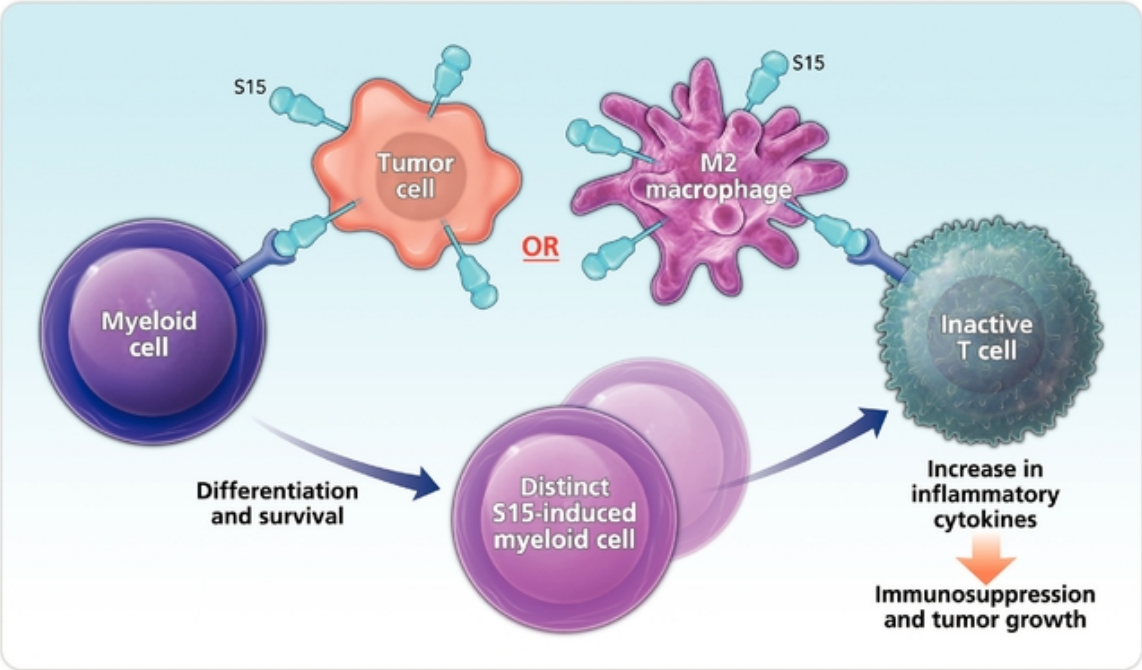
NC318 is a monoclonal antibody that binds specifically to human S15 with high affinity. We have observed in preclinical studies that blocking S15 improved the immune response in multiple animal models. We believe that NC318 may help promote an effective anti-tumor immune response by targeting multiple cell types in the TME that express S15, including macrophages and S15-positive tumor cells. Based on the results of our preclinical studies, we initiated a Phase 1/2 clinical trial of NC318 in patients with advanced or metastatic solid tumors in October 2018. We completed enrollment of the Phase 1 portion of this trial in August 2019 and preliminary data from the Phase 1 portion was presented at the SITC annual meeting in November 2019. We began enrolling patients in the Phase 2 portion of the trial in October 2019 and expect to announce initial data from the Phase 2 portion by the end of 2020. In addition, we may develop a complementary diagnostic for NC318 if we determine it is advisable. We have exclusive worldwide rights to NC318.

S15 Background

S15 is a member of the sialic acid-binding immunoglobulin lectins, or Siglec, family, a distinct subgroup of the immunoglobulin superfamily of proteins. Siglecs are expressed on most white blood cells of the immune system, except for T cells. Siglecs recognize and bind to a sugar structure called sialic acid that coats proteins and fatty acids found on the surface of all mammalian cells. This binding can affect cell signaling on immune cells. Several Siglecs play key roles in helping immune cells distinguish between self and non-self and modulating immune responses. In 2015, Dr. Chen discovered the immunosuppressive properties of S15 using the TCAA. S15 is expressed on tumor cells and, importantly, on M2 macrophages, which are highly immunosuppressive in the TME.

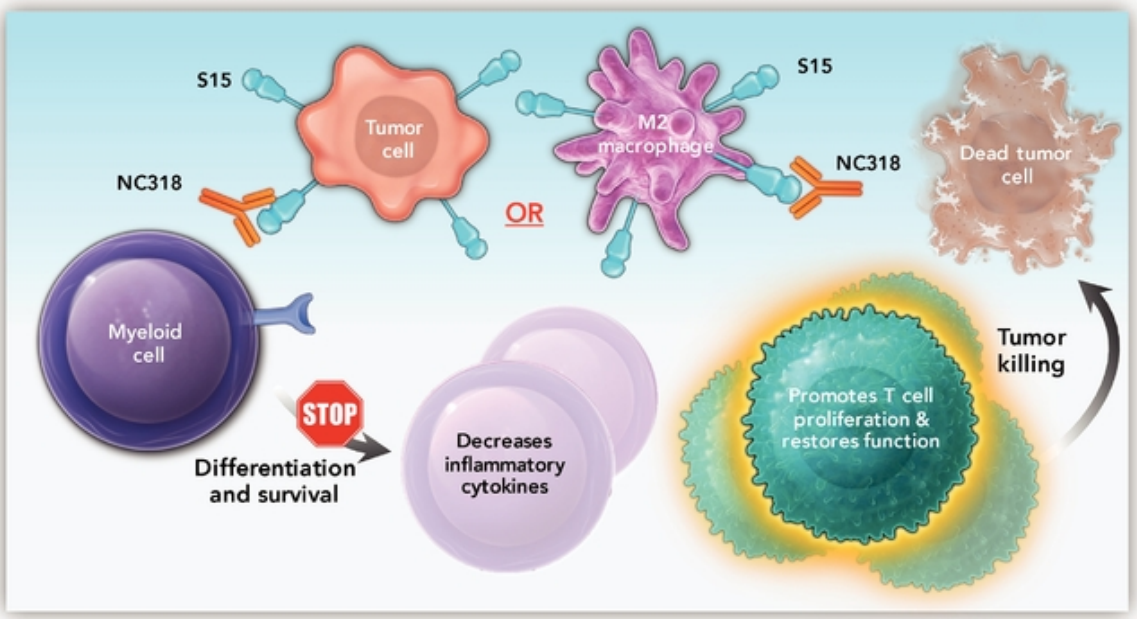
S15 molecules on M2 macrophages, as well as on tumors themselves, appear to interact with unidentified receptors on T cells and inhibit T cell proliferation and functions, leading to decreased anti-tumor immune response. It also appears that S15 interacts with myeloid cells to promote their survival and differentiation so that they contribute to the overall immunosuppressive tumor environment through production of cytokines, such as IL-6, IL-1β and TNF-α, that are tumor-promoting and immunosuppressive in the context of the TME. As shown in the figure below, the presence of S15 on either tumor cells or M2 macrophages can lead to an immunosuppressive TME, resulting in tumor growth.

S15 is Highly Immunosuppressive in the TME

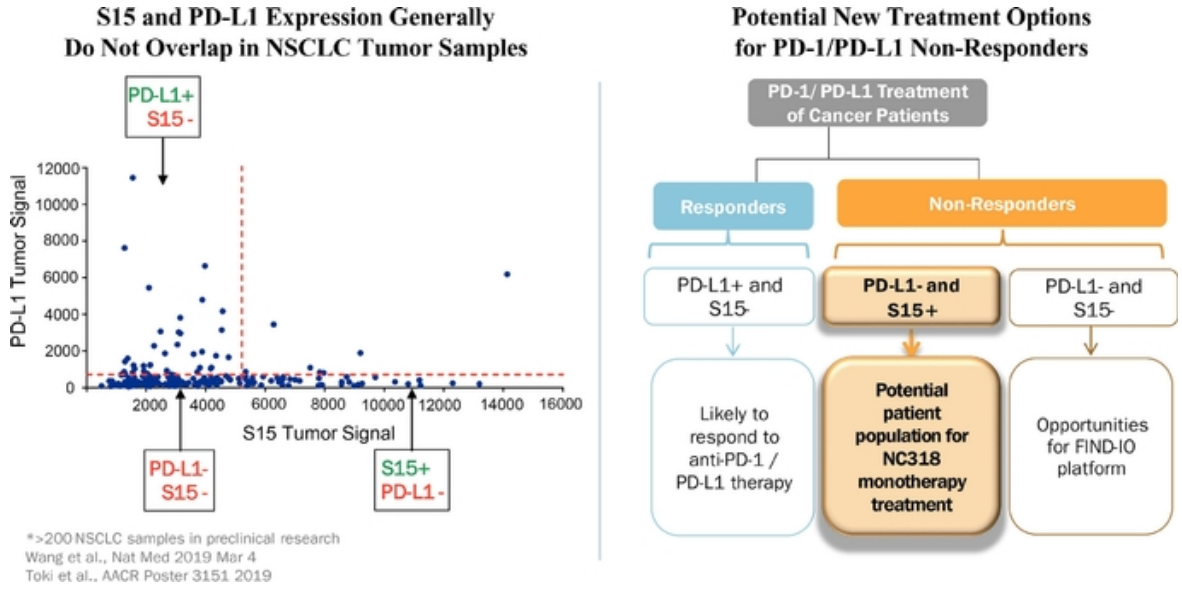


The mechanism of action of NC318 prevents immune suppression caused by S15 and promotes anti-tumor activity. As the figure below shows, by targeting M2 macrophages, S15-induced myeloid cells and S15-positive tumors, NC318 is engineered to decrease inflammatory cytokines associated with enhanced tumor growth, promote T cell proliferation and restore T cell function, which we believe will reduce and kill tumors.

NC318 is Designed to Block Immunosuppressive Activity Induced by S15



In preclinical studies, we have observed that S15 is highly expressed on both tumor cells and M2 macrophages in the TME in multiple tumor types, including human lung cancer, ovarian cancer, breast cancer and melanoma. In contrast, S15 expression on normal tissues is minimal. Our analysis shows that S15 exhibits a distinct expression pattern on tumors and functions independently from the PD-L1 pathway. The left panel of the following figure illustrates the expression of S15 relative to PD-L1 among more than 200 NSCLC tumor samples across multiple microarrays. Three distinct populations are identified: S15-positive and PD-L1-negative tumors; PD-L1-positive and S15-negative tumors; and tumors that express neither S15 nor PD-L1. This observation suggests that the expression of S15 is generally non-overlapping from PD-L1 on tumors. As reflected in the right panel of the following figure, we believe NC318 may provide a therapeutic solution for patients who have S15-positive and PD-L1-negative tumors, a patient population that is less likely to respond to a PD-1/PD-L1 directed therapy. This is consistent with our goal to develop immunomedicines that restore normal immune function in ways that differ from existing immunotherapies in order to provide effective therapies for patients who are not adequately served by currently available therapies.



First in-Human Phase 1/2 Clinical Trial

In October 2018, we initiated a Phase 1/2 clinical trial to evaluate NC318 as a monotherapy in patients with advanced or metastatic solid tumors. This ongoing first-in-human trial is an open-label Phase 1/2 clinical trial designed to assess the safety and tolerability of NC318, to define the maximum tolerable dose and/or pharmacologically active dose and to assess preliminary efficacy. Patients receive NC318 on day one of each cycle. We initiated the trial with 14-day cycles; however, we may explore alternate doses and dose administration schedules. The trial is being conducted in two phases.

The Phase 1 portion was designed to determine the pharmacologically active dose, defined as the dose that provides a maximal biologic effect, such as an increase in biomarkers of immune activation or a reduction of biomarkers associated with immune suppression, and/or the maximum tolerable dose of NC318, including defining the optimal dose administration schedule and the maximum number of tolerated doses. We completed enrollment of the Phase 1 portion of the trial in August 2019 and have dosed 49 patients across seven dose cohorts: 8 mg, 24 mg, 80 mg, 240 mg, 400 mg, 800 mg and 1,600 mg, the last of which was added to the trial because a maximum tolerated dose had not been reached through 800 mg. The most common tumors in the trial were NSCLC (13 patients), ovarian (seven patients), melanoma (seven patients), breast (four patients) and colorectal (three patients). Enrolled patients had all been subject to previous cancer treatments, with a median of three prior therapies, and all 13 NSCLC patients were PD-1 refractory and had been treated with a median of four prior therapies.

Preliminary data from the Phase 1 portion was presented in November 2019 at the SITC annual meeting. As of November 9, 2019, NC318 had been well tolerated in the Phase 1 portion of the trial and only one dose-limiting toxicity, a grade 3 pneumonitis at the highest dose level, had been observed. Treatment-related adverse events experienced by more than 5% of patients as of that date were diarrhea, infusion reactions, fatigue, headaches, pruritis, elevated amylase and elevated lipase. Most treatment-related adverse events were easily manageable, asymptomatic or mild or moderate, with the exception of one case of grade 3 episcleritis/uveitis at the 400 mg dose level that resolved after steroid therapy and two cases of grade 3 pneumonitis (one at the 400 mg dose level and one at the 1,600 mg dose level). We also observed two grade 1 cases of vitiligo (one at the 80 mg dose level and one at the 400 mg dose level) that, along with other immune-related adverse events including diarrhea, elevated amylase and lipase, pruritis, episcleritis/uveitis and pneumonitis, indicate NC318's activity as a modulator of the immune system.

Data from the trial indicate activity in multiple tumor types, including durable stable disease in patients with NSCLC, endometrial cell cancer, ovarian cancer, squamous cell carcinoma, Merkel cell cancer, and head and neck cancer. As of November 9, 2019, durable responses observed include one complete response, which remained ongoing at 55 weeks, and one partial response, which remained ongoing at 28 weeks, both in NSCLC patients, as well as 14 patients

with stable disease, which remained ongoing for between 16 and 42 weeks. The patient with the complete response had multiple lesions prior to treatment with NC318, including two lesions that were at least 10 mm. Among the 14 patients with stable disease, four patients have NSCLC, with stable disease ongoing for between 16 and 40 weeks. Three NSCLC patients (out of 13 NSCLC patients in total) had not been in the study long enough to confirm the status of their disease.

We began enrolling patients in the Phase 2 portion of the Phase 1/2 clinical trial of NC318 in October 2019. The Phase 2 portion of the trial is an open-label trial designed to detect a relevant efficacy signal, or response rate, for each tumor type at a 400 mg dose administered every two weeks. In this portion, we will enroll up to 100 patients with tumor types that have been shown to have elevated S15 expression, including NSCLC, ovarian cancer, HNSCC and TNBC. The primary endpoints for the Phase 2 portion of the trial are safety and tolerability, and secondary endpoints include response rate, progression-free survival, duration of response and overall survival. We expect to announce initial data from this portion of the trial by the end of 2020.

We designed the clinical trial for NC318 with a robust biomarker strategy to help evaluate clinical activity throughout the trial by focusing on markers of pharmacodynamics. During the trial, we are obtaining a series of blood samples from patients before and during treatment. These blood samples are being used for the analysis and characterization of the immune cell population. T cell receptor clones are also being analyzed to detect evidence of therapy-induced clonal expansion of a subpopulation of antigen-specific T cells. Other assays relevant to the objectives of the trial, such as flow cytometry analysis of intracellular cytokines, may be performed based upon emerging data. In the Phase 2 portion of this trial, we will also obtain tumor biopsy samples before the first dose of NC318 and at least once more after the third dose. The biopsy samples will be used to investigate molecular signatures associated with response or resistance to treatment with NC318. We may also examine tissue by histology and immunohistochemistry or by exploratory methods to evaluate markers of inflammation and effector T cell populations, growth, signaling, apoptosis and similar markers that may be associated with safety, response or resistance to treatment with NC318. We believe our biomarker strategy will allow us to better monitor the clinical trial and could help shape the treatment strategy of NC318 in future clinical trials and, if approved, in clinical practice.

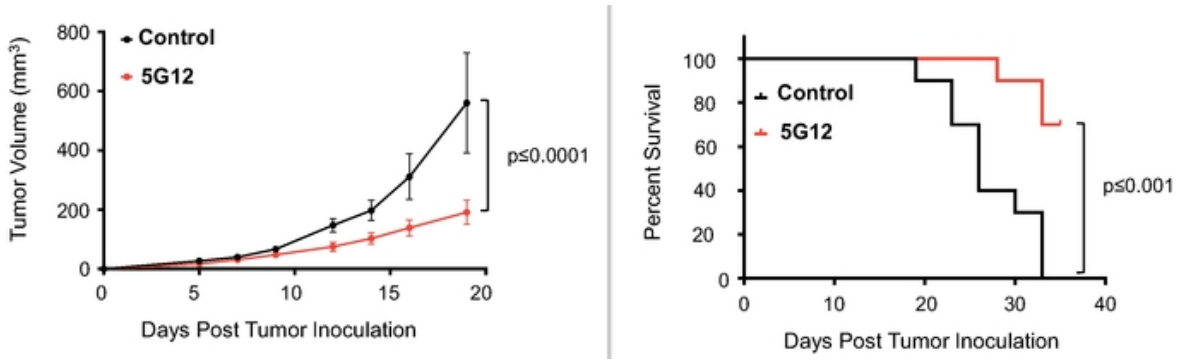
Phase 2 Combination Clinical Trial

In mid-2020, we intend to initiate a Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors. This trial will be an open-label trial designed to assess the safety and tolerability of NC318 in combination with at least two different chemotherapy regimens and to define the maximum tolerable dose of NC318 when administered with each chemotherapy. The trial will also be designed to assess preliminary efficacy of each combination in specific tumor types in a manner that can potentially support the use of such combinations in first-line therapies of advanced or metastatic solid tumors.

Preclinical Data

Most syngeneic mouse tumor cell lines, which are common mouse models used to test immunotherapies, do not express S15. In order to study the effects of our S15-targeted antibody, we generated a tumor model where the mouse expresses S15. The model was initiated by differentiating mouse bone marrow cells into S15-positive M2 macrophages *in vitro*. These cells were then implanted into mice with an S15-negative mouse colon cancer cell line called CT26. The mice were then treated with either the S15-targeted antibody 5G12, the murine parent antibody of NC318, which has similar overall functional properties to NC318, or a control antibody. Across multiple preclinical studies, we evaluated the safety and efficacy of 5G12 and observed that blocking the effects of S15 with 5G12 restored immune function and anti-tumor immunity. For example, as the figure below shows, mice treated with 5G12 every four days for seven doses had smaller tumors and increased survival when compared to the mice treated with a control antibody.

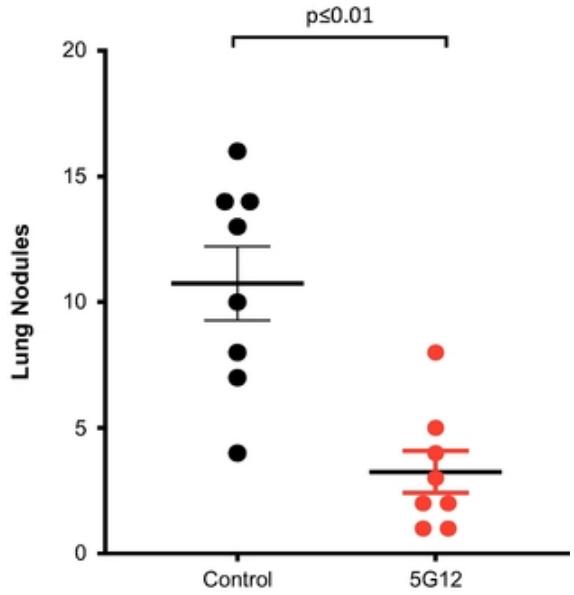
Treatment with 5G12 Reduced Tumor Growth and Increased Survival



The p-value, or probability value, cited in figures in this Annual Report as "p," is the likelihood that an observed result occurred by chance. The smaller the p-value, the less likely that chance caused the result. A result that is sufficiently unlikely to have occurred by chance is referred to as being statistically significant. The FDA generally considers a p-value of less than or equal to 0.05, meaning that there is a 5% or less chance that the results occurred by chance, to be statistically significant.

We also generated murine tumors expressing S15 on their surface. In our preclinical studies of an S15-positive murine colon cancer cell line, we observed that 5G12 delayed tumor growth and tumor metastasis, which was demonstrated by fewer lung nodules measured 28 days after treatment in the mice treated with 5G12 as compared to the mice treated with a control antibody, as shown in the figure below.

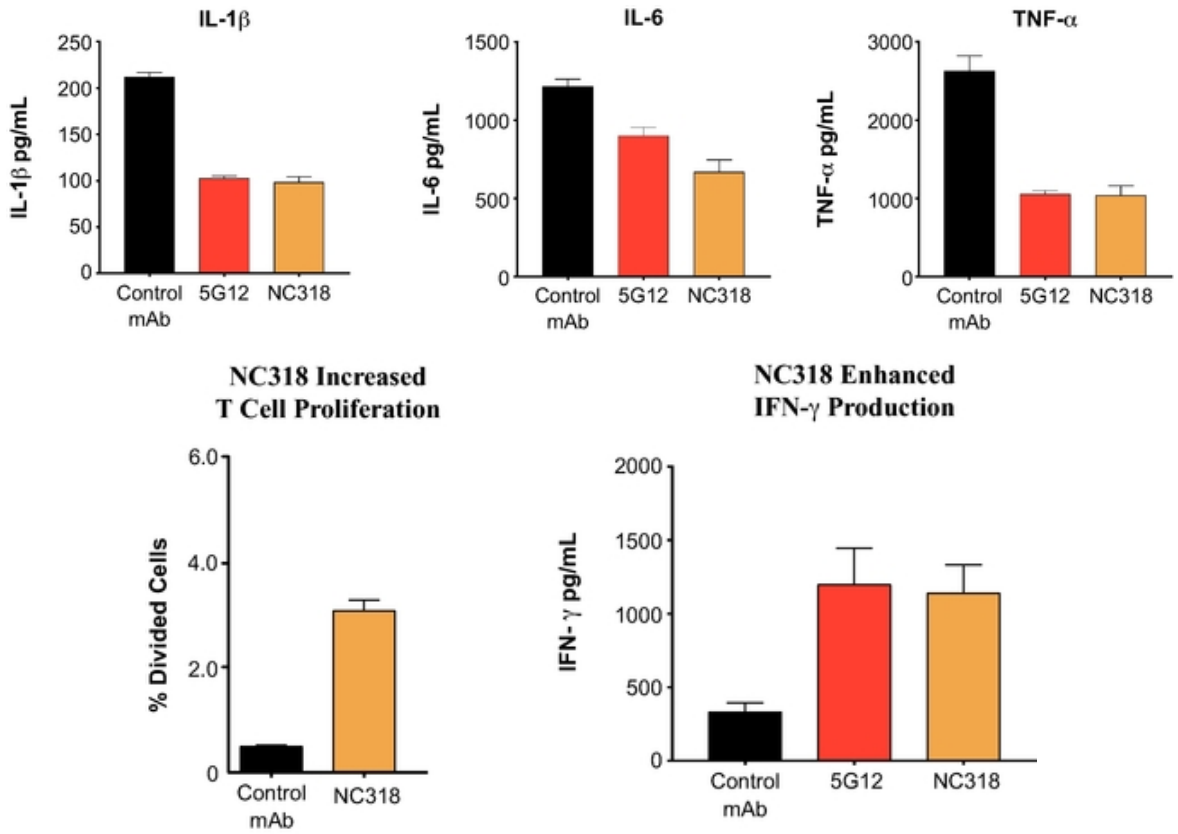
Treatment with 5G12 Delayed Tumor Metastasis in Lung Model



Based on in vitro studies, we understand that S15 drives an increase in pro-inflammatory and pro-tumorigenic cytokines, such as IL-1β, IL-6 and TNF-α. As indicated in the figure below, when human peripheral blood mononuclear cells, or PBMCs, which are blood cells that are critical components in the immune system, were cultured in the presence of S15, the amount of pro-inflammatory and pro-tumorigenic cytokines increased, indicating an immunosuppressive environment. However, when human PBMCs were cultured with S15 protein and 5G12 or NC318, the amount of pro-inflammatory and pro-tumorigenic cytokines was reduced relative to when cultured with S15 and a control antibody. In

addition, 5G12 and NC318 promoted the ability of human T cells to proliferate and produce interferon-gamma, or IFN-γ. These data, which are shown in the figures below, suggest that 5G12 and NC318 have the potential to block immune suppression mediated by S15.

NC318 Decreased Inflammatory Cytokines



NC410

NC410 is a fusion protein of LAIR-2, a naturally occurring soluble version of and decoy protein for LAIR-1, and is designed to block immune suppression mediated by LAIR-1. Multiple preclinical studies support our understanding that eliminating or blocking the binding of LAIR-1 restores normal immune function in multiple immune cells. Our translational work has shown that NC410 blocks the interaction of LAIR-1 with its binding partners, thereby promoting T cell function and dendritic cell activity to contribute to restoring anti-tumor immune activity. Consistent with our strategy, we believe NC410 has the potential to address the needs of patients who are not adequately addressed by currently available therapies. The FDA accepted our IND in the first quarter of 2020 and we intend to initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the second quarter of 2020. We have exclusive worldwide rights to NC410.

Background of LAIR Pathway in Cancer

LAIR-1 is a co-inhibitory receptor expressed on T cells and several other immune cell subsets, including monocytes, macrophages and dendritic cells. Its binding partners include certain types of collagen and complement component 1q, or C1q.

Under normal conditions, collagen forms a scaffold to provide strength and structure to tissues. C1q is part of the innate immune system to protect the host from infection and other foreign agents. Both collagen and C1q are highly

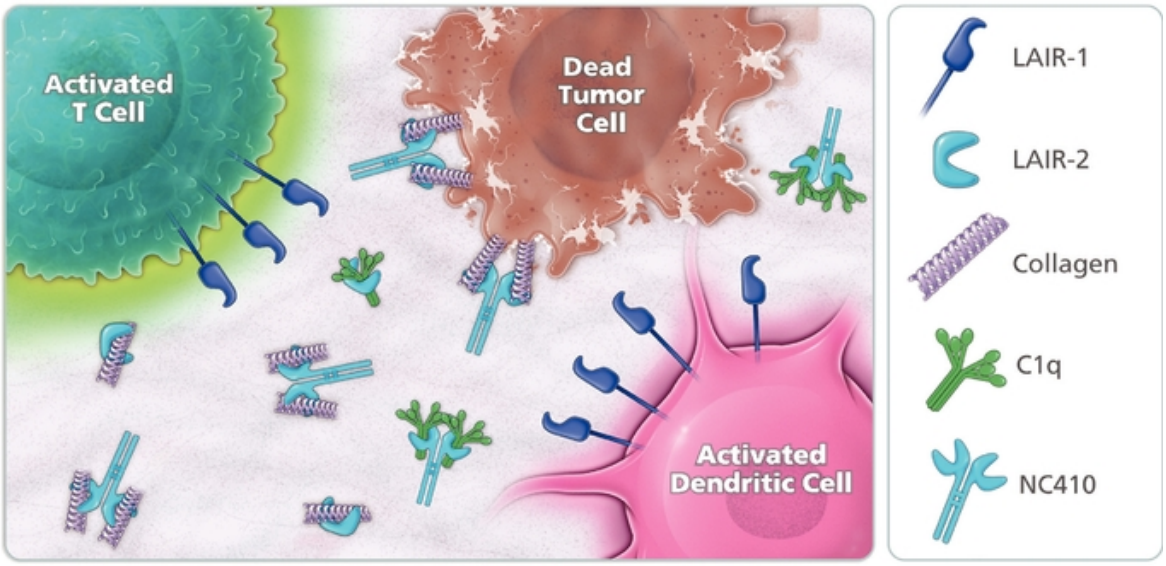
upregulated and expressed under pathologic conditions, such as in the TME and in the immune organelles close to the tumor site known as lymph nodes, which are important sites for mounting immune responses to the tumor. However, binding of LAIR-1 to collagen or C1q leads to immune suppression. Our preclinical studies have shown that LAIR-1 and LAIR-2 bind to similar ligands, including collagen and C1q. LAIR-2, which is a secreted protein as opposed to a membrane-bound protein like LAIR-1, binds to the same regions of these ligands with stronger affinity than LAIR-1. However, because LAIR-2 does not induce immune suppression when binding to these ligands, LAIR-2 functions as an efficient decoy for LAIR-1.

Under the harsh conditions of the TME, collagen and C1q are overexpressed as a membrane protein on many types of tumor cells and in the ECM surrounding the tumor. This increased expression of collagen and C1q, combined with insufficient levels of natural LAIR-2, leads to increased binding of LAIR-1, resulting in immune suppression, tumor immune evasion and tumor growth.

NC410 is a novel immunotherapeutic protein that was developed to block LAIR-1-mediated immune suppression by mimicking the natural decoy effects of LAIR-2. Our approach of using NC410 as a therapeutic is intended to take advantage of the natural LAIR-2 regulatory system in humans, which maintains human immune function under normal non-pathologic conditions.

The mechanism of action of NC410 prevents immune suppression caused by LAIR-1 binding to collagen or C1q and promotes anti-tumor immune activity. As the figure below shows, when LAIR-2 and NC410 are present in the TME, they bind to collagen or C1q preferentially compared to LAIR-1 given their higher binding affinity. This has the effect of blocking the collagen or C1q from binding to LAIR-1, which otherwise would have resulted in an immunosuppressive effect. By blocking this interaction with LAIR-1 and its binding partners, T cell function and dendritic cell activity is promoted in order to restore anti-tumor immune activity.

NC410 is Designed to Prevent Immune Suppression Caused by LAIR-1

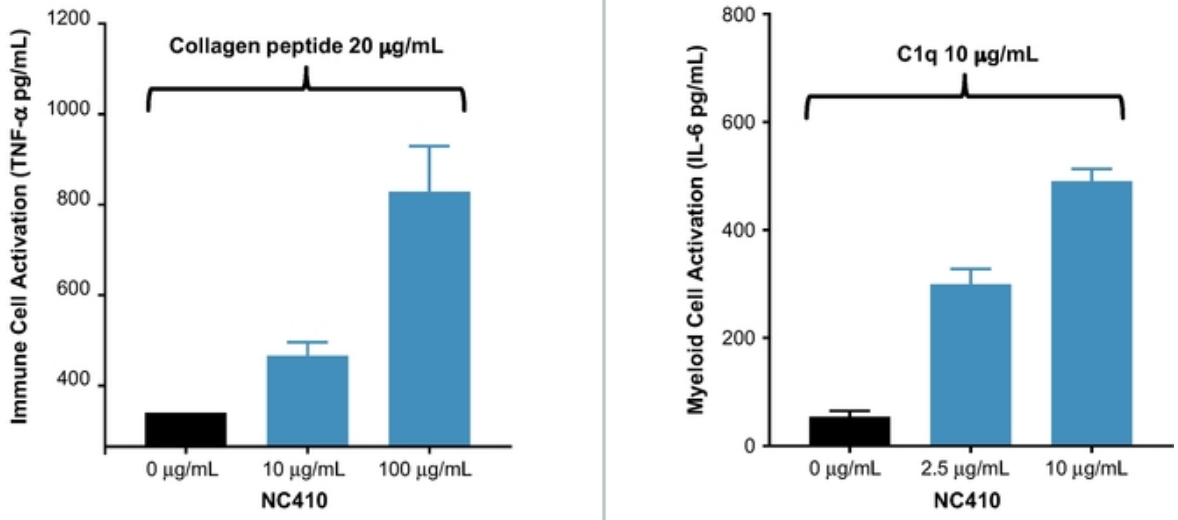


Preclinical Data

We have conducted multiple preclinical studies to assess the activity of NC410 across a variety of preclinical models. These studies support our understanding that eliminating or blocking the binding of LAIR-1 to collagen or C1q can restore normal immune function in multiple immune cells, including T cells and myeloid cells, resulting in activation of T cells and anti-tumor immunity.

We have observed *in vitro* with human cells that using NC410 to block LAIR-1 from binding with collagen or C1q reverses immune suppression and restores normal immune cell function for both peripheral blood monocytes, including T cells, and myeloid cells. In one study of peripheral blood monocytes, we added 0 µg/mL, 10 µg/mL and 100 µg/mL of NC410 to 20 µg/mL of collagen peptide *in vitro*. Similarly, we also evaluated the addition of 0 µg/mL, 2.5 µg/mL and 10 µg/mL of NC410 to 10 µg/mL of C1q on human myeloid cells. As shown in the figures below, NC410 promoted the activation of immune cells in the presence of high levels of collagen in peripheral blood monocytes and high levels of C1q in myeloid cells in a dose-dependent manner.

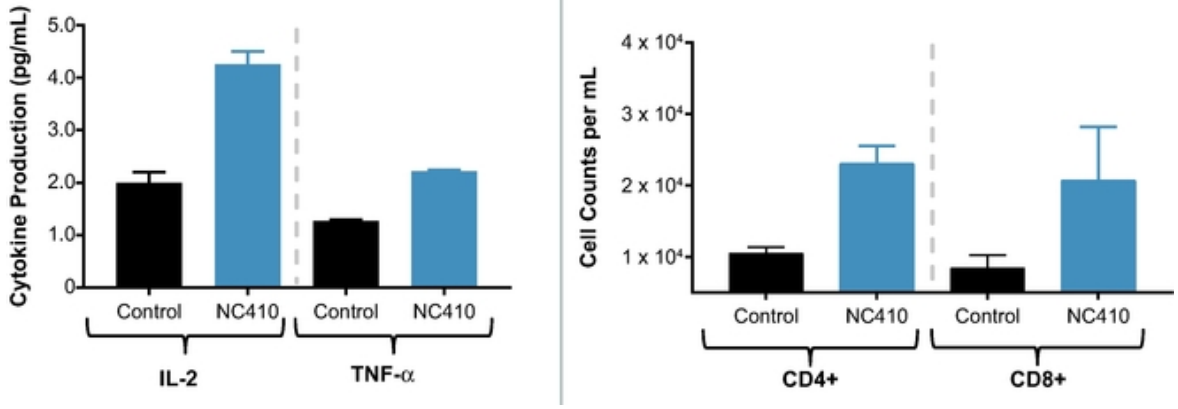
NC410 Reversed Immune Suppression Caused by LAIR-1 Binding with Collagen and C1q



In another preclinical study with human cells, we observed that NC410 promoted increases in the cytokines IL-2 and TNF-α, as shown in the left-hand panel of the following figure, which is indicative of increased immune function. In addition, simultaneous in vivo injections of NC410 and human T cells in immune-deficient mice resulted in increased amounts of CD4+ and CD8+ T cells, as shown in the right-hand panel of the figure below.

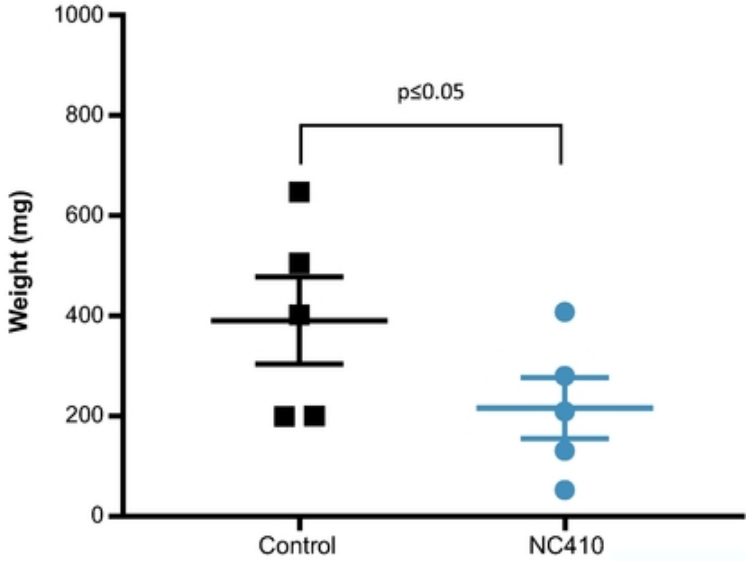
NC410 Promoted Increases in Cytokines

NC410 Promoted Generation of T Cells *In Vivo*



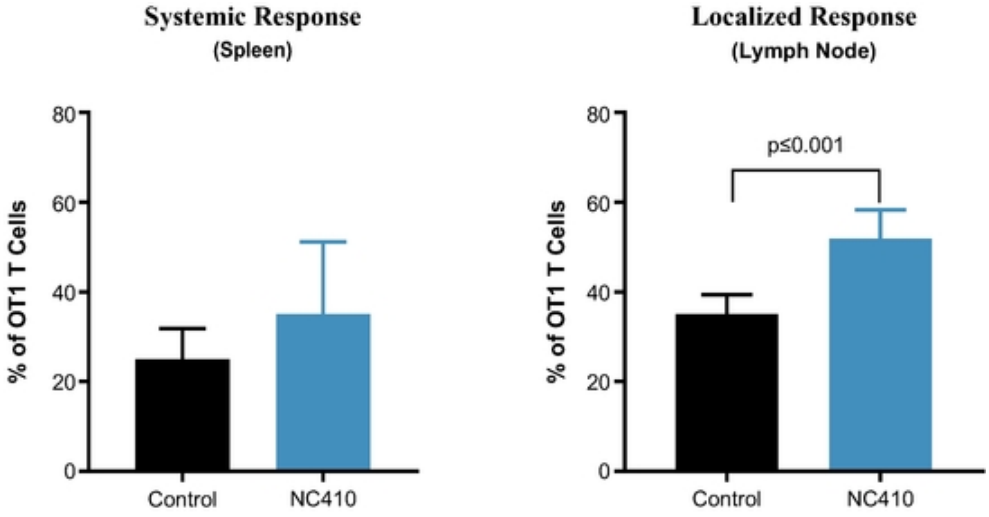
Through multiple preclinical studies in several additional tumor models, we observed that eliminating or blocking LAIR-1-mediated immune suppression prolonged survival. In addition, anti-tumor activity of NC410 correlated with a local increase in antigen-specific T cells in the TME *in vivo* using an engineered mouse model to measure localized antigen-specific responses. We used an antigen-specific tumor model of EL4, a murine lymphoma cell line. We measured the weight of the animals daily as a proxy for tumor growth. As shown in the figure below, we observed that mice treated with NC410 had smaller tumors than mice treated with a control, suggesting that NC410 has potential anti-tumor activity.

NC410 Showed Anti-Tumor Activity



We also measured T cells specific for ovalbumin, and as shown in the figures below, we observed systemic and local increases, as measured in the spleen and lymph node, respectively, in mice treated with NC410 compared to those treated with control. We believe that these data support an immune response in and around the TME.

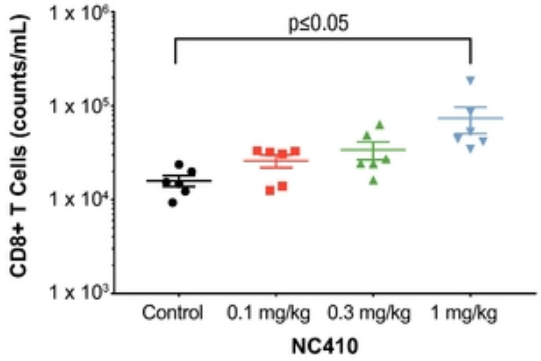
NC410 Increased T Cells Both Systemically and Locally



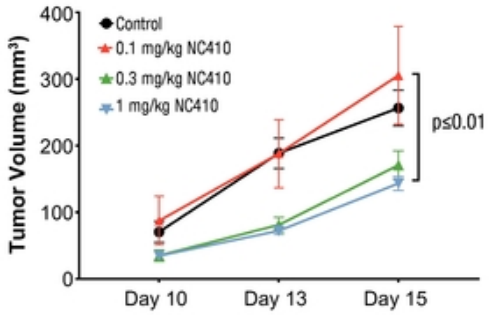
In addition, when human PBMCs were implanted into mice with mouse P815 mastocytoma tumor cells, we observed that NC410 mediated an increase in human T cells *in vivo* and that the increase in human T cells correlated with a delay in tumor growth. As shown in the figures below, NC410 increased the number of CD8+ T cells on day 13 in a dose-dependent manner and that increase corresponded to a decrease in tumor volume. To mimic human cancers, human PBMCs were also implanted into mice with human HT29 colon adenocarcinoma cells to test efficacy in a human tumor model. NC410 promoted an anti-tumor response against the human HT29 tumor cell line in a dose-dependent manner, as shown in the figure below.

Mouse P815 Mastocytoma Model

NC410 Increased CD8+ T Cells on Day 13



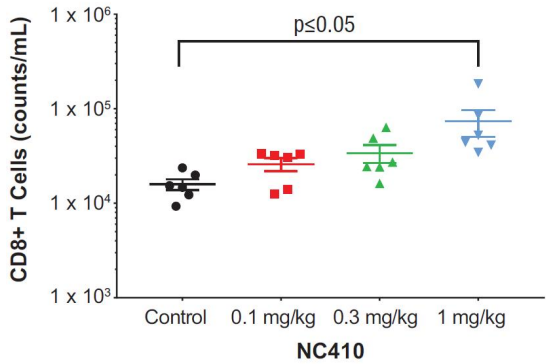
NC410 Decreased Tumor Volume



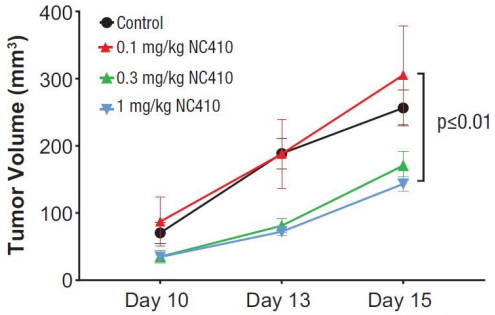
Human HT29 Colon Adenocarcinoma Model

NC410 Decreased Tumor Volume

NC410 Increased CD8+ T Cells on Day 13



NC410 Decreased Tumor Volume



Our Clinical Development Plan for NC410

We and others have analyzed genomic and protein databases and observed that LAIR-1 expression levels negatively correlate with survival rates for several cancers, including brain, renal, colorectal, glioma, lung, urothelial and ovarian cancers. These analyses support possible targeting of these tumor types as primary indications for therapeutic treatment with NC410. We are conducting expansive screening efforts on tumor samples from different solid tumor types to identify tumors that express LAIR-1 on the surface of either cancer cells or infiltrating immune cells to guide our ultimate selection of patients for planned clinical trials of NC410 in humans.

The FDA accepted our IND for NC410 in the first quarter of 2020 and we intend to initiate a Phase 1/2 clinical trial in the second quarter of 2020 in patients with advanced or metastatic solid tumors in a variety of tumor types including lung, ovarian and pancreatic cancer.

Our Research Programs

In addition to NC318 and NC410, we are also pursuing preclinical evaluation of other potential novel immunomodulatory molecules. Among these is an antibody that targets a novel member of the B7-family of immunomodulatory proteins. In our preclinical studies, this antibody has shown highly reproducible and potent anti-tumor activity with *in vivo* modeling and appears to involve an important immunomodulatory pathway in the TME that may complement the activity of NC318 and NC410. Consistent with our focus on patients who do not respond to current therapies, patients whose cancer progresses despite treatment and patients with cancer types that are not adequately addressed by currently available therapies, the target of this antibody appears to be non-overlapping with the expression of both S15 and PD-L1 on tumor cells.

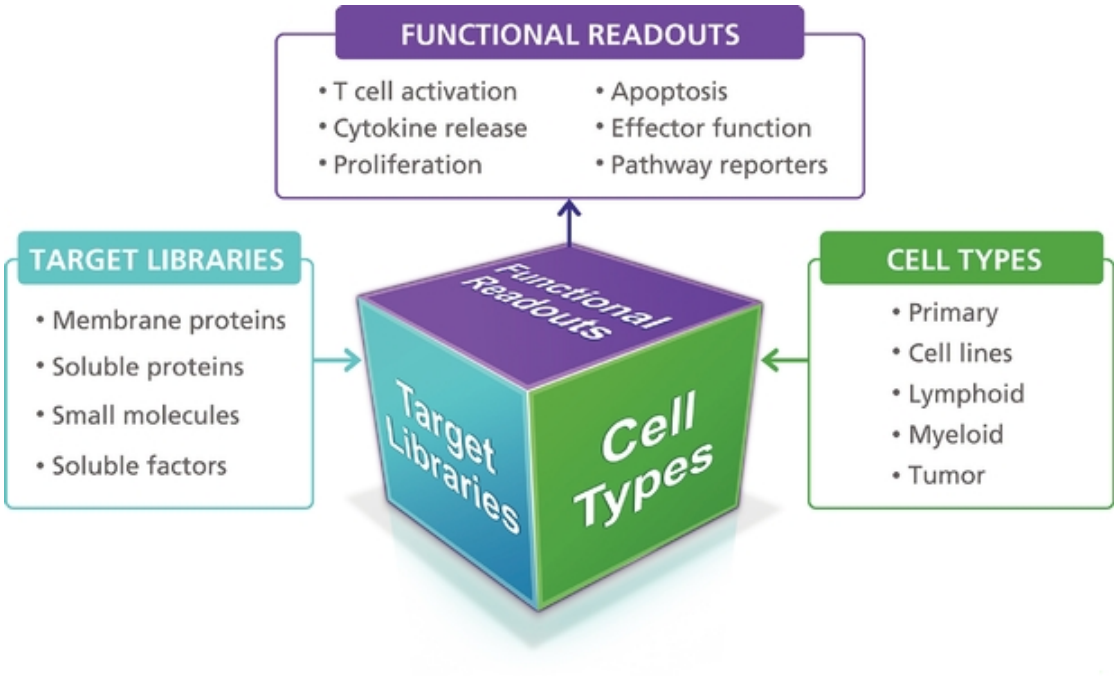
We also have an antibody in preclinical development targeting an immune modulator that is highly expressed in inflamed tissue and the TME in multiple tumor types. In our preclinical research, we observed that disrupting inhibitory signaling by this molecule with our antibody increased T cell and NK cell effector functions.

Based on our understanding of the LAIR pathway, including through our development of NC410, we are also pursuing monoclonal antibodies that target LAIR-1 and directly block LAIR-1 binding and signaling to prevent tumor growth or to eliminate the tumor. These novel LAIR-1 antibodies have unique functional properties that may provide additional opportunities in both cancer and autoimmune disorders.

Our FIND-IO Discovery Engine

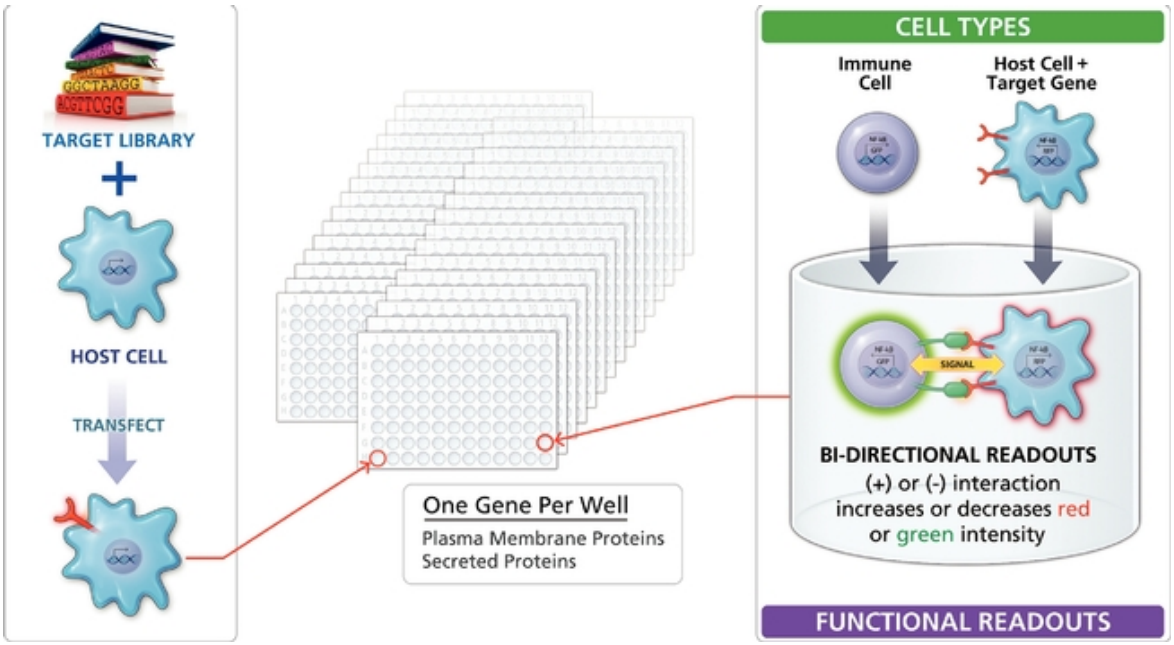
Our FIND-IO platform uses proprietary approaches to functionally assess immune pathways in both primary immune cells and established cell lines from immune lineages, including T cell subsets, monocytes, macrophage subpopulations, dendritic cells, cancer cell lines, and cells isolated from diseased patients. This platform allows us to identify proteins that can be targeted with novel immunomedicines to repair and maintain anti-tumor immunity. We have identified multiple novel targets using our FIND-IO platform, including those for which certain of our research programs are being designed to target.

There are three integrated components to our FIND-IO platform. The first component consists of gene libraries, also called target libraries, comprising genes that are expressed and queried for immune or other functions. Our target libraries are composed of genes that encode a structurally diverse set of protein molecules and that are either inserted into the plasma membrane on the host cell surface or secreted outside of the host cell. The second component encompasses a variety of immune and non-immune cell types, called responder cells, used to evaluate the functional effects of the target libraries. The immune responder cell types include primarily immune cells obtained from human volunteers and multiple immune cell lines that have been grown in culture, and the non-immune responder cell types include tumor cell lines. The third component utilizes a broad set of outputs indicative of whether a newly discovered target inhibits or stimulates functional immune responses. We utilize a cube to illustrate these three components as shown in the figure below.



Unlike other screening platforms that often focus on a single parameter or cell type, our approach uses a broad search across multiple cell types and multiple functions and is purposefully designed to produce physiologically relevant results. Although the orchestration of an immune response is complex and dynamic within the TME, we have designed the FIND-IO platform to be simple yet functional. The platform integrates multiple components to assess immune function resulting from cellular interactions in order to identify new immune modulators in an approach that mimics physiological interactions. The goal is to identify proteins that can be targeted with immunomedicines, such as monoclonal antibodies or fusion proteins. Potential targets that are preliminarily identified through the FIND-IO platform undergo reproducible, robust, relevant and comprehensive characterization resulting in functional readouts that improve the likelihood of developing immunomedicines against novel immune modulatory molecules. This approach is intended to meet our goal of extending beyond the success of current immunotherapies to treat patients who are not adequately addressed by currently available therapies and to enhance overall survival in these patients.

The first step in the application of our FIND-IO platform is to transfect the target library into a host cell on a gene-by-gene basis. The host cells then express the library genes and the proteins are present on the cell surface or secreted into the surrounding space. In addition, the host cell has been engineered to express a reporter of transcriptional activity associated with a cellular function. For example, we engineer the host cells to report transcription factor activity in a cellular pathway by linking a selected DNA with a different fluorescent reporter, such as red fluorescent protein, or RFP. Thus, if the library gene expresses a protein that can signal via the applicable pathway, then the RFP gene is transcribed, expressed as a protein and the cell will glow red. The immune or non-immune responder cells are also engineered to express a reporter of transcriptional activity associated with a cellular function. For example, we engineer the responder cells to report transcription factor activity in a cellular pathway by linking a selected DNA with a fluorescent reporter such as green fluorescent protein, or GFP. Therefore, when transcription occurs in the responder cell, the GFP gene is transcribed, expressed as a protein and the cell will glow green. The red and/or green glow of the cells can be measured quantitatively. This is called bi-directional signaling as the FIND-IO platform was designed to look at signaling events in the host cells as well as the immune and non-immune responder cells.



The FIND-IO platform allows us to select and screen multiple immune and non-immune responder cell types, including T cells, myeloid cells, leukemia cells, epithelial cancer cells, plasma B cells and multiple myeloma cells, as well as primary immune cells from healthy donors. For each of these cell types, we undertake functional screening, including activity of many reporter pathways, effector function activity and effects on cell death, in order to identify novel immunomodulatory targets with common or differentiating effects across multiple cell types.

Additionally, with our FIND-IO technology we can test for combination screens to search for synergistic or additive combinations with certain pathways, including immune checkpoint pathways, like the PD-1/PD-L1 pathway, that are currently approved for treating cancer patients. We expect that this screening will help with the identification of potential combination treatments to enhance response rates.

The goal of our FIND-IO platform is to sustain a pipeline of novel immunomedicines that restore normal immune function to treat cancer and other immune-related diseases. While we are primarily focused on cancer treatment, we believe that our proprietary technology, our approach, our understanding of biological pathways and the convergence of immunology and inflammation provide us with opportunity to explore novel immunomedicines for other significant unmet medical needs. To maximize the full potential of our platform and expertise, we are expanding the functional screening approach of our FIND-IO platform to the identification of novel targets in autoimmunity and inflammation, where we are using this approach to develop our FIND-AI platform, as well as in neuro-inflammatory diseases.

Our Collaboration Agreements

Agreements with Yale University

License Agreement with Yale

In December 2015, we entered into a license agreement with Yale, or the Yale Agreement, pursuant to which we obtained an exclusive, royalty-bearing, sublicensable worldwide license to products that either incorporate certain licensed patents used in the discovery of targets or arise out of research and development of Dr. Chen's laboratory at Yale, including S15. We are obligated to pay Yale low single-digit royalties on sales of products, including NC318, that are either covered by the patents licensed to us under the Yale Agreement or arise out of Dr. Chen's laboratory, subject to minimum annual royalty payments in the low to mid hundreds of thousands of dollars. Until we are required to pay royalties under the Yale Agreement, we must pay an annual license maintenance fee to Yale in the mid to high tens of thousands of dollars. In addition, with respect to each product covered by licenses under the Yale Agreement, we are obligated to pay Yale

milestone payments upon (i) the initiation of each of a Phase 1 clinical trial, Phase 2 clinical trial and Phase 3 clinical trial or a pivotal trial, (ii) first commercial sale in the United States and (iii) first commercial sale in China, Japan or a major European country, in an aggregate amount of up to $2,975,000. The term of the license agreement with Yale runs, on a country-by-country basis, until the later of the expiration of all licensed patents or 10 years from the first commercial sale in such country, unless Yale has cause to terminate earlier for our material breach of the license, bankruptcy or if we or any sublicensee bring a challenge against Yale in relation to the licensed patents. We have the right to terminate the Yale Agreement for Yale's material breach or at any time during the term with six months' prior written notice to Yale.

Sponsored Research Agreement with Yale

In connection with the Yale Agreement, we also entered into a corporate sponsored research agreement, or the SRA, with Yale, in which we agreed to provide an aggregate of up to $12.4 million to fund a research program aimed at discovering new targets for immunomedicines. The research program is under the direction and supervision of Dr. Chen. Pursuant to the SRA, we have the option to add any patents invented pursuant to the research program as a licensed patent under the Yale Agreement and the right to obtain a royalty-bearing, exclusive, worldwide license to any such patents. If we do not exercise our option within the exercise period, Yale is permitted to license any such patents to any third party. The SRA will expire on December 31, 2020, and we have the option of extending the term upon mutual agreement with Yale. We can terminate the SRA at any time upon 90 days' written notice to Yale. Yale can terminate for an uncured breach or with 90 days' written notice for cause.

Former Research and Development Collaboration with Lilly

Effective March 3, 2020, Eli Lilly and Company, or Lilly, terminated the multi-year collaboration agreement that we had entered into with Lilly in November 2018, or the Lilly Agreement, focused on the discovery and development of immunomedicines for oncology using our FIND-IO platform. Under the agreement, we granted Lilly the exclusive option to obtain worldwide exclusive licenses to research, develop, manufacture and commercialize multiple compounds and products directed to oncology targets identified through our research collaboration. We received an upfront, non-refundable payment of $25.0 million in cash and a $15.0 million equity investment from Lilly upon entering into the agreement. Lilly was also required to pay us quarterly research and development support payments as well as option exercise fees upon the exercise of options by Lilly, development and regulatory milestone payments, sales milestone payments and royalties. In connection with the termination of the Lilly Agreement, we are no longer eligible to receive future amounts thereunder.

Manufacturing

We have a purpose-built, dedicated, state-of-the-art cGMP manufacturing facility that utilizes single-use technology to support our pipeline and advance our product candidates into and through clinical development. The facility has an initial production capacity of 1,000 liters and was designed with additional room for expansion to support multiple product candidates. The investment in our manufacturing facility is a critical element of our ability to quickly identify whether a candidate is likely to be successful and to facilitate an efficient development path. While other companies may need to work with third parties for antibody production, we can do so in our own facility. Compared to working with third-party manufacturers, we believe our facility provides better quality assurance, greater control in scheduling and prioritizing manufacturing activities and enhanced capital efficiency. We are currently manufacturing all of the drug supply for our preclinical studies and our Phase 1/2 clinical trial of NC318 and intend to expand our cGMP manufacturing capacity, including to provide the drug supply for future clinical trials of NC318. As we advance the development of our growing pipeline of product candidates, we will continue to evaluate the merits of further expanding our internal manufacturing capabilities, including for the production of commercial drug supply, as compared to collaborating with third-party manufacturers.

Competition

The biotechnology and pharmaceutical industries, and the immuno-oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. We believe that our programs, platforms, technology, knowledge, experience and scientific resources provide us with competitive advantages, but we also face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Our competitors include larger and better funded biopharmaceutical, biotechnology and therapeutics companies, including companies focused on cancer immunotherapies,

such as Amgen, Inc., AstraZeneca plc, Bristol-Myers Squibb Company, or BMS, Genentech, Inc., GlaxoSmithKline PLC, Merck & Co., Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd and Sanofi S.A. Moreover, we may also compete with smaller or earlier-stage companies, universities and other research institutions that have developed, are developing or may be developing current and future cancer therapeutics.

Product candidates that we successfully develop and commercialize will compete with a range of therapies that are currently approved and any new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody-drug conjugates, such as Genentech Inc.'s Kadcyla, to immune checkpoint inhibitors targeting CTLA-4, such as BMS' Yervoy, and PD-1/PD-L1, such as BMS' Opdivo, Merck & Co.'s Keytruda and Genentech's Tecentriq, to T cell-engager immunotherapies, such as Amgen's Blincyto. In addition to these marketed therapies, numerous compounds are in clinical development for the potential treatment of cancer.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also 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.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our products, methods and manufacturing processes, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We rely on a combination of patent applications and trade secrets, as well as contractual protections, to establish and protect our intellectual property rights. We seek to protect our proprietary position by, among other things, filing patent applications in the United States and internationally. Our patent estate includes patent applications with claims relating to our product candidates, methods of use and manufacturing processes, and claims for potential future products and developments. As of December 31, 2019, our intellectual property portfolio includes, on a worldwide basis, 18 pending foreign patent applications relating to NC318 and NC410, one pending U.S. patent application relating to NC318, one pending U.S. patent application relating to NC410 and additional pending patent applications for other discovery and research programs. Patents resulting from our patent applications for NC318 and NC410, if issued, are expected to expire beginning in 2037 absent any patent term adjustments or extensions.

In addition, as described above, under the Yale Agreement, we have an exclusive, royalty-bearing, sublicensable worldwide license from Yale for an intellectual property portfolio, including patent applications, relating to methods of use for S15 that covers the use of NC318. Any patents from these patent applications, if issued, are expected to expire no earlier than 2036 absent any patent term adjustments or extensions.

For all patent applications, we determine strategy for claim scope on a case-by-case basis, taking into account advice of counsel and our business model and needs. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, based on our assessment of their strategic value. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that maximum coverage and value are obtained for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We also rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position, including with respect to our FIND-IO platform. We seek to protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. In addition, in the ordinary course of our business, we enter into agreements with other third parties for non-exclusive rights to intellectual property directed to other technologies that are ancillary to our business, including laboratory information management software and research and development tools. In addition, we have filed for trademark registration with the U.S. Patent and Trademark Office, or the USPTO, for "NextCure," our logo and our FIND-IO platform.

Government Regulation

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biological products. Along with third-party contractors, we will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign jurisdictions, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Government policies may change and additional government regulations may be enacted that could prevent or delay further development or regulatory approval of any product candidates, product or manufacturing changes, additional disease indications or label changes. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Review and Approval for Licensing Biologics in the United States

In the United States, the FDA regulates our current product candidates as biological products, or biologics, under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act and associated implementing regulations. Biologics, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biologics are generally derived from living material (human, animal, or microorganism) are complex in structure, and thus are usually not fully characterized. Biologics include immunomedicines for cancer and other diseases.

Biologics are also subject to other federal, state and local statutes and regulations. The failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process or after approval may subject a sponsor or applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, Warning Letters or Untitled Letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the Department of Justice, or the DOJ, or other governmental entities.

An applicant seeking approval to market and distribute a biologic in the United States must typically undertake the following:

- completion of non-clinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- manufacture, labeling and distribution of investigational drug in compliance with cGMP;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA's current Good Clinical Practices requirements, or cGCP, to establish the safety, purity and potency of the proposed biological product candidate for its intended purpose;

- preparation of and submission to the FDA of a biologics license application, or BLA, after completion of all pivotal clinical trials requesting marketing approval for one or more proposed indications;

- obtain satisfactory completion of an FDA Advisory Committee review, where appropriate, as may be requested by the FDA to assist with its review;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the proposed product, or certain components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, safety, quality, purity and potency;

- satisfactory completion of FDA audits of selected clinical investigation sites to assure compliance with cGCP requirements and the integrity of the clinical data;

- payment of user fees under the Prescription Drug User Fee Act for the relevant year;

- obtain FDA review and approval of the BLA to permit commercial marketing of the licensed biologic for particular indications for use in the United States; and

- compliance with post-approval requirements, including the potential requirements to implement a Risk Evaluation and Mitigation Strategy, or REMS, adverse event and biological product deviation reporting and to complete any post-approval studies.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Preclinical and Clinical Development

Before an applicant can begin testing the potential candidate in human subjects, the applicant must first conduct preclinical studies. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as *in vitro* and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. Preclinical studies are subject to federal regulations and requirements, including GLP regulations. The results of an applicant's preclinical studies are submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. Such authorization must be secured prior to interstate shipment and administration of a biologic that is not subject of an approved BLA. In support of a request for an IND, applicants must submit a protocol for each clinical trial. Any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Human clinical trials may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

The FDA may also place a clinical hold or partial clinical hold on such trial following commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an

investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with cGCP regulations in order to use the study as support for an IND or application for marketing approval, including cGCP regulations, including review and approval by an independent ethics committee and informed consent from subjects.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or DSMB. DSMBs provide authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Other grounds for suspension or termination may be made based on evolving business objectives and/or competitive climate. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical Trials

For purposes of BLA approval, clinical trials are typically conducted in the following sequential phases:

- Phase 1: The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These trials may also yield early evidence of effectiveness.

- Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval by the FDA.

These phases may overlap or be combined. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product, referred to as Phase 4 trials. Such post-approval trials, when applicable, are conducted following initial approval, typically to develop additional data and information relating to the biological characteristics of the product and treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: suspected serious and unexpected adverse reactions; findings from epidemiological studies, pooled analysis of multiple studies, animal or *in vitro* testing, or other clinical studies, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure.

Our planned clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the 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. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with cGCP and the integrity of the clinical data submitted.

During clinical development, the sponsor often refines the indication and endpoints on which the BLA will be based. For endpoints based on patient-reported outcomes, or PROs, and outcome reported outcomes, or OROs, the process typically is an iterative one. The FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO and ORO instruments during the clinical development process, the FDA usually reserves final judgment until it reviews the BLA.

Concurrent with clinical trials, companies often complete additional animal studies, and develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required clinical testing in accordance with all applicable regulatory requirements, an applicant may submit a BLA requesting licensing to market the biologic for one or more indications in the United States. The BLA must include the results of product development, nonclinical studies and clinical trials; detailed information on the product's chemistry, manufacture, controls and proposed labeling. Under the Prescription Drug User Fee Amendments, a BLA submission is subject to an application user fee, unless a waiver or exemption applies.

The FDA will initially review the BLA for completeness before accepting it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing and substantive review. If the agency determines that the application does not meet this initial threshold standard, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information and review of the application delayed.

With certain exceptions, BLAs must include a pediatric assessment, generally based on clinical trial data, of the safety and effectiveness of the biologic in relevant pediatric populations. Under certain circumstances, the FDA may waive or defer the requirement for a pediatric assessment, either at the sponsor's request or by the agency's initiative.

After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether a product is safe, pure and potent and if the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued identity, strength, quality, safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP and are adequate to assure consistent production of the product within required specifications. In addition, the FDA expects that all data be reliable and accurate, and requires sponsors to implement meaningful and effective strategies to manage data integrity risks. Data integrity is an important component of the sponsor's responsibility to ensure the safety, efficacy and quality of its product or products.

The FDA will typically inspect one or more clinical sites to assure compliance with cGCP regulations before approving a BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

FDA performance goals generally provide for action on a BLA within 10 months of filing, which (as discussed above) typically occurs within 60 days of submission, but that deadline is extended in certain circumstances. Furthermore, the review process is often significantly extended by the FDA's requests for additional information or clarification.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its components will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. If and when the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional data, information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, and may require additional testing or information and/or require post-marketing studies and clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

During the approval process, the FDA will determine whether a REMS is necessary to assure the safe use of the biologic. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

If the FDA approves a product, it may limit the approved indications for use for the product, or require that contraindications, warnings or precautions be included in the product labeling. The FDA may also require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

The FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of product to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot 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 itself, before releasing the lots for distribution by the manufacturer.

After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on the nature of the post-approval change. The FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Pediatric Studies

Under the Pediatric Research Equity Act, a BLA or BLA supplement must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to

support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and any other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. In addition, the FDA Reauthorization Act of 2017 requires the FDA to meet early in the development process to discuss pediatric study plans with drug sponsors. The law requires the FDA to meet with drug sponsors by no later than the end-of-Phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. For example, the requirement for such studies or clinical trials may be waived if necessary studies or clinical trials in children are impossible, there is strong evidence suggesting the drug will not be effective or safe in children, the drug does not represent a meaningful therapeutic benefit over existing therapies for children, or the drug is not likely to be used in a substantial number of children. Such studies or clinical trials may also be deferred if the drug is ready for approval in adults before pediatric studies or clinical trials are completed or due to concerns about the safety or effectiveness of the drugs in pediatric populations. When such studies or clinical trials are deferred, they will be reported as post-marketing requirements. Pediatric data requirements do not apply to products with orphan designation.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, reporting of certain deviations and adverse experiences, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their third-party contractors are required to register their facilities with the FDA and certain state agencies. These facilities are subject to routine and periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, postmarketing safety reporting and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. FDA has increasingly observed cGMP violations involving data integrity during site inspections and is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls to ensure data are complete and secure; activities documented at the time of performance; audit trail functionality; authorized access and limitations; validated computer systems; and review of records for accuracy, completeness and compliance with established standards.

Post-approval changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, Warning Letters, Untitled Letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the FDA to permit the import or export of products or Import Alert; or

- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA's regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ or the Office of the Inspector General of the Department of Health and Human Services, or HHS, as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees and permanent injunctions under which specified promotional conduct is changed or curtailed.

The distribution of prescription drug and biologic are subject to the Drug Supply Chain Security Act, or DSCSA, which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification and licensing requirements. In addition, the Prescription Drug Marketing Act and its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the product candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a product candidate for which a BLA has not been submitted.

Biosimilars and Marketing Exclusivities

The Biologics Price Competition and Innovation Act, or BPCIA, created an abbreviated approval pathway for biological product candidates shown to be highly similar to or interchangeable with an FDA licensed biological product. A biological product on which another biological product candidate's BLA relies to establish biosimilarity is known as a reference 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 candidate and the reference product in terms of safety, purity and potency. Biosimilarity must be shown through analytical trials, animal trials and at least one clinical trial, unless the Secretary of HHS waives a required element. A biosimilar product candidate may be deemed interchangeable with a prior 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. Complexities associated with the larger, and often more complex, structures of biologics, as well as the process by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure 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 biological product candidate submitted under the 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. At this time, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy laws and regulations.

If a biologic is designated and approved for an orphan indication, it will be granted seven years of orphan drug exclusivity. An orphan indication is granted to biological products and drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 individuals in the United States, or if there is no reasonable expectation that the sponsor will be able to recover the costs of developing and marketing the drug or biological product in the United States. A biosimilar may not be licensed by FDA for the protected orphan indication until after the expiration of the seven year orphan drug exclusivity period or the 12 year reference product exclusivity, whichever is later.

Pediatric exclusivity adds an additional six month exclusivity period to any marketing exclusivities and patents that a biological product has obtained. In order to obtain pediatric exclusivity, a BLA sponsor must conduct pediatric studies as requested by the FDA in a Written Request. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. While pediatric exclusivity is not an actual extension on a patent term, it effectively extends the preclusive effect of the patent on FDA's authority to approve another application that relies on the product with pediatric exclusivity.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. On December 20, 2019, President Trump signed into law H.R. 1865, the "Further Consolidated Appropriations Act, 2020", authorizing appropriations through September 30, 2020 to fund operations of certain governmental agencies, including the FDA. The law includes significant provisions related to the Trump Administration's biosimilars policy framework and FDA's implementation of the BPCIA, such as clarifying that "chemically synthesized peptides" are no longer excluded from being regulated as biologics. In addition, the Further Consolidated Appropriations Act, 2020 clarifies exclusivity and procedural issues related to certain biologics approved as drugs pursuant to new drug applications, or NDAs, to be the subject of an approved BLA, or transition biological products. The law also incorporates provisions intended to reduce price and increase competitiveness in the pharmaceutical industry. The law amends the FDCA to create a private right of action against NDA or BLA holders that refuse to provide sufficient quantities of samples of an approved reference product to generic and biosimilar developers. In July 2018, the FDA released its Biosimilars Action Plan to improve the efficiency of the biosimilar and interchangeable product development and approval process. The Further Consolidated Appropriations Act, 2020 is consistent with FDA guidance documents issued in December 2018 that were intended to

advance the agency's biosimilars policy framework. The implementation of the Further Consolidated Appropriations Act, 2020 and the ultimate impact of the agency's Biosimilars Action Plan are uncertain and may evolve over time through future laws and regulations and guidance provided by regulatory and governing bodies. In addition, other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have been the subject of recent litigation.

Regulation of Companion Diagnostics and Laboratory Developed Tests

A companion diagnostic is an *in vitro* diagnostic that can: identify the patients most likely to benefit from a particular therapeutic product; identify those likely to be at an increased risk for serious side effects; or monitor responses to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Under the FDCA, *in vitro* companion diagnostics are generally regulated as medical devices. The FDA has generally classified *in vitro* companion diagnostics as high-risk, Class III devices, which require FDA approval of a premarket approval application, or PMA, but recognizes the possibility of a moderate-risk IVD companion diagnostic (*i.e.*, Class II device), which would require clearance of a 510(k) premarket notification or grant of a *de novo* request. Approval or clearance of the *in vitro* companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population.

For those *in vitro* companion diagnostics that require PMA approval, the process involves gathering and submitting clinical and preclinical data on the device for review by the FDA. It involves a rigorous premarket review, during which the applicant must provide the FDA with reasonable assurance of the device's safety and effectiveness, as well as information regarding the device's design, manufacturing and labeling. In addition, the FDA will typically inspect the device manufacturer's facilities for compliance with the Quality System Regulation, which imposes testing, control, documentation and other quality assurance requirements.

The FDA has issued guidance on the approval of therapeutic products and *in vitro* companion diagnostic devices. According to the FDA's guidance, for novel therapeutic products including biologics, an *in vitro* companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling.

In some cases, information from a diagnostic test may be useful to a prescriber, but not necessary for the safe and effective administration of the therapeutic product. In those cases, health care providers may employ information derived from a complementary diagnostic test such as a laboratory developed test, or LDT, when administering a therapeutic product. An LDT is a type of *in vitro* diagnostic test that is designed, manufactured and used within a single laboratory. LDTs can be used to measure or detect a wide variety of analytes (substances such as proteins, chemical compounds like glucose or cholesterol, or DNA), in a sample taken from a human body.

The Centers for Medicare and Medicaid Services, or CMS, regulates LDTs and the laboratories that develop them, and enforces the Clinical Laboratories Improvement Amendments, or CLIA. CMS evaluates whether there is clinical utility for each specific test, and also performs postmarket oversight of laboratory operational processes. CMS's oversight through the CLIA program is designed to confirm that a lab assesses analytical validity, but does not confirm whether it had results from an analytical validity assessment that were sufficient to support the claimed intended use of the test.

Historically, the FDA has generally not enforced premarket review and other FDA requirements on LDTs because LDTs were relatively simple lab tests and generally available on a limited basis. Due to advances in technology, however, some LDTs are now much more complex, have a nationwide reach and present higher risks, such as detection of risk for breast cancer and Alzheimer's disease, which are similar to those of other IV *in vitro* diagnostics that have undergone premarket review.

The FDA has announced that in the future it intends to assert jurisdiction over LDTs and proposed increasing regulatory requirements for LDTs through a risk-based framework. The FDA received considerable resistance to its proposal, and to date generally exercises enforcement discretion with respect to LDTs, leaving responsibility to CMS.

New laws, regulations or changes to existing laws, regulations and policies may result in changes to the requirements for LDTs or *in vitro* diagnostic devices and to the FDA's compliance and enforcement policies.

Healthcare Regulation

Pharmaceutical Coverage and Reimbursement

Our ability to successfully commercialize any of our product candidates for which we may receive regulatory approval will depend in significant part on the availability of coverage and reimbursement from third-party payors, including governmental healthcare programs such as the Medicare and Medicaid programs in the U.S.; private health insurers; managed care organizations; and other entities. Third-party payors establish the coverage and reimbursement policies for pharmaceutical products, and the marketability of any products for which we may receive regulatory approval for commercial sale depends on those payors' coverage policies and reimbursement rates. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include one or more of our product candidates. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and health services, in addition to their cost-effectiveness, safety and efficacy.

In addition, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement rates can vary significantly from payor to payor.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our business may be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. The healthcare fraud and abuse laws and regulations that may affect our ability to operate include but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals as speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product assistance programs;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, or FCA, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, 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. Private individuals, commonly known as "whistleblowers," can bring FCA *qui tam* actions, on behalf of the government and such individuals

and may share in amounts paid by the entity to the government in recovery or settlement. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, prohibits executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibits (i) knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation and (ii) making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;

- HIPAA and its implementing regulations, which impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HIPAA includes several tiers of civil monetary penalties as well as criminal penalties. In addition, state attorneys general have authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. Research institutions that we collaborate with and healthcare providers who may prescribe our products, once commercialized, are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA;

- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- Analogous U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If governmental authorities find that our operations violate any of these

laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and 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 operations and business. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

Healthcare Reform

In the United States there have been and continue to be a number of healthcare-related legislative and regulatory initiatives and reforms that have significantly affected the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was passed in March 2010, and substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the U.S. pharmaceutical industry. Among other things, the ACA subjects biologics to potential competition by lower-cost biosimilars; addresses 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; increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; establishes annual fees and taxes on manufacturers of certain branded prescription drugs; and creates a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

The ACA and certain of its provisions have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, 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, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision that repealed 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 commonly referred to as the "individual mandate." In January 2018, President Trump signed a continuing resolution 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 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. The Bipartisan Budget Act of 2018, among other things, amended the ACA to create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off 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. Also, in 2018, CMS issued final rules permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Additional legislative or regulatory changes related to the ACA remain possible.

In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the individual mandate is (i) unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Act and (ii) not severable from the rest of the ACA, and that as a result the entire ACA is invalid. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's decision that the individual mandate is unconstitutional, but remanded the case to the district court to reconsider the severability question. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace or invalidate the ACA or its implementing regulations, or portions thereof, will impact the ACA and its implementation.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things: bring more transparency to drug pricing; reduce the cost of prescription drugs under government payor programs; review the relationship between pricing and manufacturer

patient programs; and reform government program reimbursement methodologies for drugs. The Trump Administration is currently assessing additional proposals that are designed to affect drug pricing, such as tying U.S. drug prices to prices outside the United States. Congress and the Trump Administration have each indicated that they will continue to seek new legislative and administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, 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 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.

Moreover, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Employees

As of December 31, 2019, we had 69 full-time employees, of which 86% were primarily engaged in research and development activities and 39% hold M.D. or Ph.D. degrees. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information and Access to SEC Reports

We were incorporated in Delaware in September 2015. Our primary executive offices are located at 9000 Virginia Manor Road, Suite 200, Beltsville, Maryland 20705 and our telephone number is (240) 399-4900. We make available, free of charge, on our website at www.nextcure.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to such reports as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC. The contents of our website are not incorporated into this Annual Report.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information in this Annual Report, including our financial statements and the related notes and the information described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. If any of the events described below actually occurs, our business, results of operations, financial conditions, cash flows or prospects could be harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our founding in 2015, we have incurred significant net losses. Our net losses were $33.7 million and $22.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $81.0 million. We have funded our operations to date primarily with proceeds from public offerings of our common stock, private placements of our preferred stock and upfront fees received under the Lilly Agreement. Since commencing operations, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, building

and optimizing our manufacturing capabilities and conducting discovery, research and development activities for our product candidates, our discovery programs and our FIND-IO platform.

We expect that it will be several years, if ever, before we have a commercialized product. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to advance the preclinical and clinical development of our existing product candidates and our research programs;
- leverage our FIND-IO platform to advance additional product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- expand our cGMP manufacturing capacity, including to provide drug supply of NC318 for future clinical trials;
- hire additional clinical, quality control, regulatory, scientific and administrative personnel;
- expand our operational, financial and management systems and increase personnel, including to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio;
- establish a marketing, sales, distribution and medical affairs infrastructure to commercialize any products for which we may obtain marketing approval and commercialize, whether on our own or jointly with a partner;
- acquire or in-license other technologies or engage in strategic partnerships; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

To become and remain profitable, we, whether on our own or jointly with any potential future collaborator, must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our potential future collaborators', success in:

- completing preclinical studies and clinical trials of our product candidates, including our ongoing Phase 1/2 clinical trial for NC318 and other planned clinical trials for NC318 and NC410;
- seeking and obtaining marketing approvals for any product candidates that we or our collaborators develop;

- receiving acceptance of INDs for future product candidates;
- identifying and developing new product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a marketing, sales, distribution and medical affairs infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving coverage and adequate reimbursement by hospitals and third-party payors, including governmental authorities, such as Medicare and Medicaid, private insurers and managed care organizations, for product candidates, if approved, that we or our collaborators develop;
- manufacturing cGMP supply of our product candidates for clinical trials and, if approved, commercial sales;
- obtaining market acceptance of product candidates, if approved, that we develop as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing any product candidate that is approved for commercial sale. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we receive marketing approval for any product candidates, including NC318 and NC410, we will require significant additional amounts of cash in order to launch and commercialize such product candidates. In addition, other unanticipated costs may arise. Because the designs and outcomes of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of and commercialize any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, timing, results and costs of researching and developing NC318, NC410 and our other product candidates, including targets identified through our FIND-IO platform, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approval for NC318, NC410 and any future product candidates we develop, if clinical trials are successful;

- the costs of manufacturing NC318, NC410 and any future product candidates for preclinical studies and clinical trials and in preparation for marketing approval and commercialization;
- the costs of commercialization activities, including marketing, sales and distribution costs, for NC318, NC410 and any future product candidates we develop, whether alone or with a collaborator, if any of these product candidates are approved for sale;
- the success of the SRA with Yale;
- our ability to establish and maintain additional strategic collaborations, licensing or other arrangements on favorable terms, if at all;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation;
- our current collaboration and license agreements remaining in effect and our achievement of milestones and the timing and amount of milestone payments we are required to make, or that we may be eligible to receive, under those agreements;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing therapies and other adverse developments in the oncology market.

Until we can generate sufficient product and royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. As of December 31, 2019, we had $334.6 million in cash, cash equivalents (excluding restricted cash) and marketable securities. Based on our research and development plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2023. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur that are within or beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates and changes in regulation.

If we raise additional capital through marketing, sales and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams or research programs, technologies or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain additional financing on favorable terms when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs.

Risks Related to the Discovery and Development of Our Product Candidates

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them.

We are early in our development efforts. We initiated our first clinical trial for NC318, our lead product candidate, in October 2018, and we intend to initiate our first clinical trial for our second product candidate, NC410, in the second quarter of 2020. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will

depend heavily on the successful development and eventual commercialization of NC318, NC410 and any future product candidates we develop, which may never occur. Our current product candidates and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of our current and future product candidates will depend on several factors, including the following:

- timely and successful completion of preclinical studies and our clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of INDs for any future product candidates;
- successful enrollment in and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- our ability to consistently manufacture our product candidates on a timely basis or to establish agreements with third-party manufacturers, if needed;
- whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates;
- acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities;
- receipt and maintenance of timely marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our product candidates, if approved;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved;
- entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval;
- our compliance with any post-approval requirements imposed on our products, such as postmarketing studies, a REMS or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost-prohibitive;
- competing effectively with other therapies;

- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- our ability to identify targets and immunomedicines, whether through our FIND-IO platform, through our relationships with Yale or otherwise; and
- enforcing and defending intellectual property rights and claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that NC318, NC410 or any future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate. Neither we nor any future collaborator is permitted to market any biological product in the United States until we or the future collaborator receives regulatory approval of a BLA from the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA or comparable foreign regulatory authorities.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe, pure and potent for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from current or future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, the FDA may approve any of our product candidates for fewer or more limited indications, or a more limited patient population, than we request, may grant approval contingent on the performance of costly clinical trials, development of an in vitro companion diagnostic, or other postmarketing requirements, or may approve a product candidate with a label that does not include the labeling claims we believe are necessary or desirable for the successful commercialization of such product candidates.

The FDA or comparable foreign regulatory authorities may change their policies, promulgate additional regulations, revise existing regulations or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials. Although we initiated a Phase 1/2 clinical trial of NC318 in October 2018, we may experience delays in initiating or completing our planned clinical trials and development efforts. Additionally, we cannot be certain the ongoing and planned preclinical studies or clinical trials for NC318, NC410 or any future product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate;
- the FDA or other regulatory authorities, IRBs or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs;
- the number of patients required for clinical trials may be larger than we anticipate or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical

trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease, competition from other clinical trial programs for similar indications and clinical trial subjects and the impact of public health emergencies, such as the coronavirus;

- it may be difficult to enroll a sufficient number of patients, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or may fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our CROs and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;

- any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval;

- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;

- we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates;

- the supply, quality or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and

- we, or third parties on whom we are dependent, may suffer business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters and public health emergencies, such as the coronavirus.

We could encounter delays if a clinical trial is suspended or terminated by us, or by the IRBs of the institutions in which such trials are being conducted, ethics committees or the DSMB for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. The FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials. In addition, factors outside our control, such as government shutdowns, natural disasters and public health emergencies such as the coronavirus, could disrupt business at the FDA or other regulatory authorities, which could result in delays of reviews, approvals and communications with regulatory authorities related to our clinical trials and product candidates.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates. Any such events would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates stopping early.

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

With the exception of NC318, all of our product candidates are still in the preclinical stage, and the risk of failure for such product candidates is high. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including 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 clinical trials in humans. 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 current or future product candidates. 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 of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of our potential future collaborators over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to:

- an inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA not permitting the reliance on preclinical or other data from published scientific literature.

Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development

even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Because the number of subjects in our Phase 1/2 clinical trial of NC318 is small, the results from this trial, once completed, may be less reliable than results achieved in larger clinical trials.

A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of studies with smaller sample sizes, such as our ongoing Phase 1/2 clinical trial of NC318, can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects. As a result, there may be less certainty that NC318 would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of NC318, we may not achieve a statistically significant result or the same level of statistical significance seen, if any, in our Phase 1/2 clinical trial. Similarly, if we conduct a clinical trial of any other product candidate we develop, including NC410, with a small sample size, the results of any such trial may be less reliable than results achieved in larger clinical trials and may provide less certainty of achieving statistically significant effects in any future clinical trials.

Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit, validation and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Interim data and results from our clinical trials 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 or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our approach to the discovery and development of product candidates using our FIND-IO platform is unproven and may not result in marketable products.

The success of our business depends in part upon our ability to identify targets based on our proprietary FIND-IO platform and to develop and commercialize immunomedicines. Our approach to the discovery of targets using the FIND-IO platform is novel. We have not yet initiated or completed a clinical trial of any product candidate developed for a target identified from the FIND-IO platform. The platform may fail to accurately identify targets that modulate the immune system and are appropriate for immunomedicines. Even if we are able to identify targets from the FIND-IO platform and to develop corresponding product candidates, we cannot assure that such product candidates will achieve marketing approval to safely and effectively treat cancer or other disease states.

If we uncover any previously unknown risks related to our FIND-IO platform, or if we experience unanticipated problems or delays in developing our FIND-IO product candidates, we may be unable to achieve our strategy of building an oncology pipeline of novel targets for new immunomedicines focused on non-responders.

Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication, and failures can occur at any stage of testing. As with most biologics, use of our current or future product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to immunotherapies in oncology.

The most common treatment-related adverse events reported in the Phase 1 portion of the Phase 1/2 clinical trial of NC318 as of November 9, 2019, the most recent date for which we have reported data on the trial, were diarrhea, infusion reactions, fatigue, headaches, pruritis, elevated amylase and elevated lipase. Most treatment-related adverse events have been easily manageable, asymptomatic or mild or moderate, with the exception of one case of grade 3 episcleritis/uveitis that resolved after steroid therapy and two cases of grade 3 pneumonitis. Immune-related adverse events that represent immune effects on normal tissue and can result from misdirected stimulation of the immune system are a common class of toxicity in immunomedicines such as NC318. Immune-related adverse events reported in the Phase 1 portion of the Phase 1/2 clinical trial of NC318 included diarrhea, elevated amylase and lipase, pruritis, episcleritis/uveitis, pneumonitis and vitiligo.

Possible adverse side effects that could occur with treatment with immunomedicines include an immunologic reaction early after administration which, while not necessarily adverse to the patient's health, could substantially limit the effectiveness of the treatment. In addition to any potential side effects caused by the product or product candidate, the administration process or related procedures also can cause adverse side effects. If unacceptable adverse events occur, our clinical trials or any future marketing authorization could be suspended or terminated.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies 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 any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Immunomedicines and their method of action of harnessing the body's immune system are powerful and could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that NC318, NC410 or any other product candidate is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed.

In addition, we intend to pursue NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with other therapies, which exposes us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our

product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidates may also be supplanted in the market by newer, safer or more efficacious products or combinations of products. See also "—Risks Related to the Discovery and Development of Our Product Candidates—We intend to develop NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with other therapies, which exposes us to additional regulatory risks."

Even if we successfully advance one of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to implement a REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our business. In addition, if one or more of our product candidates or our immunotherapeutic development approach generally prove to be unsafe, our entire technology platform and pipeline could be affected, which would also materially harm our business.

As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We also

expect to continue to rely on third parties to conduct our pivotal clinical trials. See "—Risks Related to Reliance on Third Parties—We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for NC318, NC410 and any future product candidates we develop. If these third parties 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 NC318, NC410 and any future product candidates we develop, and our business could be materially harmed." Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for BLA submission and FDA approval of NC318, NC410 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop.

If we or our collaborators encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise be adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until the trial's conclusion, including any follow-up period. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the nature and size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the number and location of participating clinical sites or patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- our ability to obtain and maintain patient informed consents for participation in our clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials; and
- factors outside of our control, including as a result of business interruptions resulting from natural disasters and public health emergencies, such as the coronavirus.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will 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 conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to 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 sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial.

Delays from difficulties in patient enrollment in a clinical trial may result in increased costs or affect the timing, outcome or completion of the trial, which could require us to abandon the trial altogether and could delay or prevent our receipt of regulatory approval the applicable product candidate.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current cGCP or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs or ethical committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to study subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

We have chosen to prioritize development of NC318 and NC410. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other candidates or indications for which there may be a greater likelihood of success or may be more profitable.

Because we have limited resources, we have strategically determined to prioritize development of NC318 and NC410 rather than other product candidates based, in part, on the significant resources required for developing and manufacturing immunomedicines. To date, no regulatory authority has granted approval for an immunomedicine targeting S15 or the LAIR pathway. As a result, we may be foregoing other potentially more profitable immunomedicines or therapies or those with a greater likelihood of success. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to, certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our current or future product candidates or misread trends in the oncology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

We may need to develop, or enter into a collaboration or partnership to develop, complementary or companion diagnostics for our current or future product candidates. If we, or our future collaborators, are unable to successfully develop complementary or companion diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our current or future product candidates.

One of the key elements of our product development strategy is to identify cancer patient populations that may derive meaningful benefit from our current or future product candidates. Because predictive biomarkers may be used to

identify the right patients for current or future product candidates, we believe that our success may depend, in part, on our ability to develop complementary or companion diagnostics in collaboration with partners.

We have limited experience in the development of diagnostics and, as such, we may rely in part on future collaborators in developing appropriate diagnostics to pair with our current or future product candidates. We have not yet begun substantial discussions with any potential partners with respect to the development of complementary or companion diagnostics and may be unsuccessful in entering into collaborations for the development of any such diagnostics for our current or future product candidates.

Companion diagnostics are subject to regulation by the FDA and similar comparable foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. Complementary diagnostics may be subject to regulation by CMS or the FDA and similar comparable foreign regulatory authorities and may require separate regulatory approval or clearance prior to commercialization. Gaining regulatory approval could be time consuming and costly and could delay regulatory approval of the related product candidate.

We and our collaborators may encounter difficulties in developing such tests, including issues relating to the selectivity or specificity of the diagnostic, analytical validation, reproducibility or clinical validation. If we, our collaborators, or any third parties that we engage to assist us, are unable to successfully develop complementary or companion diagnostics for our current or future product candidates or experience delays in doing so:

- development of our current or future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and

- we may not realize the commercial potential of our current or future product candidates if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved.

If any of these events were to occur, our business could be materially harmed.

Risks Related to the Regulatory Approval and Commercialization of Product Candidates and Other Legal Compliance Matters

We may be unable to obtain FDA approval of our product candidates under applicable regulatory requirements. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

To gain approval to market our product candidates in the United States, we must provide the FDA with clinical data that adequately demonstrate the safety, purity and potency, including efficacy, of the product candidate for the proposed indication or indications in a BLA submission. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

We have not previously submitted a BLA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. A BLA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

The research, testing, manufacturing, labeling, approval, marketing, sale and distribution of biological products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United

States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

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

- our inability to demonstrate to the satisfaction of the FDA or a comparable foreign regulatory authority that our product candidates are safe and effective for the requested indication;
- the FDA or a comparable foreign regulatory authority's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA or a comparable foreign regulatory authority's requirement for additional preclinical studies or clinical trials;
- the FDA or a comparable foreign regulatory authority's non-approval of the formulation, labeling, or specifications of our product candidates;
- the FDA or a comparable regulatory authority's failure to approve our manufacturing processes and facilities or the manufacturing processes and facilities of third-party manufacturers upon which we rely; or
- potential for approval policies or regulations of the FDA or a comparable foreign regulatory authority to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval from the FDA or comparable foreign regulatory authorities for any of our product candidates, the FDA or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or comparable foreign regulatory authorities also may approve any of our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or comparable foreign regulatory authorities may not approve any of our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of any such product candidates.

Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially harm our business.

Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. Our approach to targeting different components of the tumor microenvironment is novel and unproven. In addition, adverse events in clinical trials testing our product candidates or in clinical trials of others developing similar product candidates and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for our current or future product candidates. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our immunomedicines or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in

greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products.

If our current and any future product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current and any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments, including those that are not yet approved;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing, sales and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- the regulatory approval and adoption of a companion or complementary diagnostic, if needed or advisable; and
- the prevalence and severity of any side effects.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We may initially seek approval for NC318, NC410 and any other product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

We intend to develop NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with other therapies, which exposes us to additional regulatory risks.

We intend to develop NC318 in part in combination with other therapies and may develop NC410 and future product candidates in combination with one or more currently approved cancer therapies. These combinations have not

been tested before and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy.

In addition, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. Therefore, 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 risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination 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. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer.

We may also evaluate NC318, NC410, or any future product candidate in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell NC318, NC410 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics we choose to evaluate in combination with NC318, NC410 or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non-compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution.

Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require implementation of a REMS as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event and deviation reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGCP, for any clinical trials that we may conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our or our third-party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things:

- suspension of, or imposition of restrictions on, the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- Warning Letters or Untitled Letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we file, or suspension or revocation of approved biologics licenses;
- product seizure or detention, monetary penalties, refusal to permit the import or export of the product, or placement on Import Alert; and
- permanent injunctions and consent decrees including the imposition of civil or criminal penalties.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials and other components required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product or product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development and commercialization timelines and our business, financial condition, results of operations and prospects and could adversely affect our ability to meet our supply obligations.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, an approved product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, or off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. The FDA has issued guidance on the factors that it will consider in determining whether a firm's product communication is consistent with the FDA-required labeling for that product, and those factors contain complexity and potential for overlap and misinterpretation. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

The FDA 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.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Certain policies of the Trump Administration may impact our business and industry. President Trump has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, 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.

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

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or 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.

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

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information, and data to comply with cGMP and data integrity requirements. It is critical that we do so in a secure manner to maintain data security and data integrity of such information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon for the transfer of personal data are ever deemed inadequate, or if we or our vendors experience a data breach resulting in exposure of personal data subject to the applicable laws, we could be subject to government enforcement actions and significant penalties against us, criminal and civil liability for us and our officers and directors, private litigation or adverse publicity.

Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions, phishing, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption or data loss, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including HIPAA and its implementing regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

The successful commercialization of our product candidates will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by third-party payors, including managed care plans, governmental healthcare programs, such as Medicare and Medicaid and private health insurers is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or not to separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Our ability to successfully commercialize any product candidate, whether as a single agent or combination therapy, will also depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our current and future product candidates.

In addition, third-party payors are increasingly challenging prices charged for pharmaceutical and biological products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These third-party payors may deny or revoke the reimbursement status of our product candidates, if approved, or establish prices for our product candidates at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products, especially novel products like our immunomedicines. To date, no regulatory authority has granted approval for an immunomedicine targeting S15 or the LAIR pathway. The Medicare and Medicaid programs are increasingly used as models in the United States for how private third-party payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement can change, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Additionally, if we or our collaborators develop companion diagnostic tests for use with our product candidates, we, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. While we and our collaborators have not yet developed any companion diagnostic test for our product candidates, if we or our collaborators do, there is significant uncertainty regarding the ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

Moreover, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Enacted healthcare legislation, changes in healthcare law and implementation of regulations, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our product candidates, may impact our business in ways that we cannot currently predict, could affect the prices we may set, and could have a material adverse effect on our business and financial condition.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. 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, the ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biologics to potential competition by lower-cost biosimilars, addresses 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, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes annual fees and taxes on manufacturers of certain branded prescription drugs.

The ACA and certain of its provisions have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, 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, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act included a provision that repealed 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.” In January 2018, President Trump signed a continuing resolution 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 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. The Bipartisan Budget Act of 2018, among other things, amended the ACA to create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off 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. Also, in 2018, CMS issued final rules permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Additional legislative or regulatory changes related to the ACA remain possible.

In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the individual mandate is (i) unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Act and (ii) not severable from the rest of the ACA, and that as a result the entire ACA is invalid. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court’s decision that the individual mandate is unconstitutional, but remanded the case to the district court to reconsider the severability question. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace, or invalidate the ACA or its implementing regulations, or portions thereof, will impact the ACA and implementation.

Other healthcare-related legislative and regulatory initiatives and reforms 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, created measures for automatic spending reductions under certain circumstances. A Joint Select Committee on Deficit Reduction tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021 was unable to reach required goals, thereby triggering the legislation's automatic reductions. This has resulted in aggregate reductions of Medicare payments to providers of, on average, 2% per fiscal year through 2029 unless Congress takes additional action. The American Taxpayer Relief Act of 2012, which was signed into law in January 2013, among other things further reduced Medicare payments to several types of providers.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, effective January 1, 2014, CMS began bundling into the hospital outpatient prospective payment rate the Medicare payments for most laboratory tests ordered while a patient received services in a hospital outpatient setting. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidate we develop or complementary or companion diagnostics or additional pricing pressures.

CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. The Trump Administration is currently assessing additional proposals that are designed to affect drug pricing, such as tying U.S. drug prices to prices outside the United States. Congress and the Trump Administration have each indicated that they will continue to seek new legislative and administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which the U.S. federal government covers particular healthcare products and services and could limit the amounts that the U.S. federal government will pay for healthcare products and services. This could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. 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. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

Additionally, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. 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.

Our relationships with customers, third-party payors and others may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals as speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient or product assistance programs.

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, 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. Private individuals, commonly known as “whistleblowers,” can bring FCA qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

- The HIPAA fraud provisions, which prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the HIPAA fraud provisions without actual knowledge of the statutes or specific intent to violate them.

- HIPAA and its implementing regulations, also impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, which include health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HIPAA includes several tiers of civil monetary

penalties, as well as criminal penalties. State attorneys general have authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. Research institutions with which we collaborate and healthcare providers who may prescribe our products, once commercialized, are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- Analogous U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time and resource consuming and can divert management's attention from the business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil and administrative sanctions, including exclusion from government funded healthcare programs. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA. We plan to engage third parties for clinical trials or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could also result in prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Risks Related to Manufacturing

Given our limited operating history, our manufacturing experience as an organization and with our manufacturing facility is limited.

Manufacturing is a critical component of our approach to developing immunomedicines and we have invested significantly in our manufacturing facility. We currently manufacture our product candidates for preclinical and clinical trials.

The manufacture of drugs for clinical trials and for commercial sale is subject to oversight by the FDA to ensure compliance with cGMP and by other regulatory authorities under other laws, regulations and standards. We cannot assure you that we can successfully manufacture our products in compliance with cGMP and with any other applicable laws, regulations and standards in sufficient quantities for clinical trials or for commercial sale, or in a timely or economical manner.

Our manufacturing facility requires specialized personnel and is expensive to operate and maintain. Validation is an ongoing process that must be maintained to allow us to manufacture under cGMP guidelines. We cannot guarantee that our facility will remain in compliance with cGMP.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time. We are currently the sole manufacturer of NC318 and NC410 and if anything were to interfere with our continuing manufacturing operations in our facility, it could materially adversely affect our business and financial condition.

If we fail to develop sufficient manufacturing capacity and experience, whether internally or with a third party, or fail to manufacture our product candidates economically or on reasonable scale or volumes, or in accordance with cGMP, our development programs and commercialization of any approved products will be materially adversely affected. This may result in delays in commencing or continuing our clinical trials for NC318 or NC410. Any such delays could materially adversely affect our business and financial condition.

We may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing and, if approved, commercializing our product candidates.

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. Currently, our product candidates are manufactured in small quantities for use in various preclinical studies and our ongoing Phase 1/2 clinical trial of NC318. We intend to expand our manufacturing capacity, including to provide drug supply of NC318 for future clinical trials, which will require us to incur significant expenses. If one or more of our product candidates progress to late-stage development, we may incur additional significant expenses in the further expansion or construction of manufacturing facilities and increases in personnel in order to manufacture product candidates in sufficient quantities. We cannot assure you that we will be able to successfully manufacture product candidates at a larger scale in a timely or economical manner, or at all. If we are unable to successfully increase our manufacturing scale or capacity, the development, testing and clinical trials of our current or future product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

The loss of our third-party manufacturing partners or our, or our partners', failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

Although we currently manufacture our product candidates for preclinical and clinical trials, certain elements of manufacturing, including Master Cell Bank manufacturing and fill-finish services, take place at qualified third-party contract manufacturing organizations, or CMOs. If approved, commercial supply of NC318, NC410 and any future product candidates may be manufactured at a CMO or CMOs.

The facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs, and are completely dependent on them for compliance with current regulatory

requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing immunomedicines, including our product candidates, is complex, time-consuming, highly regulated and subject to several risks, including:

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. 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 products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, including due to restrictions on the movement of people or goods, natural disasters, public health emergencies, power failures, other business disruptions and numerous other factors; and

- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes 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 or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our

process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We depend on third-party suppliers for key materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.

We rely on third-party suppliers for certain materials and components required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Risks Related to Intellectual Property

We have filed patent applications for our lead product candidates, but no patent has yet issued from these applications. If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We and our licensors 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 technology that are important to our business. No patent has yet issued from our patent applications.

The patent position of biotechnology and pharmaceutical companies generally is highly 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 that effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, we may challenge their ownership, for example in a derivation proceeding before the USPTO, to determine who has the right to the claimed subject matter in the applications. Similarly, if our patent applications are challenged in a derivation proceeding, the USPTO may hold that a third-party is entitled to certain patent ownership rights instead of us. We may then be forced to seek a license from the third party that may not be available on commercially favorable terms, or at all.

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. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

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 technologies or products that do not infringe our patents.

We are party to a license agreement with Yale University under which we acquired rights to intellectual property related to certain of our product candidates. If we breach our obligations under this agreement, the agreement could be terminated, which would adversely affect our business and prospects.

We are a party to a license agreement with Yale pursuant to which we in-license patents and technology for certain of our product candidates. This license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these and other obligations or otherwise materially breach this license agreement, Yale may have the right to terminate the license. If this agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates or products covered by the agreement, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents or applications and any patent rights we own or may own in the future. We rely, in part, on our outside counsel or our licensing partners to pay these fees due to the USPTO and to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

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

Filing, prosecuting and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are and could remain less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may be less likely to be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

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. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, 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 or ownership of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. 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 have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. Depending on future 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 have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors, or we may be required to defend against claims of infringement. Countering infringement or unauthorized use claims or defending against claims of infringement can be expensive and time-consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future marketing, sales or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own, develop or license.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce any patent that is issued covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents, including portions of our FIND-IO platform. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business and financial condition.

Our commercial success depends upon our ability and the ability of any collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including post grant review and *inter partes* review before the USPTO. The risks of being involved in such litigation and proceedings may also increase as our product candidates approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any of our product candidates or technologies covered by the asserted third-party patents.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access

to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Others may claim an ownership interest in our intellectual property and our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects.

While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. For example, a third party may claim an ownership interest in one or more of our, or our licensors', patents or other proprietary or intellectual property rights. A third party could bring legal actions against us to seek monetary damages or enjoin clinical testing, manufacturing or marketing of the affected product candidate or product. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any such action is successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product candidate or product, in which case we could be required to pay substantial royalties or grant cross-licenses to patents. We cannot, however, assure you that any such license would be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases, which may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

Trade secrets and know-how can be difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, there can be no assurance that such inventions will not be assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all. We also seek to preserve the integrity and confidentiality of our trade secrets by other means, including maintaining physical security of our premises and physical and electronic security of our information technology systems. However, these security measures may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the

scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. For example, a public presentation in the scientific or popular press on the properties of our product candidates could motivate a third party, despite any perceived difficulty, to assemble a team of scientists having backgrounds similar to those of our employees to attempt to independently reverse engineer or otherwise duplicate our antibody technologies to replicate our success.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers.

Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or current employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license or may own in the future;
- we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;

- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Reliance on Third Parties

We rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for NC318, NC410 and any future product candidates we develop. If these third parties 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 NC318, NC410 and any future product candidates we develop, and our business could be materially harmed.

We currently do not have the ability to independently conduct preclinical studies that comply with GLP requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, including cGCP, or requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and cGCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our cGCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our current or future product candidates. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and cGCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 10 days' prior written notice. Some of these agreements may also be terminated by such third parties under certain other circumstances. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, including as a result of natural disasters or public health emergencies such as the coronavirus, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLP and cGCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We may depend on Yale or other third-party collaborators for the discovery, development and commercialization of certain of our current and future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We agreed pursuant to the SRA with Yale to provide funding for a research program aimed at discovering new targets for immunomedicines. We have and expect to continue to have limited control over the amount and timing of resources that are employed in the research program. The research program may not be successful, and as a result, we may not be able to identify, develop and commercialize products from this collaboration.

In the future, we may form or seek other strategic alliances, joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop.

Our collaborations pose, and potential future collaborations involving our product candidates may pose, the following risks to us:

- collaborators may 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 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 or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- 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;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- if a present or future collaborator 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 we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, 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 net income that justifies such transaction. Any of the factors set forth above and 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.

Effective March 3, 2020, Lilly terminated the Lilly Agreement, which was focused on using our FIND-IO platform to identify novel oncology targets for additional research and drug discovery by ourselves and Lilly. The termination of the Lilly Agreement prevented us from receiving future research and development support payments, option exercise fees, development and regulatory milestone payments, sales milestone payments or royalties under the agreement.

In the event a present or future collaborator terminates their agreement with us, we would be prevented from receiving the benefits of any such agreement, which could have a materially adverse effect on our results of operations.

We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, 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 current or future product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

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 other 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 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 and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently only have "key person" insurance on Michael Richman, our President and Chief Executive Officer, and on Dr. Lieping Chen, our scientific founder, in his role as consultant to us. The loss of the services of Mr. Richman, Dr. Chen or one or more of our other executive officers could impede the achievement of our research, development and commercialization objectives.

We continue to work with Dr. Chen on discovering novel immunomedicines through his consulting agreement and the SRA with Yale. If we are no longer able to leverage our relationships with Dr. Chen and Yale, our ability to

discover additional targets for immunomedicines may be impeded, which may adversely impact the achievement of our objectives.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current or future product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions and from products and therapies that currently exist or are being developed, some of which products and therapies we may not currently know about. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products, and they may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than our product candidates or our FIND-IO platform or, in the case of drugs, have a better safety profile than our product candidates. These competitors may also be more successful than us in manufacturing and marketing their products, and have significantly greater financial resources and expertise in research and development.

There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody-drug conjugates, such as Genentech's Kadcyla, to immune checkpoint inhibitors targeting CTLA-4, such as BMS' Yervoy, and PD-1/PD-L1, such as BMS' Opdivo, Merck & Co.'s Keytruda and Genentech's Tecentriq, to T cell-engager immunotherapies, such as Amgen's Blincyto. In addition, numerous compounds are in clinical development for cancer treatment. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well-capitalized and have significant clinical experience. See "Business —Competition."

Smaller and other early stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our current and future product candidates. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

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, have a broader label,

are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors may also obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable.

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

As our development plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, marketing, sales, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for NC318, NC410 and any future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize NC318, NC410 and any future product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize NC318, NC410 and any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

If we are unable to establish marketing, sales and distribution capabilities for NC318, NC410 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for NC318, NC410 and any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own marketing, sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own marketing, sales and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish marketing, sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate we may develop;

- withdrawal of trial participants;

- termination of clinical trial sites or entire trial programs;

- injury to our reputation and significant negative media attention;

- initiation of investigations by regulators;

- significant time and costs to defend the related litigation;

- substantial monetary awards to trial subjects or patients;

- diversion of management and scientific resources from our business operations; and

- the inability to commercialize any product candidates that we may develop.

While we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

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 errors or mistakes. 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.

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. As of December 31, 2019, we had federal and state net operating loss carryforwards of $55.0 million and $54.0 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2036. Limitations imposed by the applicable jurisdictions on our ability to utilize net operating loss carryforwards could cause income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such net operating loss carryforwards to expire unused, in each case reducing or eliminating the benefit of such net operating loss carryforwards. Furthermore, we may not be able to generate sufficient taxable income to utilize our net operating loss carryforwards before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our net operating loss carryforwards. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn net taxable income, our ability to use our net operating loss and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations.

Global health concerns, including the novel coronavirus outbreak, could impact our business.

Beginning in December 2019, a novel strain of coronavirus was reported in China and other countries, including the United States. Global health concerns, such as coronavirus, could result in social, political, economic and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the collaborators, contract organizations, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as this one could disproportionately impact the hospitals and clinical sites, as well as recruitment and retention for clinical trials, in a region or city whose health care system becomes overwhelmed due to the illness or where restrictions are put in place on the movement of people or goods. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the coronavirus outbreak and the actions to contain the coronavirus and to address its impact, including on financial markets or otherwise. The occurrence of any of these developments and any disruption related to coronavirus could have a material adverse effect on our business and our results of operation and financial condition.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained, and you may not be able to sell your shares at or above a recently reported market price, or at all.

Prior to our initial public offering, or IPO, there was no public market for shares of our common stock. Although our common stock is listed on the Nasdaq Global Select Market, or Nasdaq, an active, liquid trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, you may not be able to sell your common stock at or above a recently reported market price or at the time that you would like to sell.

The price of our common stock may be volatile and fluctuate substantially.

Our stock price is likely to be volatile. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above a recently reported price, or at all. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our ongoing or future clinical trials, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- our failure to commercialize our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- the size and growth of our target markets;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' products or product candidates;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts or publications of research reports about us or our industry;
- variations in our annual or quarterly financial results or those of companies that are perceived by investors to be similar to us;
- our cash position;

- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our directors, officers or their affiliated funds or our other stockholders;
- changes in the structure of healthcare payment systems;
- significant lawsuits, including patent or stockholder litigation;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our 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 or our business. As a newly public company, we have only limited coverage by equity research analysts. If additional analysts do not commence coverage of us, the trading price of our stock could decrease. In addition, if one or more of the analysts covering our business issue adverse reports about us or downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock or fail to publish reports on us regularly, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline. As of December 31, 2019, we had outstanding a total of 27,499,260 shares of common stock.

We have registered on Registration Statements on Form S-8 5,167,502 shares of common stock that were either subject to outstanding options or reserved for future issuance under our existing equity incentive plans as of May 13, 2019, and as a result these shares will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, the holders of certain shares of our common stock outstanding as of December 31, 2019 are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of these securities by these stockholders could have a material adverse effect on the market price of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

These provisions also include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in 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. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own, in the aggregate, a majority of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of 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 nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the last day of the first fiscal year in which we have total annual gross revenues of at least $1.07 billion, (iii) the last day of the first fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million on June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2020. When we lose our status as an "emerging growth 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. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

We have incurred and will continue to incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an emerging growth company, we have incurred and expect to continue to incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to

their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware or, if subject matter jurisdiction over the matter that is the subject of such action is vested exclusively in the federal courts, the United States District Court for the District of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or the bylaws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery or the United States District Court for the District of Delaware, as applicable, having personal jurisdiction over the indispensable parties named as defendants therein. In addition, any person holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to this provision of our bylaws. The choice of forum provision does not apply to any actions arising under the Securities Act or the Exchange Act. The 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 employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery or the United States District Court for the District of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the jurisdiction. The Court of Chancery or the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs, which could have a material adverse effect on our business, financial condition or results of operations.

Item 1B. Unresolved Staff Comments

Not Applicable.

Item 2. Properties

Our corporate headquarters are located in Beltsville, Maryland and consist of 11,329 square feet of office space, 13,579 square feet of laboratory and manufacturing space and 10,209 square feet that we are in the process of converting into office space, or collectively the Current Space, under a lease that expires in August 2025, or the Original Lease. In June 2019, we took possession of an additional 14,075 square feet of space to be used for future office, laboratory and manufacturing space under a new lease entered into in January 2019, or the New Lease. In August 2019, we entered into an amendment to the New Lease for an additional 14,446 square feet to be used for future office, laboratory and manufacturing space, which we expect the landlord to deliver in April 2020. The New Lease expires in March 2030 and will also cover the Current Space upon expiration of the Original Lease. We believe that these facilities are adequate for our current needs and that suitable additional or substitute space will be available in the future if needed.

Item 3. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings as part of our ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

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

Market Information and Holders of Record

Our common stock trades on the Nasdaq Global Select Market, or Nasdaq, under the symbol "NXTC." As of March 11, 2020 we had 21 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders 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 shareholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business.

Use of Proceeds from Initial Public Offering

On May 13, 2019, we closed our IPO pursuant to which we issued and sold 5,750,000 shares of common stock at a public offering price of $15.00 per share for aggregate gross proceeds of $86.3 million. The offer and sale of the shares was made pursuant to a registration statement on Form S-1 (File No. 333-230837) that the SEC declared effective on May 9, 2019. Morgan Stanley & Co. LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated and Piper Jaffray & Co. acted as joint book-running managers of our IPO. The net offering proceeds to us were approximately $76.9 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of approximately $3.4 million. During the period from the closing of our IPO on May 13, 2019 through December 31, 2019, $0.5 million of the net proceeds from our IPO have been used for payment to Yale University in connection with the closing of our IPO, and the remainder has been invested in temporary investments pending other uses.

None of the offering expenses or net proceeds were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus that forms a part of our Registration Statement on Form S-1 (Reg. No. 333-230837), as filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on May 9, 2019.

Item 6. Selected Financial Data

As a smaller reporting company, we are not required to provide the information requested by this Item.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the financial statements and the related notes appearing elsewhere in this Annual Report. This discussion contains forward-looking statements that are based on management's current expectations, estimates, and projections about our business and operations, and involve risks and uncertainties. Our actual results could differ materially from

those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" and elsewhere in this Annual Report.

Overview

We are a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases by restoring normal immune function. We view the immune system holistically and, rather than target one specific immune cell type, we focus on understanding biological pathways, the interactions of cells and the role each interaction plays in an immune response. Through our proprietary Functional, Integrated, NextCure Discovery in Immuno-Oncology, or FIND-IO, platform, we study various immune cells to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. We are focused on patients who do not respond to current therapies, patients whose cancer progresses despite treatment and patients with cancer types not adequately addressed by available therapies. We are committed to discovering and developing first-in-class immunomedicines, which are immunomedicines that use new or unique mechanisms of action to treat a medical condition, for these patients.

Our lead product candidate, NC318, is a first-in-class immunomedicine against a novel immunomodulatory receptor called Siglec-15, or S15. In October 2018, we initiated a Phase 1/2 clinical trial of NC318 in patients with advanced or metastatic solid tumors. We completed enrollment of the Phase 1 portion of this trial in August 2019 and preliminary data from the Phase 1 portion was presented at the Society for Immunotherapy of Cancer annual meeting in November 2019. We began enrolling patients in the Phase 2 portion of the trial in October 2019 and expect to announce initial data from the Phase 2 portion by the end of 2020. We intend to initiate an additional Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors in mid-2020. Our second product candidate, NC410, is a novel immunomedicine designed to block immune suppression mediated by an immune modulator called Leukocyte-Associated Immunoglobulin-like Receptor 1. The U.S. Food and Drug Administration, or the FDA, accepted our investigational new drug application, or IND, for NC410 in the first quarter of 2020 and we intend to initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the second quarter of 2020.

Financial Overview

Since commencing operations in 2015, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, building and optimizing our manufacturing capabilities and conducting discovery, research and development activities for our product candidates, discovery programs and FIND-IO platform.

We have not generated any revenue from product sales and only limited revenue from other sources and, as a result, we have never been profitable and have incurred net losses since the commencement of our operations. Our net losses for the years ended December 31, 2019 and 2018 were $33.7 million and $22.8 million, respectively. As of December 31, 2019, we had an accumulated deficit of $81.0 million primarily as a result of research and development and general and administrative expenses. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a product candidate, and we cannot assure you that we will ever generate significant revenue or profits.

We have funded our operations to date primarily with proceeds from public offerings of our common stock, private placements our preferred stock and upfront fees received under our former research collaboration and development agreement with Eli Lilly and Company, or Lilly. From our inception through December 31, 2019, we received gross proceeds of $164.4 million through private placements of preferred stock and an upfront payment of $25.0 million in connection with our agreement with Lilly, or the Lilly Agreement. In April 2018, we received gross proceeds of $31.0 million from the sale and issuance of shares of our Series A-3 Preferred Stock, and in November 2018, we received gross proceeds of $93.4 million from the sale and issuance of shares of our Series B Preferred Stock, including $15.0 million from Lilly as described below.

In November 2018, we entered into the Lilly Agreement, to use our FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by us and Lilly. We received an upfront payment of $25.0 million in cash and an equity investment of $15.0 million from Lilly upon entering into the Lilly Agreement, and we were

eligible for quarterly research and development support payments during a portion of the term of the Lilly Agreement. Effective March 3, 2020, Lilly terminated the Lilly Agreement.

On May 13, 2019, we closed our initial public offering, or IPO, in which we sold 5,750,000 shares of common stock, at a public offering price of $15.00 per share, for aggregate gross proceeds of $86.3 million. The net offering proceeds to us were approximately $76.9 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of $3.4 million. See Note 1 to our audited financial statements included elsewhere in this Annual Report for more information.

On November 19, 2019, we completed an underwritten public offering, in which we issued and sold 4,077,192 shares of common stock at a public offering price of $36.75 per share. On December 2, 2019, the underwriters exercised in full their option to purchase an additional 611,578 shares of common stock at the public offering price of $36.75, for total net proceeds to us of approximately $160.9 million after deducting underwriting discounts and commissions of approximately $10.3 million and offering expenses of approximately $1.0 million.

As of December 31, 2019, we had cash, cash equivalents and marketable securities, excluding restricted cash, of $334.6 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into the first half of 2023. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

We expect to incur substantial expenditures in the foreseeable future as we advance our product candidates through clinical development, the regulatory approval process and, if approved, commercialization, and as we expand our pipeline through research and development activities related to our FIND-IO platform and discovery programs. Specifically, in the near term, we expect to incur substantial expenses relating to our ongoing Phase 1/2 clinical trial and planned Phase 2 clinical trial of NC318, our planned Phase 1/2 clinical trial of NC410 and other research and development activities. We expect to incur significantly increased costs as a result of 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 to pursue our development strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through a combination of public and private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. 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 be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs.

Components of Our Results of Operations

Revenue

For the year ended December 31, 2019, we recognized $6.3 million in revenue under the Lilly Agreement. Through December 31, 2019, we have not generated any revenue from product sales. Through December 31, 2018, we had not generated any revenue from product sales or otherwise. For additional information about our revenue recognition policy, see Note 2 to our audited financial statements included elsewhere in this Annual Report.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our discovery efforts, research activities, development and testing of our product candidates as well as for clinical trials, including:

- salaries, benefits and other related costs, including stock-based compensation, for personnel engaged in research and development functions;

- expenses incurred under agreements with third parties, including agreements with third parties that conduct research, preclinical activities or clinical trials on our behalf, such as our corporate sponsored research agreement, or the SRA, and our license agreement with Yale University, or Yale;

- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;

- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials; and

- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Our expenses related to clinical trials are based on actual costs incurred and estimates of other incurred costs. These estimated costs are based on several factors, including patient enrollment and related expenses at clinical investigator sites, contract services received, consulting agreement costs and efforts expended under contracts with research institutions and third-party contract research organizations that conduct and manage clinical trials on our behalf. We generally accrue estimated costs related to clinical trials based on contracted amounts applied to the level of patient enrollment and other activity according to the protocol. If future timelines or contracts are modified based on changes in the clinical trial protocol or scope of work to be performed, we would modify our estimates of accrued expenses accordingly on a prospective basis. Historically, any such modifications have not been material.

Due to the early-stage nature of our programs and the discovery-related nature of our efforts, we do not track costs on a program-by-program basis other than costs incurred for the Lilly Agreement. However, as our current and future product candidates proceed along a development path further in clinical trials, we intend to track the costs of each program. We measure costs incurred under the Lilly Agreement as an input to recording revenue from the Lilly Agreement.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance our product candidates through development, including conducting our ongoing Phase 1/2 clinical trial of NC318, our planned Phase 2 clinical trial in combination with standard of care chemotherapies and preclinical studies and a Phase 1/2 clinical trial of NC410, as we develop a complementary diagnostic for NC318 if we determine it is advisable, and as we expand our current good manufacturing practice, or cGMP, manufacturing capacity, including to provide drug supply of NC318 for future clinical trials, and as we expand our pipeline through research and development activities related to our FIND-IO platform and discovery programs.

We cannot determine with certainty the duration and costs of future clinical trials of NC318, NC410 or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we may obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of NC318, NC410 and any other product candidate we may develop will depend on a variety of factors, including:

- the scope, progress, results and costs of clinical trials of NC318 and NC410, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;

- uncertainties in selection of indications, clinical trial design and patient enrollment rates;

- the probability of success for our product candidates, including safety and efficacy, early clinical data, competition, ease and ability of manufacturing and commercial viability;

- significant and changing government regulation and regulatory guidance;

- the timing and receipt of any development or marketing approvals; and

- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could lead to a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time to complete clinical development for any such product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including payroll and stock-based compensation, for personnel in executive, finance, human resources, business and corporate development and other administrative functions, professional fees for legal, intellectual property, consulting and accounting services, rent and other facility-related costs, depreciation and other general operating expenses not otherwise classified as research and development expenses. General and administrative expenses also include all patent-related costs incurred in connection with filing and prosecuting patent applications, which are expensed as incurred.

We anticipate that our general and administrative expenses will increase substantially during the next few years as a result of staff expansion and additional occupancy costs, as well as costs associated with being a public company, including higher legal and accounting fees, investor relations costs, higher insurance premiums and other compliance costs associated with being a public company.

Other Income, Net

Other income, net consists primarily of interest income earned on U.S. Treasury obligations and payment of interest on our term loan with a commercial bank, or the Term Loan.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

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

	Year Ended December 31,		
	2019	2018	Change
Revenue:			
Revenue from research and development arrangement	$ 6,347	$ —	$ 6,347
Operating expenses:			
Research and development	34,216	19,787	14,429
General and administrative	9,613	3,409	6,204
Loss from operations	(37,482)	(23,196)	(14,286)
Other income, net	3,745	397	3,348
Net loss	$ (33,737)	$ (22,799)	$ (10,938)

Revenue from Research and Development Arrangement

Revenue was $6.3 million and $0 for the years ended December 31, 2019 and 2018, respectively. The 2019 revenue is related to the recognition of a portion of the upfront consideration under the Lilly Agreement and the premium on the proceeds from Lilly's investment in shares of our Series B-3 Preferred Stock. We expect to record as revenue the remaining deferred revenue balance of $22.4 million at December 31, 2019 in the first quarter of 2020 as a result of the termination of the Lilly Agreement in March 2020.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2019 increased by $14.4 million to $34.2 million compared to $19.8 million for the year ended December 31, 2018. The increase was driven primarily by $4.4

million increase in lab supplies and services for NC318, NC410, other early-stage programs and discovery activities. Other significant components of the increase in research and development expenses included $4.1 million in personnel-related costs due to an increase in headcount, $3.0 million in clinical research costs related to advancing NC318, $0.7 million payments pursuant to the SRA and other sponsored research agreements and $0.6 million in research and development license costs.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2019 increased by $6.2 million to $9.6 million as compared to $3.4 million for the year ended December 31, 2018. The increase was driven primarily by increases, largely in connection with our IPO and operating as a public company, of $2.8 million for professional fees related to legal, finance and audit services, public relations, compensation and investor relations support, $1.2 million in insurance expenses and $0.7 million in personnel-related costs due to an increase in headcount.

Other Income, Net

Other income, net for the year ended December 31, 2019 increased by $3.3 million to $3.7 million from $0.4 million for the year ended December 31, 2018. The increase was driven primarily by interest income earned on higher cash and marketable securities balances, partially offset by interest expense related to an increase in the outstanding principal balance of our term loan from $1.0 million to $5.0 million in January 2019.

Liquidity and Capital Resources

We have financed our operations primarily with proceeds from public offerings of our common stock, private placements of our preferred stock and upfront fees received under the Lilly Agreement. On May 13, 2019, we closed our IPO in which we sold 5,750,000 shares of common stock, at a public offering price of $15.00 per share, for aggregate gross proceeds of $86.3 million. The net offering proceeds to us were approximately $76.9 million after deducting underwriting discounts and commissions and offering expenses. On November 19, 2019, we completed an underwritten public offering, in which we sold 4,077,192 shares of common stock at a public offering price of $36.75 per share. On December 2, 2019, the underwriters exercised in full their option to purchase an additional 611,578 shares of common stock at the public offering price of $36.75. The total gross proceeds to us were $172.2 million and the total net offering proceeds to us were approximately $160.9 million after deducting underwriting discounts and commissions and offering expenses. Since inception, we have received aggregate gross proceeds of $164.4 million from the sale and issuance of shares of our preferred stock. In addition, in November 2018, we received an upfront payment of $25.0 million in cash from Lilly pursuant to the Lilly Agreement. Our cash and cash equivalents are held in money market funds.

As of December 31, 2019, we had cash, cash equivalents and marketable securities, excluding restricted cash, of $334.6 million. We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into the first half of 2023.

In addition, in April 2016, we entered into a term loan to finance laboratory equipment purchases. In January 2019, we amended the term loan to increase our borrowing capacity from $1.0 million to $5.0 million. As amended, the term loan matures in January 2023. Our obligations under the term loan are secured by a security interest in our certificates of deposit, money market accounts, cash, securities, investment property and deposit or investment accounts. The term loan bears interest at a rate equal to the greater of (i) the prime rate less 1.0% and (ii) 4.25% and is subject to mandatory prepayment upon the occurrence of specified events, including failure to pay the term loan when due, uncured breach, bankruptcy or dissolution. Under the term loan, we will make interest-only payments through January 2020 and 36 equal monthly payments of principal plus accrued interest thereafter through January 2023. As of December 31, 2019, our outstanding borrowings under this term loan were $5.0 million.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through sale of equity, debt financings, strategic alliances and licensing arrangements. Adequate additional 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 of our product candidates or delay our efforts to expand our pipeline of product candidates. Our need to raise additional capital will depend on many factors, including:

- the scope, progress, results and costs of researching and developing NC318, NC410 and our other programs, including targets identified through our FIND-IO platform, and of conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for NC318, NC410 and any future product candidates we develop, if clinical trials are successful;
- the costs of manufacturing NC318, NC410 and any future product candidates we develop for preclinical studies and clinical trials in preparation for marketing approval and commercialization;
- the costs of commercialization activities, including marketing, sales and distribution costs, for NC318, NC410 and any future product candidates we develop, whether alone or with a collaborator, if any such product candidates are approved for sale, including marketing, sales and distribution costs;
- the success of the SRA with Yale;
- our ability to establish and maintain additional collaborations, licenses or other arrangements on favorable terms, if at all;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation;
- our current collaboration and license agreements remaining in effect and our achievement of milestones and the timing and amount of milestone payments we are required to make, or that we may be eligible to receive, under those agreements;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing therapies and other adverse developments in the oncology market.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through government or private grants, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our future revenue streams, product candidates or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to retain for ourselves. See the section entitled "Risk Factors" for additional risks associated with our substantial capital requirements.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Year Ended December 31,	
	2019	2018
Net cash (used in) provided by :		
Operating activities	$ (35,623)	$ 7,992
Investing activities	(303,923)	(3,063)
Financing activities	243,043	121,417
Net (decrease) increase in cash and cash equivalents	$ (96,503)	$ 126,346

Cash Used in/Provided by Operating Activities

Net cash used in operating activities was $35.6 million for the year ended December 31, 2019, which was primarily due to our net loss of $33.7 million. Net cash provided by operating activities was $8.0 million for the year ended December 31, 2018, which was primarily due to deferred revenue, including the $25.0 million upfront payment pursuant to the Lilly Agreement, as well as a non-cash charge for depreciation and amortization and the timing of cash payments, partially offset by our net loss of $22.8 million as we continued our research and development activities. The amount of cash used in operating activities in any period is influenced by the timing of cash payments for research-related expenses.

Cash Used in Investing Activities

Cash used in investing activities for the year ended December 31, 2019 was $303.9 million, which was primarily due to the purchase of marketable securities. Cash used in investing activities for the year ended December 31, 2018 was $3.1 million, which consisted primarily of purchases of laboratory equipment.

Cash Provided by Financing Activities

Cash provided by financing activities was $243.0 million for the year ended December 31, 2019, which consisted primarily of net proceeds from the Company's public offering. Cash provided by financing activities was $121.4 million for the year ended December 31, 2018, which consisted of gross proceeds from the sale and issuance of shares of our Series A and B Preferred Stock, partially offset by issuance costs, deferred offering costs and payments under the Term Loan.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019 (in thousands):

	Payments Due by Period				
	Within 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years	Total
Long-term debt obligations	$ 1,667	$ 3,333	$ —	$ —	$ 5,000
Operating lease obligations	602	2,857	—	—	3,459
Total	$ 2,269	$ 6,190	$ —	$ —	$ 8,459

We had operating lease obligations consisting of two operating leases for our corporate headquarters for a total of approximately 50,000 square feet as of December 31, 2019. The terms of the leases expire in August 2025 and March 2030. Under the terms of the leases, we will have lease obligations aggregating $8.8 million through 2025.

The contractual obligations table does not include any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under license agreements we have entered into with various entities pursuant to which we have in-licensed intellectual property, including, our license agreement with Yale and the SRA with Yale. We excluded the contingent payments given that the

timing and amount (if any) of any such payments cannot be reasonably estimated at this time. See "Business—Our Collaboration Agreements" for additional information.

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, non-clinical studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. The most significant assumptions used in the financial statements are the underlying assumptions used in revenue recognition and valuing share-based compensation, including the fair value of our common stock in periods before our IPO. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses, Including Clinical Trial Accruals

Research costs consist of employee-related costs, contractor expenses, laboratory supplies and facility costs, for research and development of product candidates are expensed as incurred. Development costs, including clinical trial-related expenses, incurred by third parties, such as CROs, are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone results are probable of being achieved. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. For further discussion of research and development expenses, see Note 2 to our audited financial statements included elsewhere in this Annual Report.

Revenue Recognition

We account for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect consideration to which we are entitled in exchange for the goods or services we transfer to the customer. For further discussion of revenue recognition, see Note 2 to our audited financial statements included elsewhere in this Annual Report.

Stock-Based Compensation

We account for stock-based compensation, including stock options and restricted stock units, based on the fair value of the award as of the grant date. We utilize the Black-Scholes option-pricing model as the method for estimating the fair value of our stock option grants. The Black-Scholes option-pricing model requires the use of highly subjective and complex assumptions, including the options' expected term and the price volatility of the underlying stock. The fair value of the portion of the award that is ultimately expected to vest is recognized as compensation expense over the award's

requisite service period. We recognize stock-based compensation to expense using the straight-line method. If there are any modifications or cancelations of stock-based awards, we may be required to accelerate, increase or decrease any remaining unrecognized stock-based compensation expense.

Stock-based compensation expense, net of estimated forfeitures, is reflected in the statements of operations and comprehensive loss as follows:

(in thousands)	Year Ended December 31, 2019	2018
Research and development expense	$ 691	$ 85
General and administrative expense	1,195	178
Total stock-based compensation expense	$ 1,886	$ 263

As of December 31, 2019, total unamortized stock-based compensation was $6.9 million.

The intrinsic value of all outstanding stock options as of December 31, 2019 was $113.3 million.

Common Stock Valuation

Before our IPO, there was no public market for our common stock to date and the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants.

Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using an option pricing method, or OPM, which used market approaches to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

Since the closing of our IPO, our board of directors has determined the fair value of our common stock based on the closing price of our common stock on the Nasdaq Global Select Market as reported on the date of grant.

For further discussion of our accounting for stock-based compensation, see Note 2 to our audited financial statements included elsewhere in this Annual Report.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to take advantage of this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002. We will remain an emerging growth company until the earliest of (i) December 31, 2024, (ii) the last day of the first fiscal year in which we have total annual gross revenues of at least $1.07 billion, (iii) the last day of the first fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700.0 million on June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Recent Accounting Pronouncements

See Note 2 to our audited financial statements included elsewhere in this Annual Report for a discussion of recent accounting pronouncements that have impacted or may impact our financial position and results of operations.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

As a smaller reporting company, we are not required to provide the information requested by this Item.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of NextCure, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of operations and comprehensive loss, preferred stock and stockholders' equity (deficit) and cash flows for the years then ended 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 at December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended 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 2018.
Baltimore, MD
March 12, 2020

NEXTCURE, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 34,091	$ 135,173
Marketable securities	300,514	—
Restricted cash	1,706	460
Prepaid expenses and other current assets	3,684	152
Total current assets	339,995	135,785
Property and equipment, net	12,090	11,407
Other assets	4,083	436
Total assets	$ 356,168	$ 147,628
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,861	$ 2,483
Accrued liabilities	4,871	2,411
Deferred rent, current portion	215	28
Term loan, current portion	1,667	387
Deferred revenue, current portion	6,428	4,989
Total current liabilities	15,042	10,298
Deferred rent, net of current portion	359	242
Term loan, net of current portion	3,333	73
Deferred revenue, net of current portion	15,950	21,736
Total liabilities	34,684	32,349
Redeemable preferred stock:		
Series A Preferred Stock, par value of $0.001 per share; 0 and 68,181,819 shares authorized, issued and outstanding at December 31, 2019 and 2018, respectively	—	71,000
Series B Preferred Stock, par value $0.001 per share; 0 and 56,828,852 shares authorized at December 31, 2019 and 2018, respectively, 0 and 56,828,851 shares issued and outstanding at December 31, 2019 and 2018, respectively	—	91,223
Total redeemable preferred stock	—	162,223
Stockholders' equity (deficit):		
Preferred stock, par value of $0.001 per share; 10,000,000 and 0 shares authorized at December 31, 2019 and 2018. No shares issued and outstanding at December 31, 2019 and 2018, respectively	—	—
Common stock, par value of $0.001 per share; 100,000,000 and 158,745,671 shares authorized at December 31, 2019 and 2018, respectively, 27,499,260 and 1,374,812 shares issued and outstanding at December 31, 2019 and 2018, respectively	27	1
Additional paid-in capital	402,529	352
Accumulated other comprehensive loss	(38)	—
Accumulated deficit	(81,034)	(47,297)
Total stockholders' equity (deficit)	321,484	(46,944)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 356,168	$ 147,628

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

NEXTCURE, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2018
Revenue:		
Revenue from research and development arrangement	$ 6,347	$ —
Operating expenses:		
Research and development	34,216	19,787
General and administrative	9,613	3,409
Total operating expenses	43,829	23,196
Loss from operations	(37,482)	(23,196)
Other income, net	3,745	397
Net loss	(33,737)	(22,799)
Net loss per common share — basic and diluted	$ (2.15)	$ (16.64)
Weighted average number of common shares — basic and diluted	15,695,461	1,369,846
Comprehensive loss:		
Net loss	(33,737)	(22,799)
Unrealized loss on marketable securities	(38)	—
Total comprehensive loss	$ (33,775)	$ (22,799)

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

NEXTCURE, INC.
STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)

	Preferred Stock				Stockholders' Equity (Deficit)					
	Series A		Series B		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	(Deficit)
Balance as of December 31, 2017	40,000,000	$ 40,000	—	$ —	1,369,212	$ 1	$ 85	$ —	$ (24,498)	$ (24,412)
Stock-based compensation	—	—	—	—	—	—	263	—	—	263
Issuance of common stock	—	—	—	—	5,600	—	4	—	—	4
Issuance of Series A-3 preferred stock, net of issuance costs of $0	28,181,819	31,000	—	—	—	—	—	—	—	—
Issuance of Series B preferred stock, net of issuance costs of $485	—	—	56,828,851	91,223	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	(22,799)	(22,799)
Balance as of December 31, 2018	68,181,819	71,000	56,828,851	91,223	1,374,812	1	352	—	(47,297)	(46,944)
Stock-based compensation	—	—	—	—	—	—	1,886	—	—	1,886
Issuance of common stock	—	—	—	—	125,109	—	119	—	—	119
Public offerings of common stock, net of issuance costs of $20.7M	—	—	—	—	10,438,770	10	237,965	—	—	237,975
Conversion of preferred stock to common stock	(68,181,819)	(71,000)	(56,828,851)	(91,223)	15,560,569	16	162,207	—	—	162,223
Unrealized loss on marketable securities	—	—	—	—	—	—	—	(38)	—	(38)
Net loss	—	—	—	—	—	—	—	—	(33,737)	(33,737)
Balance as of December 31, 2019	—	$ —	—	$ —	27,499,260	$ 27	$ 402,529	$ (38)	$ (81,034)	$ 321,484

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

NEXTCURE, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (33,737)	$ (22,799)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,688	1,677
Stock-based compensation	1,886	263
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,255)	(19)
Accounts payable	(622)	1,342
Accrued liabilities	2,460	847
Deferred rent	304	(44)
Deferred revenue	(4,347)	26,725
Net cash (used in) provided by operating activities	(35,623)	7,992
Cash flows from investing activities:		
Purchase of property and equipment	(3,371)	(3,063)
Purchase of marketable securities	(300,552)	—
Net cash used in investing activities	(303,923)	(3,063)
Cash flows from financing activities:		
Proceeds from public offerings, net of issuance costs	238,384	—
Proceeds from issuance of preferred stock, net of issuance costs	—	122,223
Proceeds from other issuance of common stock	119	4
Proceeds from the term loan	4,540	—
Deferred financing costs	—	(410)
Payments of the term loan	—	(400)
Net cash provided by financing activities	243,043	121,417
Net (decrease) increase in cash, cash equivalents and restricted cash	(96,503)	126,346
Cash, cash equivalents and restricted cash — beginning of year	135,633	9,287
Cash, cash equivalents and restricted cash — end of year	$ 39,130	$ 135,633
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 191	$ 25
Cash paid for income taxes	$ —	$ —
Supplemental disclosures of noncash investing and financing activities:		
Purchase of property and equipment included in accrued liabilities	$ 73	$ —
Deferred financing costs included in accrued liabilities	$ 1	$ 284
Conversion of convertible preferred stock into common stock	$ 162,223	$ —

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

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Organization

NextCure, Inc. ("NextCure" or the "Company") was incorporated in Delaware in September 2015 and is headquartered in Beltsville, Maryland. The Company is a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases by restoring normal immune function. Through its proprietary Functional, Integrated, NextCure Discovery in Immuno-Oncology ("FIND-IO") platform, the Company studies various immune cells in order to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. Since inception, the Company has devoted substantially all of its efforts and financial resources to organizing and staffing the Company, identifying business development opportunities, raising capital, securing intellectual property rights related to the Company's product candidates, building and optimizing the Company's manufacturing capabilities and conducting discovery, research and development activities for the Company's product candidates, discovery programs and its FIND-IO platform.

Public Offerings of Common Stock

On May 13, 2019, the Company closed its initial public offering ("IPO"), in which the Company issued and sold 5,750,000 shares of common stock at a public offering price of $15.00 per share, for net proceeds to the Company of approximately $76.9 million after deducting underwriting discounts and commissions of $6.0 million and offering expenses of approximately $3.4 million.

In preparation for the IPO, on May 3, 2019, the Company effected a one-for-8.0338 reverse stock split of its issued and outstanding common stock. The par value and authorized shares of common stock were not adjusted as a result of the reverse stock split. All of the share and per share information presented in the accompanying financial statements has been adjusted to reflect the reverse common stock split on a retroactive basis for all periods and as of all dates presented.

Upon the closing of the IPO, on May 13, 2019, all of the outstanding shares of the Company's convertible preferred stock automatically converted into 15,560,569 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding.

Upon the closing of the IPO, on May 13, 2019, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

On November 19, 2019, the Company completed an underwritten public offering, in which the Company issued and sold 4,077,192 shares of common stock at a public offering price of $36.75 per share. On December 2, 2019, the underwriters exercised in full their option to purchase an additional 611,578 shares of common stock at the public offering price of $36.75, for total net proceeds to the Company of approximately $160.9 million after deducting underwriting discounts and commissions of approximately $10.3 million and offering expenses of approximately $1.0 million.

Liquidity

The Company has not generated any revenue to date from product sales and does not expect to generate any revenues from product sales in the foreseeable future. Through December 2019, the Company has funded its operations primarily with proceeds from public offerings of its common stock, private placements of its preferred stock and upfront fees received under the Company's former agreement with Eli Lilly and Company (Note 7). The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future.

The Company expects that its operating losses and negative cash flows will continue for the foreseeable future. As of the issuance date of the financial statements for the year ended December 31, 2019, the Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through

at least two years from the issuance date of the financial statements. The future viability of the Company beyond that date may depend on its ability to raise additional capital to finance its operations.

The Company plans to seek additional funding through public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances, licensing arrangements or other methods. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be required to delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects.

Although management continues to pursue these funding plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company, if at all, to fund continuing operations past two years from the issuance date of these financial statements.

Risks and Uncertainties

The Company is subject to risks common to early-stage companies in the biotechnology industry including, but not limited to: having a limited operating history and no products approved for commercial sale; having a history of significant losses; its need to obtain additional financing; dependence on its ability to advance its current and future product candidates through clinical trials, marketing approval and commercialization; the unproven approach to the discovery and development of product candidates based on the Company's FIND-IO platform; the lengthy and expensive nature and uncertain outcomes of the clinical development process; the lengthy, time-consuming and unpredictable nature of the regulatory approval process; the results of preclinical studies and early-stage clinical trials that may not be predictive of future results; dependence on its key personnel; its limited manufacturing experience as an organization and with its manufacturing facility; risks related to patent protection and the Company's pending patent applications; dependence on third-party collaborators for the discovery, development and commercialization of current and future product candidates; and significant competition from other biotechnology and pharmaceutical companies. Pursuit of the Company's business efforts will require significant amounts of additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Segment and Geographic Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The chief operating decision makers view the operations and manage the business in one operating segment that operates exclusively in the United States.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements include the accounts of the Company. The Company's financial statements have been prepared in accordance with United States generally accepted accounting principles (''GAAP''). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (''ASC'') and Accounting Standards Update (''ASU'') of the Financial Accounting Standards Board (''FASB'').

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the

date of the financial statements and the reported amounts of revenues and expenses for the period presented. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits its cash primarily in checking, sweep account and money market accounts. Cash equivalents are stated at amortized cost plus accrued interest, which approximates fair value.

Restricted Cash

At December 31, 2019 and 2018, the Company had restricted cash of $5.0 million and $460,000, respectively. The Company is required, as a condition of its Term Loan (Note 9), to maintain cash collateral on deposit in a segregated money market bank account equal to the principal portion outstanding under the Term Loan on a quarterly basis. The bank may restrict withdrawals or transfers by, or on behalf of, the Company. The required reserve totaled $5.0 million and $480,000 as of December 31, 2019 and December 31, 2018, respectively. The amounts are presented in part as restricted cash and in part as other assets on the accompanying balance sheets.

The following table reconciles cash and cash equivalents and restricted cash per the balance sheet to the statement of cash flows:

	December 31,	
(in thousands)	2019	2018
Cash and cash equivalents	$ 34,091	$ 135,173
Restricted cash (including $3,333 in other assets as of December 31, 2019)	5,039	460
Total	$ 39,130	$ 135,633

Marketable Securities

Marketable securities primarily consist of government debt securities, corporate bonds and agency bonds. These marketable securities are classified as available-for-sale, and as such, are carried at fair value as determined by prices for identical or similar securities at the balance sheet date. Marketable securities consist of Level 2 financial instruments in the fair-value hierarchy. The Company's policy is to classify all investments with contractual maturities within one year as current. Investment income is recognized when earned and reported net of investment expenses. Unrealized holding gains and losses are reported within accumulated other comprehensive income (loss) as a separate component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and interest on securities are included in other income, net, on the Company's statements of operations.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. If a decline in the fair value of a marketable security below the Company's cost basis is determined to be other-than-temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. The Company considers factors including the significance of the decline in value compared to the cost basis, underlying factors contributing to a decline in the prices of securities in a single asset class, the length of time the market value of the security has been less than its cost basis, the security's relative performance versus its peers, sector or asset class, expected market volatility and the market and economy in general. The Company also evaluates whether it is more likely than not that it will be required to sell a security prior to recovery of its fair value. The cost of securities sold is based on the specific identification method.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents. The Company maintains its cash and cash equivalents at one accredited financial institution that is federally insured. While balances deposited often exceed federally insured limits, the Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The counterparties are various corporations, financial institutions and government agencies of high credit standing.

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents. The Company maintains its cash and cash equivalents at one accredited financial institution in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or 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 a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier value hierarchy that distinguishes between the following:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3—Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use. Use of these inputs involves significant and subjective judgments to be made by a reporting entity – e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Property and Equipment, Net

Property and equipment are valued at cost less accumulated depreciation. Depreciation is recognized on a straight-line basis over the estimated useful lives of the related assets. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life or term of the lease. Upon retirement or disposal, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is recorded to general and administrative expenses in the accompanying statement of operations and comprehensive loss. Routine expenditures for maintenance and repairs are expensed as incurred.

Estimated useful lives for property and equipment are as follows:

	Estimated Useful Life
Computers and peripherals	3 years
Equipment	5 years
Furniture and fixtures	7 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

The Company reviews long-lived assets, which primarily consist of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or group of assets may not be

fully recoverable based on the criteria for accounting for the impairment or disposal of long-lived assets under ASC Topic 360, Property, Plant and Equipment. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, the Company evaluates recoverability by comparing the carrying amount of the assets group to future undiscounted net cash flows expected to be generated by the assets group. Assets are grouped at the lowest level for which there is identifiable cash flows that are largely independent of the cash flows generated by other asset groups. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, an impairment loss is recognized for the difference between the fair value and carrying value of assets within the group. Fair value is generally determined by estimates of discounted cash flows. The discount rate used in any estimate of discounted cash flows would be the rate required for a similar investment of like risk. No impairment losses were recognized during the years ended December 31, 2019 or 2018.

Construction in progress (Note 5) is carried at cost and consists of specifically identifiable direct and indirect development and construction costs. While under construction, costs of the property are included in construction in progress until the property is placed in service, at which time costs are transferred to the appropriate property and equipment account including, but not limited to, leasehold improvements or other such accounts.

Leases

The Company enters into lease agreements for its office and laboratory facilities and accounts for them in accordance with ASC Topic 840, Leases. These leases are classified as operating leases. Rent expense is recognized on a straight-line basis over the term of the lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. Incentives granted under the Company's facilities leases, including allowances to fund leasehold improvements, are deferred and are recognized as adjustments to rental expense on a straight-line basis over the term of the lease.

Preferred Stock

The Company's preferred stock is classified outside of stockholders' deficit for the period during which it was outstanding because the shares carried deemed liquidation rights that were a contingent redemption feature not solely within the control of the Company.

Research and Development Costs, Including Clinical Trial Accruals

Research costs consist of employee-related costs, contractor expenses, laboratory supplies and facility costs, for research and development of product candidates are expensed as incurred. Development costs, including clinical trial-related expenses, incurred by third parties, such as clinical research organizations (CROs), are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone results are probable of being achieved. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs.

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third parties. Third-party clinical trial expenses include investigator fees, site and patient costs, CRO costs, and costs for central laboratory testing and data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the balance sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could

differ from the estimates made. The historical clinical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying statement of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"). ASC 718 requires all share-based payments to employees, consultants and directors, including grants of incentive stock options, nonqualified stock options, restricted stock awards, unrestricted stock awards or restricted stock units to employees, consultants and directors of the Company, to be recognized as expense in the statement of operations and comprehensive loss based on their grant date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model ("Black-Scholes") for stock option grants to both employees and non-employees and the fair value of common stock to determine the fair value of restricted stock.

The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the simplified method also as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero because the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company recognizes forfeitures as they occur as allowed by ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09").

There are significant judgments and estimates inherent in the determination of the fair value of the Company's common stock. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to its common stock at the time of a liquidity event, such as the IPO or a sale, and the likelihood of such an event.

The Company expenses the fair value of its share-based compensation awards on a straight-line basis over the requisite service period, which is generally the vesting period.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax base. Deferred tax assets and liabilities, which relate primarily to the carrying amount of the Company's deferred revenue and its net operating loss carryforwards, are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is more-likely-than-not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available

positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. Because of the uncertainty of the realization of deferred tax assets, the Company has recorded a full valuation allowance against its deferred tax assets.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes; however, the Company currently has no interest or penalties related to uncertain income tax benefits.

Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The Company evaluates customer options for material rights or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral to or dependent on other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the goods or services promised in the contract. Consideration generally may include fixed consideration or variable consideration. Should an arrangement include variable consideration, the Company will evaluate the amount of potential payments and the likelihood that the payments will be received. The Company will utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and will be included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The Company's contracts may include development and regulatory milestone payments, which would be assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, will not be considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments would be recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at

the later of (i) when the related sales occur and (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company allocates the transaction price based on the estimated stand-alone selling price of each of the performance obligations. The Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the stand-alone selling price for service obligations, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs. Additionally, in determining the standalone selling price for material rights, the Company may reference comparable transactions, clinical trial success probabilities and estimates of option exercise likelihood. Variable consideration will be allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated are consistent with the amounts the Company would expect to receive for the satisfaction of each performance obligation.

The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts are recorded as accounts receivable when the Company’s right to consideration is unconditional.

Comprehensive Loss

Comprehensive loss is the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss and the change in accumulated other comprehensive loss for the period. Accumulated other comprehensive loss consisted entirely of unrealized gains and losses on available-for-sale marketable securities at December 31, 2019.

Net Loss per Share

Basic loss per common share is determined by dividing loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted loss per share is computed by dividing the loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants.

During the year ended December 31, 2018, the Company calculated basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company considered its Series A Preferred Stock and Series B Preferred Stock to be participating securities because in the event a dividend was paid on common stock, the holders of Series A Preferred Stock and Series B Preferred Stock were entitled to receive dividends on a basis consistent with the common stockholders. Under the two-class method, the net loss attributable to common stockholders is not allocated to the preferred stock as the holders of the preferred stock do not have a contractual obligation to share in losses. Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

Recently Issued Accounting Pronouncements

The Company qualifies as an emerging growth company ("EGC") as defined under the Jumpstart Our Business Startups Act (the "JOBS Act"). Using exemptions provided under the JOBS Act provided to EGCs, the Company has elected to defer compliance with new or revised financial accounting standards until it is required to comply with such standards.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). The new guidance will require lessees to record most leases on their balance sheets and recognize the related expenses on their income statements in a manner similar to current practice. ASU 2016-02 states that a lessee would recognize a lease liability for the obligation to make lease payments and a right-to-use asset for the right to use the underlying asset for the lease term. The standard is effective for the Company January 1, 2021. The Company continues to determine if it will elect to use the practical expedients permitted by the guidance and continues to gather data required to comply with the guidance. Based on the work completed to date, the Company is considering the implications of adopting the new standard, including the discount rate to be used in valuing new and existing leases and all applicable financial statement disclosures required by the new guidance. The Company is continuing to evaluate the effect of adoption and anticipates that it will result in the recognition of additional assets and corresponding liabilities related to the existing leases on its balance sheet. The Company is assessing any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 will require credit losses to be reported using an expected losses model rather than the incurred losses model that is currently used, and will require additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard will require allowances to be recorded instead of reducing the amortized cost of the investment. ASU 2016-13 will be effective for non-emerging growth companies for fiscal years beginning December 15, 2019 and interim periods within those fiscal years, and will be effective for the Company for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021, assuming the Company remains an emerging growth company. Early adoption is permitted. The Company is currently evaluating the effects the adoption of ASU 2016-13 will have on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement—Disclosure Framework-Changes to the Disclosure Requirement for Fair Value Measurement ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements in ASC Topic 820, Fair Value Measurement, based on the concepts in the FASB Concepts Statement, including the consideration of costs and benefits. ASU 2018-13 will be effective for all companies for fiscal periods beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the effects the adoption of ASU 2018-13 will have on its financial statements.

3. Marketable Securities

Marketable securities consist of the following:

	December 31, 2019			
(in thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
U.S. treasury securities	$ 4,991	$ —	$ —	$ 4,991
Agency bonds	24,437	15	(1)	24,451
Corporate bonds	271,124	103	(155)	271,072
Total	$ 300,552	$ 118	$ (156)	$ 300,514

As of December 31, 2019, none of the Company's fixed maturity investments were in continuous unrealized loss positions for more than 12 consecutive months. Unrealized losses on all fixed maturity investments in a continuous loss position for less than 12 consecutive months were approximately $156,000 as of December 31, 2019. All of the Company's investments at each year end are classified as available for sale and are carried at fair value. As of December 31, 2019, no

investments are considered to be other-than-temporarily impaired. The Company uses the specific identification method when calculating realized gains and losses. The Company did not have any realized gains or losses on available-for-sale securities during the years ended December 31, 2019. The Company did not have any marketable securities as of or during the year ended December 31, 2018. The Company recorded interest income of $2.0 million and $0 during the years ended December 31, 2019 and 2018, respectively, which is included in other income on the statement of operations and comprehensive loss.

The following table summarizes maturities of the Company's investments available-for-sale as of December 31, 2019:

	December 31, 2019	
(in thousands)	Cost	Fair Value
Maturities:		
Within 1 year	$ 168,186	$ 168,204
From more than 1 to 5 years	132,366	132,310
Total investments available for sale	$ 300,552	$ 300,514

4. Fair Value Measurements

The following tables set forth the fair value of the Company's financial assets by level within the fair value hierarchy as of December 31, 2019 and 2018:

	December 31, 2019			
(in thousands)	Total	Quoted Prices in Active Markets or Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable (Level 3)
Cash equivalents:				
Money market (Note 2)	$ 19,341	$ 19,341	$ —	$ —
Marketable securities:				
U.S. treasury securities	4,991	—	4,991	—
Agency bonds	24,451	—	24,451	—
Corporate bonds	271,072	—	271,072	—
Total	$ 319,855	$ 19,341	$ 300,514	$ —

	December 31, 2018			
(in thousands)	Total	Quoted Prices in Active Markets or Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable (Level 3)
Cash equivalents:				
Money market (Note 2)	$ 5,000	$ 5,000	—	—

The Company did not transfer any assets measured at fair value on a recurring basis between fair value levels during the years ended December 31, 2019 and 2018.

The carrying value of financial instruments, including trade receivables, accounts payable and accrued liabilities approximate fair value because of the short-term maturity of these items. The estimated fair values may not represent actual values of the financial instruments that could be realized as of the balance sheet date or that will be realized in the future.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

5. Property and Equipment, Net

Property and equipment consist of the following:

(in thousands)	December 31, 2019	2018
Research equipment	$ 10,703	$ 7,787
Leasehold improvements	5,368	4,825
Computer equipment	463	167
Furniture and fixtures	93	70
Construction in progress	609	1,027
Property and equipment, gross	17,236	13,876
Less: accumulated depreciation and amortization	(5,146)	(2,469)
Property and equipment, net	$ 12,090	$ 11,407

Construction in progress at December 31, 2019 consists of the costs incurred for research equipment and for the build-out of additional lab and office space and at December 31, 2018 consists of the costs incurred for the build-out of a manufacturing suite at the Company's headquarters in Beltsville, Maryland.

Depreciation and amortization expense was $2.7 million and $1.7 million for the years ended December 31, 2019 and 2018, respectively.

6. Accrued Liabilities

Accrued liabilities consist of the following:

(in thousands)	December 31, 2019	2018
Construction in progress	$ 73	$ —
Payroll and related benefits	1,173	1,008
Clinical trial costs	1,702	271
Operating expenses	1,769	719
Financing costs	1	284
Office lease	135	127
Interest	18	2
Total accrued liabilities	$ 4,871	$ 2,411

7. Agreement with Eli Lilly and Company

On November 2, 2018, the Company entered into a multi-year research and development collaboration agreement (the "Lilly Agreement") with Eli Lilly and Company ("Lilly"), pursuant to which the Company agreed to use its proprietary FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by the Company and Lilly. Under the Lilly Agreement, Lilly and the Company granted one another an equal number of exclusive options to research, develop, manufacture and commercialize compounds and products directed to oncology targets identified through the Lilly Agreement.

During the research term under the Lilly Agreement, as a part of target discovery, the Company was responsible for providing Lilly with oncology targets identified using the Company's FIND-IO platform. From the targets provided by the Company, Lilly could select targets to advance to target validation using criteria developed by both parties. Following completion of the agreed upon target validation plan with respect to a given target, either party could propose to advance that target to compound discovery. For each target advanced to compound discovery, Lilly had the option to obtain an exclusive license with respect to the compounds and products directed to the target. If Lilly did not exercise its option with respect to a given target or has previously exercised all of its options, the Company had the option to obtain licenses with respect to compounds and products directed to that target.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

In November 2018, the Company received an upfront, non-refundable payment of $25.0 million under the Lilly Agreement and a concurrent $15.0 million equity investment (Note 10). In addition, Lilly agreed to make quarterly research and development support payments during a portion of the research term as well as to pay option exercise fees upon option exercises by Lilly.

Pursuant to the Lilly Agreement, Lilly agreed to pay an aggregate of up to $1.4 billion in development and regulatory milestones and sales milestones. Additionally, Lilly agreed to pay mid to high single-digit royalties on net sales for all products directed to each target optioned by Lilly. The Company agreed that upon the Company's exercise of an option with respect to a given target, the Company would pay Lilly option exercise payments and also agreed to pay an aggregate of up to $710.0 million in development and regulatory milestones and sales milestones, as well as royalties.

The Company evaluated the Lilly Agreement under the provisions of ASC 606 and concluded that Lilly was a customer prior to the exercise of its option to obtain an exclusive license with respect to the compounds and products directed to a target advanced to compound discovery. The Company identified the following material promises under the Lilly Agreement: (i) a limited research license to conduct activities under the research collaboration; (ii) research and development services together with the provision of a data package in connection with Lilly's option; (iii) various governance obligations, most notably participation on a joint steering committee; and (iv) rights related to an optional term extension by Lilly. The Company evaluated Lilly's option to obtain an exclusive license with respect to the compounds and products directed to a target that has been advanced to compound discovery and concluded that the option was not issued at a significant and incremental discount, and therefore does not provide material rights. As such, they are excluded as performance obligations at the outset of the arrangement. The Company determined that the research license was not capable of being distinct and the related research and development services and governance activities are not distinct in the context of the contract and, as such, the Company determined that these promises should be combined into a single performance obligation, resulting in a total of two performance obligations under the Lilly Agreement; one for research and development services and one for the right related to an optional term extension by Lilly.

The transaction price at the outset of the arrangement was determined to be $32.7 million, comprised of the upfront fee received from Lilly, quarterly research and development support payments to be received from Lilly during a portion of the research term and an equity investment premium as determined by the Company with reference to a valuation of the Company's preferred stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

The transaction price was allocated to the two performance obligations based on their relative standalone selling price determined with reference to the Company's estimated costs attendant to the obligations. Revenue allocated to the research and development performance obligation was recognized as the research and development services were provided using an input method calculated by comparing research and development costs incurred to date to estimated total research and development costs as a measure of progress towards satisfying the performance obligation. Revenue allocated to Lilly's right related to an optional term extension was deferred until the right was exercised or lapsed, and will subsequently be recognized accordingly.

While the Lilly Agreement was executed in November 2018, the performance initiated in January 2019. Under the Lilly Agreement, the Company recognized revenue of $6.3 million and $0 for the years ended December 31, 2019 and 2018, respectively.

Deferred revenue consists of the following:

(in thousands)	December 31, 2019	2018
Deferred revenue, beginning of period	$ 26,725	$ —
Up-front payment	—	25,000
Attributed premium on the proceeds from Lilly's investment in the Company	—	1,725
Research and development support billing	2,000	—
Revenue from research and development arrangement recognized	(6,347)	—
Total deferred revenue, end of period	22,378	26,725
Less: Deferred revenue, current portion	(6,428)	(4,989)
Deferred revenue, non-current portion	$ 15,950	$ 21,736

On January 10, 2020, Lilly notified the Company of termination of the Lilly Agreement. Refer to Note 16 for additional information on this termination.

8. Commitments and Contingencies

Operating Leases

On February 9, 2016, the Company entered into a non-cancelable facilities operating sublease (the "2016 Sublease"). On March 15, 2019, the Company amended and restated the 2016 Sublease (as amended, the "Amended 2016 Sublease") to include additional square footage to be used for office space, which the Company took possession of upon entering into the Amended 2016 Sublease. The Amended 2016 Sublease expires in August 2025. The base rent under the Amended 2016 Sublease is currently $32,254 per month plus the Company's prorated share of the sublandlord's operating expense and is subject to annual rent increases of 3%.

On January 30, 2019, the Company entered into a new lease to be used for office and laboratory space (the "New Premises"), which the Company took possession of on June 1, 2019 (the "2019 Lease"). On August 2, 2019, the Company amended the 2019 Lease (as, the "Amended 2019 Lease") to include additional space to be used for office and laboratory space (the "Expansion Premises"), which the Company expects to take possession of on April 1, 2020. The Amended 2019 Lease expires in March 2030. Upon expiration of the Amended 2016 Sublease, the Amended 2019 Lease will also cover the space the Company is currently subleasing under the Amended 2016 Sublease. Base rent is abated until April 1, 2020 for the New Premises and until seven months after delivery of the Expansion Premises for the Expansion Premises, after which the base rent will be $19,646 per month for the New Premises and $18,178 per month for the Expansion Premises, each subject to annual rent increases of 3%. In connection with this lease, the Company executed a $39,000 letter of credit, which has not been drawn down on. Additionally, there is a base rate adjustment of 8.5% per annum multiplied by the outstanding balance of amounts paid for tenant improvements. The budgeted amounts of tenant improvements are approximately $1,477,000 for the New Premises and $1,517,000 for the Expansion Premises, which are to be fully reimbursed by the landlord.

At December 31, 2019, the Company's minimum obligations under non-cancelable operating leases are as follows:

(in thousands)	
Year Ending December 31,	
2020	602
2021	915
2022	972
2023	970
Thereafter	7,736
Total future minimum payments	$ 11,195

Rent expense incurred under operating leases was approximately $679,000 and $420,000 for the years ended December 31, 2019 and 2018, respectively.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company is not a party to any litigation or legal proceedings, nor is management aware of any pending or threatened litigation that, in the opinion of the Company's management, are likely to have a material adverse effect on the Company's business. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as incurred. As of December 31, 2019, and 2018, the Company was not involved in any material legal proceedings.

9. Term Loan

In April 2016, the Company entered into a $1.0 million term loan (the "Term Loan"). On January 25, 2019, the Company amended the Term Loan to increase the Company's borrowing capacity to $5.0 million, which amount remains secured by the Company's certificates of deposit, money market account, investment property and deposit or investment accounts. As amended, the Term Loan bears interest at the greater of the prime rate less 1% and 4.25%. The effective interest rate was 4.40% and 3.95% for the years ended December 31, 2019 and 2018, respectively. Under the Term Loan, the Company is required to make monthly interest-only payments through January 2020 and is required to make 36 equal monthly payments of principal plus accrued interest thereafter through January 2023. The Term Loan is secured by all certificates of deposit, money market accounts, cash, securities, investment property and deposit or investment accounts. Interest expense under the Term Loan was approximately $209,000 and $25,000 for the years ended December 31, 2019 and 2018, respectively. The outstanding balance on the Term Loan totaled $5.0 million and $460,000 as of December 31, 2019 and 2018, respectively.

Future maturities of the Term Loan as of December 31, 2019 are as follows:

(in thousands)	
2020	1,528
2021	1,667
2022	1,667
2023	138
Total	5,000
Less: current portion of term loan	(1,667)
Term loan, net of current portion	$ 3,333

10. Preferred Stock

Upon the closing of the IPO, on May 13, 2019, all of the outstanding shares of the Company's preferred stock automatically converted into shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding.

The Company's preferred stock that was outstanding as of December 31, 2018 is classified outside of stockholders' equity (deficit) because the shares contained deemed liquidation rights that were a contingent redemption feature not solely within the control of the Company.

As of December 31, 2019, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 10,000,000 shares of $0.001 par value preferred stock, and there were no shares of preferred stock issued or outstanding. The Company can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by its stockholders.

11. Common Stock

As of December 31, 2019, the Company's Certificate of Incorporation, as amended and restated, authorized the Company to issue 100,000,000 shares of $0.001 par value common stock, of which 27,499,260 were issued and outstanding.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of any preferred stock. No dividends have been declared or paid by the Company through December 31, 2019.

In the event of any liquidation or dissolution of the Company, the holders of common stock are entitled to the remaining assets of the Company legally available for distribution after the payment of the full liquidation preference for any preferred stock.

12. Stock-Based Compensation

Employee Equity Plans

The NextCure, Inc. 2015 Omnibus Incentive Plan (the "2015 Plan") provides for the grant of awards of stock options, restricted stock awards, unrestricted stock awards and restricted stock units to employees, consultants and directors of the Company. The 2015 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors.

On May 3, 2019, the Company's stockholders approved the NextCure, Inc. 2019 Omnibus Incentive Plan (the ''2019 Plan''), which became effective on May 8, 2019, the date on which the Company's Registration Statement on Form S-1 (Reg. No. 333-230837) was declared effective (the "Effective Date"). The Company's board of directors (the "Board") determined not to make additional awards under the 2015 Plan following the effectiveness of the 2019 Plan. The 2019 Plan provides for the grant of awards of stock options, stock appreciation rights, restricted stock, restricted stock units, deferred stock units, unrestricted stock, dividend equivalent rights, other equity-based awards and cash bonus awards to the Company's officers, employees, non-employee directors and other key persons (including consultants). The number of shares of common stock reserved for issuance under the 2019 Plan is 2,900,000 plus the number of shares of stock related to awards outstanding under the 2015 Plan that subsequently terminate by expiration or forfeiture, cancellation or otherwise without the issuance of such shares. The number of shares reserved for issuance under the 2019 Plan will automatically increase on January 1, 2020 and each January 1st thereafter during the term of the 2019 Plan by 4% of the number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year or such lesser number of shares determined by the Board.

As of December 31, 2019, 2,661,566 shares were reserved for future issuance under the 2019 Plan.

Stock options granted under the 2015 Plan and 2019 Plan (together, the "Plans") to employees generally vest over four years and expire after 10 years.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

A summary of stock option activity for awards under the Plans is presented below:

	Options Outstanding and Exercisable			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value[(1)] (in thousands)
Outstanding as of January 1, 2018	506,586	$ 0.94	9.0	$ 137
Granted	1,570,136	$ 5.92	9.9	—
Exercised	(5,599)	$ 0.84	—	—
Forfeitures	(14,232)	$ 1.11	—	—
Outstanding as of December 31, 2018	2,056,891	$ 4.74	9.4	$ 5,946
Granted	258,897	$ 18.88	9.5	—
Exercised	(125,108)	$ 0.96	7.4	—
Forfeitures	(20,468)	$ 19.66	9.5	—
Outstanding as of December 31, 2019	2,170,212	$ 6.51	8.6	$ —
Vested and expected to vest as of December 31, 2019	2,170,212	$ 6.51	—	$ 113,295
Exercisable as of December 31, 2019	716,393	$ 3.75	—	$ 39,370

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the common stock for the options that were in the money at December 31, 2019 and 2018.

The weighted average grant date fair value per share of stock options granted during the years ended December 31, 2019 and 2018 was $11.92 and $3.80, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2019 and 2018 was $7,225,000 and $38,000, respectively.

The aggregate grant date fair value of stock options and restricted stock vested during the year ended December 31, 2019 and 2018 was approximately $7,637,000 and $157,000, respectively.

The Company's potential dilutive securities, which as of December 31, 2019 include common stock options, have been excluded from the computation of diluted net loss per share because the effect would be anti-dilutive. Therefore, the weighted average number of common shares used to calculate both basic and diluted net loss per common share is the same. The Company excluded 2,170,212 and 2,056,891 potential shares of common stock, presented based on amounts outstanding as of December 31, 2019 and 2018, respectively, from the computation of diluted net loss per common share for the periods indicated because including them would have had an anti-dilutive effect.

On May 3, 2019, the Company's stockholders approved the NextCure, Inc. 2019 Employee Stock Purchase Plan (the "ESPP"), which became effective on the Effective Date. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Internal Revenue Code. A total of 240,000 shares of common stock were reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2020 and each January 1st thereafter until expiration of the ESPP, in an amount equal to the lesser of (i) 1% of the number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, (ii) 480,000 shares of common stock and (iii) a number of shares of common stock determined by the administrator of the ESPP. As of December 31, 2019, no shares of common stock had been issued pursuant to the ESPP and 240,000 shares were reserved for future issuance thereunder.

Stock-Based Compensation

The Company recorded stock-based compensation expense of $1.9 million and $0.3 million during the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was $6.9 million of unrecognized compensation cost related to unvested stock-based compensation arrangements granted under the Plans. This remaining compensation expense is expected to be recognized over a weighted-average period of three years as of December 31, 2019.

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

Stock-based compensation expense recorded as research and development and general and administrative expenses is as follows:

	Year Ended December 31,	
	2019	2018
Research and development	$ 691	$ 85
General and administrative	1,195	178
Total stock-based compensation expense	$ 1,886	$ 263

The assumptions used in the Black-Scholes option-pricing model for stock options granted were as follows:

	Year Ended December 31,	
	2019	2018
Expected term	6.1 years	6.1 years
Expected volatility	69.7 %	69.7 %
Risk free interest rate	1.90 %	2.77 %
Expected dividend yield	— %	— %

Restricted Common Stock

In May 2016, the Company issued 62,237 shares of restricted common stock, which are restricted as to sale or transferability, under the 2015 Plan. These restrictions lapse over a four-year period.

13. Net Loss Per Share Attributable to Common Stockholders

The Company's potential dilutive securities, which include common stock options and for the year ended December 31, 2018 included preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders for the period indicated because including them would have had an anti-dilutive effect:

	December 31,	
	2019	2018
Preferred stock convertible into common stock	—	15,560,569
Outstanding options to purchase common stock	2,170,212	2,056,891
Total	2,170,212	17,617,460

14. Income Taxes

The reconciliation of federal statutory income tax rate to the Company's effective income tax rate is as follows:

	December 31,	
	2019	2018
Expected income tax benefit at the federal statutory rate	21.0 %	21.0 %
State taxes, net of federal benefit	7.0	6.5
Research and development credit, net	4.9	7.2
Non-deductible items	(0.5)	(2.2)
Prior year provision to return adjustments	(2.5)	(7.7)
Other	—	0.3
Change in valuation allowance	(29.9)	(25.1)
Total	— %	— %

NEXTCURE, INC.
NOTES TO FINANCIAL STATEMENTS

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The principal components of the Company's deferred tax assets consisted of the following as of December 31, 2019 and 2018:

(in thousands)	December 31, 2019	2018
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 15,080	$ 11,946
Research and development tax credits	4,197	3,393
Deferred revenue	5,928	—
Charitable contribution carryforwards	306	165
Accruals and other	826	313
Gross deferred tax assets	26,337	15,817
Less: valuation allowance	(25,633)	(15,525)
Total deferred tax assets	$ 704	$ 292
Deferred tax liabilities:		
Depreciation and amortization	$ (704)	$ (292)
Gross deferred tax liabilities	$ (704)	$ (292)
Net deferred tax assets	$ —	$ —

Based on the Company's history of losses, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2019. The Company increased its valuation allowance by approximately $10.1 million for the year ended December 31, 2019. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2019, the Company had federal and state net operating loss carryforwards of $55.0 million and $54.0 million, respectively, some of which begin to expire in the year ending December 31, 2036. Approximately $32.3 million of the federal and state net operating loss carryforwards do not expire. The Company had federal and state research and development tax credit carryforwards of approximately $4.1 million and $0.1 million, respectively, as of December 31, 2019. The federal credits begin to expire in the year ending December 31, 2036 and the state credits begin to expire in the year ending December 31, 2024.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code (the "IRC"), certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss and credit carryforwards that can be used to reduce future income taxes if there has been a significant change in ownership of the Company, as defined by the IRC. Future owner or equity shifts could result in limitations on net operating loss and credit carryforwards.

The Company files income tax returns in the U.S. federal jurisdiction as well as in Maryland. The tax years 2016 to 2018 remain open to examination by the major jurisdictions in which the Company is subject to tax. Fiscal years outside the normal statute of limitation remain open to audit by tax authorities due to tax attributes generated in those early years, which have been carried forward and may be audited in subsequent years when utilized.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2019, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized.

On December 22, 2017, the U.S. government signed into law the Tax Cuts and Jobs Act (the "Tax Act") that significantly reforms the Internal Revenue Code of 1986, as amended. In 2018, the Company finished its analysis of the impact of the Tax Act. Where the Company made reasonable estimates in 2017 of the effects related to the Tax Act, the

Company recorded provisional amounts. After the completed analysis, the resulting impact to the Company's financial statements did not differ from the recorded provisional amounts.

15. Employee Benefit Plan

The Company sponsors a 401(k) plan that stipulates that eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100% of eligible compensation on a pre-tax basis. Through December 31, 2019, the Company has not provided any contributions to this plan.

16. Subsequent Events

On January 10, 2020, Lilly notified the Company of its termination of the Lilly Agreement (Note 7), effective as of March 3, 2020 (the "Lilly Termination Date"). Effective as of the Lilly Termination Date, both parties have been relieved of all obligations under the agreement, including future quarterly research and development support payments to be paid by Lilly to the Company.

As of December 31, 2019, the Company had deferred revenue related to the Lilly Agreement of $22.4 million, which is composed of a non-refundable up-front payment and a premium on the proceeds from Lilly's investment in the Company. The Company will recognize all of the deferred revenue as of the Lilly Termination Date in the statement of operations in the first quarter of 2020.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2019. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be contained in our definitive proxy statement for our 2020 annual meeting of stockholders, or our Proxy Statement, to be filed with the SEC within 120 days of December 31, 2019, and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item will be contained in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item will be contained in the Proxy Statement and is incorporated herein by reference.

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

The information required by this Item will be contained in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item will be contained in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this report:

(1) Financial Statements

See Index to Financial Statements in Part II Item 8 of this Annual Report.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable, or the required information is shown in the financial statements or notes thereto.

(3) Exhibits

The documents listed in the following Exhibit Index are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with Company's Current Report on 8-K filed with the Commission on May 13, 2019 (File No. 001-38905)).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 filed with Company's Current Report on 8-K filed with the Commission on May 13, 2019 (File No. 001-38905)).
4.1	Amended and Restated Investors' Rights Agreement, dated as of November 5, 2018, by and among the Company and the investors party thereto (incorporated by reference to Exhibit 4.1 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
4.2	Description of Registered Securities.
10.1†	License Agreement, dated as of December 29, 2015, by and between the Company and Yale University (incorporated by reference to Exhibit 10.1 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.2†	Corporate Sponsored Research Agreement, dated as of December 29, 2015, by and between the Company and Yale University (incorporated by reference to Exhibit 10.2 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.3+	NextCure, Inc. 2015 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.6 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.4+	Form of Stock Option Agreement under the NextCure, Inc. 2015 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.7 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).

10.5+	NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.8 filed with Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)).
10.6+	Forms of Stock Option Agreement under the NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.9 filed with Company's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)).
10.7+	Form of Restricted Stock Agreement under the NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.10 filed with Company's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)).
10.8+	Form of Restricted Stock Unit Agreement under the NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.11 filed with Company's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)).
10.9+	NextCure, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.12 filed with Company's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)).
10.10+	Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.13 filed with Company's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)).
10.11+	Form of Indemnification Agreement by and between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.5 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.12+	Employment Letter, dated as of September 12, 2016, by and between the Company and Michael Richman (incorporated by reference to Exhibit 10.15 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.13+	Employment Letter, dated as of December 18, 2017, by and between the Company and Steven P. Cobourn (incorporated by reference to Exhibit 10.16 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.14+	Employment Letter, dated as of September 12, 2016, by and between the Company and Sol Langermann, Ph.D. (incorporated by reference to Exhibit 10.17 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.15†	Lease Agreement, dated as of January 30, 2019, by and between the Company and ARE-8000/9000/10000 Virginia Manor, LLC (incorporated by reference to Exhibit 10.14 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
10.16†	First Amendment to Lease Agreement, dated August 2, 2019, by and between the Company and ARE-8000/9000/10000 Virginia Manor, LLC (incorporated by reference to Exhibit 10.1 filed with Company's Quarterly Report on Form 10-Q filed on November 12, 2019 (File No. 001-38905)).
10.17†	Amended and Restated Sublease Agreement, dated as of March 15, 2019, by and between the Company and Lupin, Inc. (incorporated by reference to Exhibit 10.4 filed with Company's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
31.1	Certification of Michael Richman pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2	Certification of Steven P. Cobourn pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Michael Richman and Steven P. Cobourn pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
EX-101.LAB	XBRL Taxonomy Extension Label Linkbase Document
EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates a management contract or compensatory plan.
† Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

NEXTCURE, INC.

Date: March 12, 2020

By: /s/ Michael Richman
Name: Michael Richman
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Michael Richman Michael Richman	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 12, 2020
/s/ Steven P. Cobourn Steven P. Cobourn	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 12, 2020
/s/ David Kabakoff, Ph.D. David Kabakoff, Ph.D.	Chair of the Board	March 12, 2020
/s/ Elaine V. Jones, Ph.D. Elaine V. Jones, Ph.D.	Director	March 12, 2020
/s/ Chau Q. Khuong Chau Q. Khuong	Director	March 12, 2020
/s/ Judith J. Li Judith J. Li	Director	March 12, 2020
/s/ Briggs Morrison, M.D. Briggs Morrison, M.D.	Director	March 12, 2020
/s/ Tim Shannon, M.D. Tim Shannon, M.D.	Director	March 12, 2020
/s/ Stephen Webster Stephen Webster	Director	March 12, 2020
/s/ Stella Xu Stella Xu	Director	March 12, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of the end of the period covered by the Annual Report on Form 10-K of which this exhibit forms a part, the only class of securities of NextCure, Inc. ("we" and "our") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is our common stock, $0.001 par value per share.

COMMON STOCK

The following summary describes our common stock and certain provisions of our amended and restated certificate of incorporation, our amended and restated bylaws, our amended and restated investors' rights agreement and the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, our amended and restated bylaws and our amended and restated investors' rights agreement, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and the applicable provisions of the Delaware General Corporation Law.

General

Our amended and restated certificate of incorporation authorizes 100,000,000 shares of common stock, $0.001 par value per share.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of our stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of our directors. In addition, the affirmative vote of holders of 66 2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, such as the provisions relating to the classified board.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Other Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. For example, the issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation.

Registration Rights

Under the terms of our amended and restated investors' rights agreement, the holders of certain shares of common stock, or their transferees, have the right to require us to register their shares under the Securities Act of 1933, as amended, or the Securities Act, so that those shares may be publicly resold, and the right to include their shares in any registration statement we file subject to certain limitations. These rights will expire, with respect to any particular stockholder, upon the earlier of May 13, 2024 and when that stockholder can sell all of its shares under Rule 144 under the Securities Act without limitation during any three-month period without registration.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Amended and Restated Bylaws and Delaware Law

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly traded Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could have the effect of delaying, deferring, preventing or otherwise impeding any attempt to change control of us.

Special Stockholder Meetings

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that a special meeting of stockholders may be called only by or at the direction of our board of directors or by the Chair of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies; Board Size

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors are elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock. Any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by a resolution of our board of directors unless our board of directors determines that such vacancies shall be filled by our stockholders. Furthermore, the authorized number of directors may be changed only by a resolution of our board of directors. This system of electing and removing directors, filling vacancies and fixing the size of our board may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated bylaws provide that unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware or, if subject matter jurisdiction of such action is vested exclusively in the federal courts, the United States District Court for the District of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or the bylaws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery or the United States District Court for the District of Delaware, as applicable, having personal jurisdiction over the indispensable parties named as defendants therein. In addition, any person holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to this provision of our bylaws. The choice of forum provision does not apply to any actions arising under the Securities Act or the Exchange Act. Although our amended and restated bylaws contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

Amendment of Charter Provisions

The amendment of any of the above provisions that are in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue undesignated preferred stock, would require approval by a stockholder vote by the holders of at least a 662/3% of the voting power of our then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “NXTC”.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar’s address is 6201 15th Avenue, Brooklyn, New York 11219.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-8 No. 333-231438) pertaining to the NextCure, Inc. 2019 Employee Stock Purchase Plan; and

(2) Registration Statement (Form S-8 No. 333-231436) pertaining to the NextCure, Inc. 2015 Omnibus Incentive Plan and the NextCure, Inc. 2019 Omnibus Incentive Plan;

of our report dated March 12, 2020, with respect to the financial statements of NextCure, Inc. included in this Annual Report (Form 10-K) of NextCure, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Baltimore, Maryland
March 12, 2020

EXHIBIT 31.1

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Michael Richman, certify that:

1. I have reviewed this annual report on Form 10-K of NextCure, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

   (c) 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 12, 2020

/s/ Michael Richman
Name: Michael Richman
Title: President and Chief Executive Officer

EXHIBIT 31.2

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Steven P. Cobourn, certify that:

1. I have reviewed this annual report on Form 10-K of NextCure, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

   (c) 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 12, 2020

/s/ Steven P. Cobourn
Name: Steven P. Cobourn
Title: Chief Financial Officer

EXHIBIT 32.1

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 of NextCure, Inc. (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned each hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge, on the date hereof:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) 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.

Dated: March 12, 2020

/s/ Michael Richman
Name: Michael Richman
Title: President and Chief Executive Officer

Dated: March 12, 2020

/s/ Steven P. Cobourn
Name: Steven P. Cobourn
Title: Chief Financial Officer