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As filed with the Securities and Exchange Commission on November 12, 2019

Registration No. 333-

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## NextCure, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

(Primary Standard Industrial Classification Code Number) **47-5231247** (I.R.S. Employer Identification Number)

9000 Virginia Manor Road, Suite 200 Beltsville, Maryland 20705 (240) 399-4900

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Michael Richman Chief Executive Officer NextCure, Inc. 9000 Virginia Manor Road, Suite 200 Beltsville, Maryland 20705 (240) 399-4900

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering, o

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting 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 7(a)(2)(B) of the Securities Act. o

#### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee
Common stock, \$0.001 par value per share	\$143,593,600.00	\$18,638.45

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act and includes the aggregate offering price of shares that the underwriters have an option to purchase.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATE NOVEMBER 12, 2019

3,200,000 Shares



NextCure, Inc.

Common Stock

NextCure, Inc. is offering 3,200,000 shares of common stock.

Our common stock is listed on the Nasdaq Global Select Market under the symbol "NXTC". On November 11, 2019, the last reported sale price of our common stock on the Nasdaq Global Select Market was \$39.02 per share. The final public offering price will be determined through negotiation between us and the lead underwriters in the offering and the recent market price used throughout the prospectus may not be indicative of the actual offering price.

We are an "emerging growth company" as defined under U.S. federal securities laws and will be subject to reduced public company reporting requirements. Investing in our common stock involves risks. See "Risk Factors" beginning on page 13.

	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discounts and Commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

<sup>(1)</sup> We refer you to "Underwriters" for additional information regarding total underwriter compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 480,000 shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about , 2019.

Joint Book-Running Managers

MORGAN STANLEY BofA SECURITIES PIPER JAFFRAY

Co-Managers

NEEDHAM & COMPANY BTIG

The date of this prospectus is , 2019

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Neither we nor any of the underwriters has authorized anyone to provide you any information that is different than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States must inform themselves about, and observe any restrictions as to, this offering and the distribution of this prospectus applicable to that jurisdiction.

#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should read this entire prospectus carefully, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes contained elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the "company," "NextCure," "we," "us" and "our" refer to NextCure, Inc.

#### 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 at the Society for Immunotherapy of Cancer, or 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. 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. We expect to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for NC410 in the first 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, 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 dysfunction that allows tumors to evade the immune system. We are seeking 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.

The advancement of cancer to late stages indicates a failure of the immune system to mount an effective anti-tumor immune response. Immuno-oncology, which focuses on stimulating the immune system to respond to cancer and includes checkpoint inhibitors targeting PD-L1, PD-1 and CTLA-4, is one of the most significant advances in the history of cancer treatment. In 2011, the first checkpoint inhibitor was approved, and today, despite only a modest breadth of efficacy, this class of therapies is estimated to have had global sales of more than \$17 billion in 2018 and is predicted to reach more than \$33 billion in

global sales by 2022. However, despite the recent success of 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, non-small cell lung cancer, or NSCLC, urothelial cancer and head and neck squamous cell carcinoma, do not respond to single-agent therapy with checkpoint inhibitors. In addition, some patients develop resistance after initial treatment with these therapies. As a result, the standard of care in cancer today leaves many patients underserved. We believe broader efficacy and more meaningful clinical responses in oncology may be obtained by focusing on the tumor microenvironment, or TME.

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.

In November 2018, we entered into a multi-year collaboration agreement with Eli Lilly and Company, or Lilly, focused on the discovery and development of immunomedicines for oncology using our FIND-IO platform. The collaboration seeks to discover novel cancer targets utilizing our platform and provides that we and Lilly will each receive options to exclusively develop antibodies resulting from the collaboration. In connection with the agreement, we received an upfront payment of \$25.0 million in cash and an equity investment of \$15.0 million and are eligible to receive development and regulatory milestones and sales milestones in an aggregate of up to \$1.4 billion, as well as royalty payments.

#### **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 Programs**

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 by Dr. 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 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 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.

In preclinical studies, we evaluated the safety and efficacy of 5G12, the murine parent antibody of NC318, which has similar overall functional properties to NC318, and observed that blocking the effects of S15 with 5G12 restored immune function and anti-tumor immunity, reduced tumor growth and increased survival.

Our 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 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 administration schedules depending on pharmacokinetics, pharmacodynamics, biomarker data, safety results and feedback from investigators. We designed this clinical trial with a robust biomarker strategy to help evaluate clinical activity throughout the

trial by focusing on markers of pharmacodynamics. We are initially evaluating NC318 for the treatment of advanced or metastatic solid tumors, including NSCLC, ovarian cancer, head and neck squamous cell carcinoma and triple-negative breast cancer, or TNBC.

We completed enrollment of the Phase 1 portion of the trial in August 2019 and have dosed 49 patients across seven dose cohorts between 8 mg and 1,600 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 September 26, 2019, the cutoff date of the data discussed by the NC318 trial investigator at the SITC annual meeting, tumor responses were evaluable in 45 patients, and four patients had not yet been assessed. Treatment-related adverse events experienced by more than 5% of patients as of that date were diarrhea (16%), infusion reactions (8%), fatigue (6%), headaches (6%), pruritis (6%), elevated amylase (8%) and elevated lipase (6%).

As of November 9, 2019, NC318 has 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, was observed. Treatment-related adverse events experienced by more than 5% of patients as of that date continued to be 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 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). 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 remains ongoing at 55 weeks, and one partial response, which remains ongoing at 28 weeks, both in NSCLC patients, as well as 14 patients with stable disease, which remain ongoing for between 16 and 42 weeks. Among those 14 patients, four patients have NSCLC, with stable disease ongoing for between 16 and 40 weeks. Three NSCLC patients (out of 13 NSCLC patients in total) have 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, based on tumor bank analyses, have been shown to have elevated S15 expression, including NSCLC, ovarian cancer, head and neck squamous cell carcinoma and TNBC. We expect to announce initial data from the Phase 2 portion of the trial by the end of 2020.

In the first half of 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.

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.

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 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 currently conducting IND-enabling studies for NC410 and expect to submit an IND and initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the first quarter of 2020. We are currently focused on opportunities for NC410 in ovarian cancer, NSCLC and renal cancer.

In addition to NC318 and NC410, we are also pursuing discovery and 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. 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 addition, 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 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 is the result of our industrialization, expansion and optimization of a predecessor platform that Dr. Chen used to discover the immunosuppressive properties of S15. 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, proteins or other molecules through the FIND-IO platform, we aim to develop next-generation immunomedicines that restore normal immune function in the TME.

## **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.
- Building an oncology pipeline of novel targets for new immunomedicines focused on non-responders.
- Leveraging our fully integrated development, quality systems and cGMP manufacturing capabilities.
- Expanding our current focus and creating new opportunities outside of the oncology field, including through strategic partnerships.

#### **Our Team**

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 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 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. In December 2015, we entered into a license agreement with Yale, 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 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, our partnership with Lilly and our relationship with Dr. Chen and Yale positions us to build a sustainable portfolio of first-in-class immunomedicines.

#### **Risks Associated with Our Business**

Our ability to implement our business strategy is subject to numerous risks and uncertainties. You should carefully consider all of the information set forth in this prospectus and, in particular, the information in the section entitled "Risk Factors" beginning on page 13 before making an investment decision. Risks include, among others, the following:

- 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.
- Even with the expected net proceeds from this offering, 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, commercial efforts or other operations.
- 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.

- Our approach to the discovery and development of product candidates based on our FIND-IO platform is unproven and may not result in marketable products.
- 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.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and we may ultimately be unable to obtain regulatory approval for our product candidates.
- 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.
- 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.
- Given our limited operating history, our manufacturing experience as an organization and with our manufacturing facility is limited.
- 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.
- We may depend on Lilly, Yale or other third-party collaborators for the discovery, development and commercialization 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 face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

For additional information about the risks we face, see the section entitled "Risk Factors."

## **Corporate Information**

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. Our website address is *www.nextcure.com*. The information contained on, or that can be accessed through, our website is not part of this prospectus and should not be considered as part of this prospectus or in deciding whether to purchase our common stock.

NextCure, FIND-IO and our logo are some of our trademarks used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus may appear without the ® and TM symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and tradenames.

### Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, as such, we have elected to comply with certain reduced public company reporting requirements for our filings, including this prospectus.

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, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise 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.

We are also a "smaller reporting company" and will remain a smaller reporting company while either (i) the market value of our stock held by non-affiliates was less than \$250 million as of the last business day of our most recently completed second fiscal quarter or (ii) our annual revenue was less than \$100 million during our most recently completed fiscal year and the market value of our stock held by non-affiliates was less than \$700 million as of the last business day of our most recently completed second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies, including many of the same exemptions from disclosure requirements as those that are available to emerging growth companies, such as reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not smaller reporting companies.

#### THE OFFERING

Common stock offered by us

3,200,000 shares

Common stock to be outstanding immediately after this offering

25,939,345 shares (or 26,419,345 shares if the underwriters exercise their option to purchase additional shares in full)

Option to purchase additional shares offered by us

480,000 shares

Use of proceeds

We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately \$116.5 million, or approximately \$134.1 million if the underwriters exercise their option to purchase additional shares in full, assuming an offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, to advance NC318 (i) through completion of our ongoing Phase 1/2 clinical trial, (ii) through completion of our planned Phase 2 combination clinical trial, (iii) through completion of additional Phase 2 clinical trials and (iv) into Phase 3 clinical trials, as well as to develop a complementary diagnostic for NC318 if we determine it is advisable.

We also intend to use net proceeds and our existing cash, cash equivalents and marketable securities (i) to expand our cGMP manufacturing capacity, including to provide drug supply of NC318 for future clinical trials, (ii) to advance NC410 through completion of a Phase 1/2 clinical trial and into future clinical development, (iii) for research and development activities related to our FIND-IO platform and discovery programs, including advancement of two discovery programs through submission of INDs and (iv) for personnel expenses, working capital and other general corporate purposes.

See the section entitled "Use of Proceeds" on page 67 for a more complete description of the intended use of proceeds from this offering.

Risk factors

You should carefully read the section entitled "Risk Factors" on page 13 for a discussion of factors that you should consider before deciding to invest in shares of our common stock.

Nasdaq Global Select Market symbol

"NXTC"

The number of shares of common stock to be outstanding after this offering is based on 22,739,345 shares of common stock outstanding as of September 30, 2019, which includes 114,875 shares of restricted common stock that were unvested or subject to repurchase at September 30, 2019 and excludes:

- 2,248,953 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2019, with a weighted average exercise price of \$6.30 per share;
- 2,653,969 shares of our common stock available for future issuance under our 2019 Omnibus Incentive Plan, or the 2019 Plan, as of September 30, 2019; and
- 240,000 shares of our common stock reserved for future issuance under our 2019 Employee Stock Purchase Plan, or the ESPP, as of September 30, 2019.

In addition, unless we specifically state otherwise, all information in this prospectus reflects or assumes:

- no exercise of outstanding stock options subsequent to September 30, 2019; and
- no exercise by the underwriters of their option to purchase up to an additional 480,000 shares of our common stock in this offering.

Unless we specifically state otherwise and unless the context requires, we refer to our previously outstanding Series A-1, Series A-2, Series A-3, Series B-1, Series B-2 and Series B-3 Preferred Stock collectively as "preferred stock" in this prospectus.

#### SUMMARY FINANCIAL DATA

The following tables present summary financial data for our business. We derived the statement of operations and comprehensive loss data for the years ended December 31, 2018 and 2017 from our audited financial statements appearing elsewhere in this prospectus. We derived the statement of operations data for the six months ended September 30, 2019 and 2018 and the balance sheet data as of September 30, 2019 from our unaudited condensed financial statements appearing elsewhere in this prospectus. These unaudited condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in management's opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair statement of such financial data. Our historical results are not necessarily indicative of the results that may be expected in any future period. You should read the following data together with our financial statements and the related notes, as well as the information included in the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

		Nine Months Ended September 30,			Year Ended I	mber 31,		
		2019		2018		2018		2017
	(unaudited) (in thousands, except share and per share amounts)					is)		
Statement of Operations Data:								
Revenue:								
Revenue from research and development arrangement	\$	4,342	\$	_		_		_
Operating expenses:								
Research and development	\$	22,819	\$	13,539	\$	19,787	\$	12,954
General and administrative		6,995		2,590		3,409		2,595
Total operating expenses		29,814		16,129		23,196		15,249
Loss from operations		(25,472)		(16,129)		(23,196)		(15,549)
Other income, net		2,662		192		397		80
Net loss	\$	(22,810)	\$	(15,937)	\$	(22,799)	\$	(15,469)
Net loss per common share, basic and diluted <sup>(1)</sup>	\$	(1.81)	\$	(11.64)	\$	(16.64)	\$	(11.30)
Weighted average number of common shares, basic and $\operatorname{diluted}^{(1)}$	_	12,609,219	_	1,369,212	_	1,369,846	_	1,369,212

<sup>(1)</sup> See Note 12 to our audited financial statements and Note 8 to our unaudited condensed financial statements included elsewhere in this prospectus for further details on the calculations of our basic and diluted net loss per share and the weighted average number of shares used in the computation of the per share amounts.

The table below presents our balance sheet data as of September 30, 2019:

- on an actual basis;
- on an as adjusted basis to give effect to the sale of 3,200,000 shares of common stock in this offering, assuming an offering price of \$39.02 per share, which is the last reported sale price of our

common stock on the Nasdaq Global Select Market on November 11, 2019, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of September 30, 2019				
	Actual As Adjusted (unaudited) (in thousands)			d)	
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	\$	184,082	\$	300,588	
Working capital <sup>(2)</sup>		176,541		293,047	
Total assets		205,124		321,630	
Total liabilities		34,475		34,475	
Preferred stock		_		_	
Accumulated deficit		(70,107)		(70,107)	
Total stockholders' equity		170,649		287,155	

- (1) The as adjusted information is illustrative only and will depend on the actual public offering price and the other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, would increase or decrease, respectively, our as adjusted amounts of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by \$3.0 million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1.0 million in the number of shares we are offering in this offering would increase or decrease, respectively, our as adjusted amounts of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by \$36.7 million, assuming the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (2) We define working capital as current assets less current liabilities.

#### 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 prospectus, 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 \$22.8 million for the year ended December 31, 2018 and the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of \$70.1 million. We have funded our operations to date primarily with proceeds from the sale of preferred stock, upfront fees received in connection with the Lilly agreement and proceeds from the sale of our common stock in connection with our initial public offering, or IPO. 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 quarter to quarter. 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 current good manufacturing practice, or 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 Lilly or 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 our 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 existing or 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 the INDs for NC410 and 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.

Even with the expected net proceeds from this offering, 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 success of our collaboration with Lilly, including whether Lilly exercises its licensing options under its collaboration agreement with us, each of which would trigger additional payments to us;
- 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 our corporate sponsored research agreement, or SRA, with Yale University;
- 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 September 30, 2019, we had \$184.1 million in cash, cash equivalents and marketable securities. Based on our research and development plans, we expect that the net proceeds from this offering, together with 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 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 additional sales of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. See the section entitled "Dilution" for a more detailed description of the dilution to investors in the offering. 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 our second product candidate, NC410, is in preclinical development. 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, including NC318 and NC410, 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 the INDs for NC410 and 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 Risk Evaluation and Mitigation Strategy, or 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;
- 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 biologics license application, or 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 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 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.

In addition, 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, Institutional Review Boards, or 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 and competition from other clinical trial programs for similar indications and clinical trial subjects;
- 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; and
- 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.

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 Data Safety Monitoring Board, or 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. Further, 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.

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 discovery 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 Lilly or 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.

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, or meet our obligations under the Lilly Agreement.

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 have been 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.

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; and
- 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.

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 of difficulties in patient enrollment may result in increased costs or may affect the timing, outcome or completion of clinical trials, which would adversely affect our ability to advance the development of the product candidates we develop.

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 smaller 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.

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 good clinical practices requirements, or 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 such 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 expect to rely 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.

Complementary or 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. 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; 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 systems and infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. 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 the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, and its implementing rules and regulations, as well a

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 change frequently, 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, in March 2010, 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, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products 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 now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by President Trump's administration to repeal or replace certain aspects of the ACA, and to alter the implementation of the ACA and related laws. 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 repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, the President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Also, in 2018, the Centers for Medicare and Medicaid Services, or 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. In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the entire ACA is unconstitutional because the tax penalty associated with the "individual mandate" was repealed by Congress as part of the Tax Act. This ruling is under appeal and stayed pending appeal. While the United States District Court Judge for the Northern District of Texas, as well as the Trump Administration and CMS, have stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals and other efforts to invalidate the ACA, regulations promulgated under the ACA and related laws, or portions thereof will impact the ACA, its implementation and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. 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 reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

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 that legislators intend 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. The Trump Administration's budget proposals for fiscal 2019 and 2020 contain drug price control measures, including measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. For example, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase

manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or 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 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.

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 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 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective
  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. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties
  directly applicable to business associates and

gave state attorneys general new 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;

- 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 and/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 filing our IND for 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. If one or more of our product candidates progress to late-stage development, we may incur additional significant expenses in the further expansion and/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, natural disasters, power failures 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 U.S. Patent and Trademark Office, or 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 and/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 and/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 reexamination, 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 pe

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 and/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 the regulatory requirements known as current good laboratory practice, or 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, 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 Lilly, 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.

In November 2018, we entered into the Lilly Agreement, which is focused on using our FIND-IO platform to identify novel oncology targets for additional research and drug discovery by ourselves and Lilly. Pursuant to the Lilly Agreement, we granted Lilly the exclusive right to obtain worldwide exclusive licenses to research, develop, manufacture and commercialize compounds and products directed to

oncology targets identified through our research collaboration. Lilly will have the exclusive ability to control the development and commercialization of any targets it chooses to license on a global basis. Our lack of control over the clinical development of certain programs under the Lilly Agreement could result in delays or other difficulties in the development and commercialization of product candidates. Our right to receive certain milestone and royalty payments may be subsequently delayed, if we receive any at all. In the event Lilly terminates the Lilly Agreement, we would be prevented from receiving any milestone payments, royalty payments and other benefits under that agreement, which would have a materially adverse effect on our results of operations. Furthermore, in the event Lilly does not purchase and exercise any of its options, we will not be eligible to receive any future milestone payments under the Lilly Agreement, which could require us to seek additional funding in order to avoid delaying, reducing the scope of, or suspending, one or more of our research and development programs or clinical trials.

We have also entered into the SRA with Yale in which we agreed to provide funding for a research program aimed at discovering new targets for immunomedicines. We have and would expect 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 of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new product candidates.

If 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.

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 our 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 September 30, 2019, we had federal and state net operating loss carryforwards of \$43.5 million and \$43.0 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, including this offering, 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.

#### Risks Related to Our Common Stock and this Offering

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 the public offering price, or at all

Prior to our 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 the public offering price or at the time that you would like to sell.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

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 the public offering 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.

#### If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The public offering price of our common stock is substantially higher than the as adjusted net tangible book value per share of our common stock. Therefore, if you purchase our common stock in this offering, you will pay a price per share that substantially exceeds the as adjusted net tangible book value per share after the closing of this offering. To the extent outstanding options to purchase shares of our common stock are exercised, you will incur further dilution. Based on the assumed public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, and our net tangible book value as of September 30, 2019, you will experience immediate dilution of \$27.96 per share, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the assumed public offering price. See the section entitled "Dilution" for a more detailed description of the dilution to investors in the offering.

## 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 September 30, 2019, we had outstanding a total of 22,739,345 shares of common stock.

The resales of 10,889,633 shares of our common stock are subject to lock-up agreements pertaining to this offering that will expire 90 days from the date of this prospectus, subject to earlier release of all or a portion of the shares subject to such agreements by the underwriters in this offering. After the lock-up agreements expire, substantially all of the shares of common stock outstanding prior to this offering will be eligible for sale in the public market, subject to the applicable volume, manner of sale and other limitations imposed under the federal securities laws.

We have registered 5,167,502 shares of common stock on Registration Statements on Forms S-8 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 and the lock-up agreements described above. 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 6,336,439 shares, or approximately 27.87%, of our common stock outstanding as of September 30, 2019 are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. See "Description of Capital Stock—Registration Rights." 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 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.

See the section entitled "Principal Stockholders" for more information regarding the ownership of our outstanding common stock by our executive officers, directors and their affiliates.

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 this prospectus and 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 have broad discretion in how we use the net proceeds from this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not use the net proceeds from this offering in ways that ultimately increase the value of your investment. If we do not use these proceeds in ways that enhance stockholder value, we may fail to achieve expected financial results or cause delays to our clinical development timelines, which could cause our stock price to decline.

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, which we anticipate could be between \$2.5 million and \$4.5 million annually. 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.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this prospectus. 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. These 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;
- 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, Dr. Lieping Chen and Lilly;
- our estimates regarding our expenses, future revenues, capital requirements and our needs for or ability to obtain additional financing and the period over which we expect the proceeds of this offering, together with 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;
- the impact of current and future laws and regulations; and
- our intended use of proceeds from this offering.

These 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. We discuss many of these risks in greater detail in the section entitled "Risk Factors" and elsewhere in this prospectus. While we believe that our internal expectations, estimates, forecasts and projections are reasonable, no independent source has verified such expectations, estimates, forecasts and projections, as a result we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Accordingly, you should not rely upon forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date of this prospectus, and except as required by law, after the date of this prospectus, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by the foregoing cautionary statements.

#### **USE OF PROCEEDS**

We estimate that the net proceeds from the sale of shares of our common stock in this offering will be approximately \$116.5 million, or approximately \$134.1 million if the underwriters exercise their option to purchase additional shares in full, assuming a public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, would increase or decrease, respectively, the net proceeds from this offering by approximately \$3.0 million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease, respectively, the net proceeds from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$36.7 million, assuming the public offering price remains the same. We do not expect that a change in the public offering price or the number of shares offered by us by these amounts would have a material effect on our intended use of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

As of September 30, 2019, we had \$184.1 million in cash, cash equivalents and marketable securities, excluding restricted cash. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, as follows:

- approximately \$160.7 million to \$184.8 million to advance NC318 through completion of our ongoing Phase 1/2 clinical trial, our planned Phase 2 clinical trial in combination with chemotherapies in patients with advanced or metastatic solid tumors and additional Phase 2 clinical trials and into Phase 3 clinical trials, as well as to develop a complementary diagnostic for NC318 if we determine it is advisable;
- approximately \$14.3 million to \$16.4 million to expand our cGMP manufacturing capacity, including to provide the drug supply for future clinical trials of NC318;
- approximately \$56.1 million to \$64.5 million to advance NC410 through completion of a Phase 1/2 clinical trial and into future clinical development; and
- the remainder for research and development activities related to our FIND-IO platform and discovery programs, including advancement of additional discovery programs into clinical development, personnel expenses, working capital and other general corporate purposes.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of our research and development activities may vary significantly depending on numerous factors, including the progress of our development efforts, the timing and costs associated with the manufacture and supply of any of our product candidates and any unforeseen cash needs. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

Pending the uses described above, we intend to invest the net proceeds from this offering in interest-bearing, investment-grade securities, certificates of deposit or government securities.

We believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from this offering, 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. After this offering, we will require substantial additional capital in order to continue to advance NC318, NC410 and future product candidates through preclinical studies, clinical trials, regulatory approval and commercialization.

# DIVIDEND POLICY

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.

# CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and our capitalization as of September 30, 2019:

- · on an actual basis; and
- on an as adjusted basis to give effect to the sale of 3,200,000 shares of common stock in this offering, assuming a public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes and other financial information appearing elsewhere in this prospectus.

		As of Sept 20	er 30,						
	_	Actual (unau	dited						
		share and	isands, except and per share mounts)						
Cash, cash equivalents and marketable securities	\$	184,082	\$	300,588					
Term loan	\$	5,000	\$	5,000					
Stockholders' equity:									
Common stock, par value \$0.001 per share—100,000,000 shares authorized, 22,739,345 shares									
issued and outstanding, actual; 25,939,345 shares issued and outstanding, as adjusted		23		26					
Preferred stock, par value \$0.001 per share—10,000,000 shares authorized, no shares issued or									
outstanding, actual and as adjusted		_		_					
Additional paid-in capital		240,791		357,294					
Accumulated other comprehensive loss		(58)		(58)					
Accumulated deficit		(70,107)		(70,107)					
Total stockholders' (deficit) equity		170,649		287,155					
Total capitalization	\$	175,649	\$	292,155					

<sup>(1)</sup> The as adjusted information is illustrative only and will depend on the actual public offering price and the other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, would increase or decrease, respectively, our as adjusted amounts of cash, cash equivalents and marketable securities, additional paid-in capital, total assets and total stockholders' equity and total capitalization by \$3.0 million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1.0 million in the number of shares we are offering in this offering would increase or decrease, respectively, our as adjusted amounts of cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization by \$36.7 million, assuming the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The actual and as adjusted information set forth in the table above excludes the following:

- 2,248,953 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2019, with a weighted average exercise price of \$6.30 per share;
- 2,653,969 additional shares of our common stock available for future issuance under the 2019 Plan as of September 30, 2019; and
- 240,000 shares of our common stock reserved for future issuance under our ESPP as of September 30, 2019.

### DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering.

As of September 30, 2019, we had a historical net tangible book value of \$170.6 million, or \$7.50 per share of our common stock. Our net tangible book value per share represents total tangible assets less total liabilities divided by the number of shares of common stock outstanding on September 30, 2019, including 114,875 shares of restricted common stock that were unvested or subject to repurchase.

After giving effect to the sale of 3,200,000 shares of common stock in this offering, assuming a public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2019 would have been \$287.0 million, or \$11.06 per share. This represents an immediate increase in net tangible book value of \$3.57 per share to existing stockholders and an immediate dilution of \$27.96 per share to new investors participating in this offering. The following table illustrates this per share dilution to new investors:

Assumed public offering price per share		\$ 39.02
Historical net tangible book value per share as of September 30, 2019	\$ 7.50	
Increase in net tangible book value per share attributable to investors participating in this offering	3.57	
As adjusted net tangible book value per share after this offering	<u> </u>	11.06
Dilution per share to new investors participating in this offering		\$ 27.96

The as adjusted information is illustrative only and will depend on the actual public offering price and the other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, would increase or decrease, respectively, our as adjusted net tangible book value as of September 30, 2019 after this offering by \$4.2 million, or \$0.16 per share, and would increase or decrease, respectively, dilution to investors in this offering by \$0.84 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase of 1.0 million in the number of shares we are offering in this offering would increase our as adjusted net tangible book value as of September 30, 2019 after this offering by \$36.7 million, or \$1.36 per share, and would decrease dilution to investors in this offering by \$0.95 per share, and a decrease of 1.0 million in the number of shares we are offering in this offering would decrease our as adjusted net tangible book value as of September 30, 2019 after this offering by \$36.7 million, or \$1.47 per share, in each case each assuming the assumed public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase 480,000 additional shares of our common stock in full, the as adjusted net tangible book value after this offering would be \$11.74 per share, the increase in net tangible book value per share would be \$0.68 and the dilution per share to new investors would be \$27.28 per share, assuming a public offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock reflected in this discussion is based on 22,739,345 shares of our common stock outstanding as of September 30, 2019, which gives effect to the adjustments described above and excludes:

- 2,248,953 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2019, with a weighted average exercise price of \$6.30 per share;
- 2,653,969 additional shares of our common stock available for future issuance under the 2019 Plan as of September 30, 2019; and
- 240,000 shares of our common stock reserved for future issuance under the ESPP as of September 30, 2019.

# SELECTED FINANCIAL DATA

The following tables present our selected financial data for the periods and as of the dates indicated. We derived the statement of operations and comprehensive loss data for the years ended December 31, 2018 and 2017 and the balance sheet data as of December 31, 2018 and 2017 from our audited financial statements appearing elsewhere in this prospectus. We derived the statement of operations data for the nine months ended September 30, 2019 and 2018 and the balance sheet data as of September 30, 2019 from our unaudited condensed financial statements appearing elsewhere in this prospectus. These unaudited condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in management's opinion, contain all adjustments, consisting of normal and recurring adjustments, necessary for the fair statement of such financial data. Our historical results are not necessarily indicative of the results that may be expected in any future period. You should read the following data together with our financial statements and the related notes appearing elsewhere in this prospectus and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the audited financial statements and the related notes appearing elsewhere in this prospectus.

		Nine Mont Septeml				Year Ended December 31,				
		2019		2018		2018		2017		
		(unaud						_		
		(in thou	sanc	ls, except share	an	d per share am	ount	ts)		
Statement of Operations Data:										
Revenue:										
Revenue from research and development arrangement	\$	4,342	\$	_		_				
Operating expenses:										
Research and development	\$	22,819	\$	13,539	\$	19,787	\$	12,954		
General and administrative		6,995		2,590		3,409		2,595		
Total operating expenses		29,814		16,129		23,196		15,249		
Loss from operations		(25,472)		(16,129)		(23,196)		(15,549)		
Other income, net		2,662		192		397		80		
Net loss	\$	(22,810)	\$	(15,937)	\$	(22,799)	\$	(15,469)		
Net loss per common share, basic and diluted <sup>(1)</sup>	\$	(1.81)	\$	(11.64)	\$	(16.64)	\$	(11.30)		
Weighted average number of common shares, basic and $\operatorname{diluted}^{(1)}$	_	12,609,219		1,369,212	_	1,369,846	_	1,369,212		

<sup>(1)</sup> See Note 12 to our audited financial statements and Note 8 to our unaudited condensed financial statements included elsewhere in this prospectus for further details on the calculations of our basic and diluted net loss per share and the weighted average number of shares used in the computation of the per share amounts.

The table below presents our balance sheet data as of September 30, 2019:

- on an actual basis;
- on an as adjusted basis to give effect to the sale of 3,200,000 shares of common stock in this offering, assuming an offering price of \$39.02 per share, which is the last reported sale price of our common stock on the Nasdaq Global Select Market on November 11, 2019, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

		As of	As of Dec	ember 31,
		nber 30, 2019 naudited)	2018	2017
	(u		housands)	
Balance Sheet Data				
Cash, cash equivalents and marketable securities	\$	184,082	\$ 135,173	\$ 8,427
Working capital <sup>(1)</sup>		176,541	125,487	6,296
Total assets		205,124	147,628	19,467
Total liabilities		34,475	32,349	3,879
Preferred stock		_	162,223	40,000
Accumulated deficit		(70,107)	(47,297)	(24,498)
Total stockholders' (deficit) equity		170,649	(46,944)	(24,412)

<sup>(1)</sup> We define working capital as current assets less current liabilities.

# 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 section entitled "Selected Financial Data" and our financial statements and the related notes appearing elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements, such as statements of our plans, objectives, expectations and intentions, that 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 section entitled "Risk Factors."

### 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 was presented at the Society for Immunotherapy of Cancer, or 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. We expect 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 the first half of 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, or LAIR-1. We expect to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for NC410 in the first quarter of 2020.

On May 13, 2019, we closed our IPO, in which we sold 5,750,000 shares of our common stock, at a public offering price of \$15.00 per share, for aggregate gross proceeds of \$86.3 million.

### **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, 2018 and 2017 were \$22.8 million and \$15.5 million, respectively, and our net losses for the nine months ended September 30, 2019 and 2018

were \$22.8 million and 15.9 million, respectively. As of September 30, 2019, we had an accumulated deficit of \$70.1 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 the sale of preferred stock, proceeds from our multi-year research collaboration and development agreement with Eli Lilly and Company, or Lilly, and proceeds from our IPO. From our inception through September 30, 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 a multi-year research and development collaboration agreement with Lilly, or the Lilly Agreement, pursuant to which we will use our FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by us and Lilly. Under this 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. In addition, Lilly granted us the exclusive option to obtain worldwide exclusive licenses to research, develop, manufacture and commercialize an equal number of compounds and products directed to oncology targets for which Lilly does not exercise its option. The Lilly Agreement will expire upon the earlier of the exercise of all options granted to Lilly or four years from the date of the agreement.

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 are eligible for quarterly research and development support payments during a portion of the term of the Lilly Agreement, option exercise payments and milestone payments in an aggregate of up to \$1.4 billion, as well as mid to high single-digit royalty payments on net sales for all products directed to each target optioned by Lilly. The milestone payment amount assumes that Lilly exercises all of the options available to it, as well as the successful achievement of all clinical development and sales milestones for each target optioned by Lilly pursuant to the Lilly Agreement. If Lilly obtains approval in additional indications in different therapeutic areas, then additional amounts may become due. Upon our exercise of an option with respect to a given target, we will owe Lilly option exercise, milestone and royalty payments in amounts equivalent to a portion of the amounts payable by Lilly were Lilly to exercise an option. For more information on the Lilly Agreement, see "Business—Our Collaboration Agreements—Research and Development Collaboration with Lilly." We expect to recognize revenue from this agreement, including deferred revenue included on our balance sheets as of December 31, 2018 of \$26.7 million, which consists of the \$25.0 million upfront payment plus \$1.7 million attributed as a premium on the proceeds from Lilly's investment in shares of our Series B-3 Preferred Stock, on a proportional performance basis over the term of the Lilly Agreement.

In December 2015, we entered into a license agreement with Yale University, or the Yale Agreement, pursuant to which we obtained a 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 also pay an annual license maintenance fee in the mid to high tens of thousands of dollars. In addition, we are obligated to pay Yale milestone payments in an aggregate of up to approximately \$3.0 million per product.

In connection with the Yale Agreement, we also entered into a corporate sponsored research agreement with Yale, or the SRA, in which we agreed to provide an aggregate of up to \$12.4 million to fund a research program under the direction and supervision of Dr. Chen aimed at discovering new targets for immunomedicines. As of December 31, 2018, we have made payments in an aggregate of \$7.4 million under the SRA, including \$2.5 million in the year ended December 31, 2018. 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.

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 \$77.0 million after deducting underwriting discounts and commissions of \$6.0 million and offering expenses of \$3.4 million. See Note 1 to our unaudited condensed financial statements included elsewhere in this prospectus for more information.

As of September 30, 2019, we had cash, cash equivalents and marketable securities, excluding restricted cash, of \$184.1 million. We believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from this offering, 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, preclinical studies and 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 or 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 three and nine months ended September 30, 2019, we recognized \$1.6 million and \$4.3 million, respectively, in revenue under the Lilly Agreement. Through September 30, 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 and Note 2 to our unaudited condensed financial statements included elsewhere in this prospectus. For the foreseeable future, we expect all of our revenue will be generated from the Lilly Agreement.

# **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 the SRA and the Yale Agreement;
- 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, including the IND for NC410; 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 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 Three and Nine Months Ended September 30, 2019 and 2018

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

	Three Months Ended <u>September 30,</u> 2019 2018 Change						_	Nine Mon Septem 2019		_ Change		
Revenue:												
Revenue from research and development												
arrangement	\$	1,583	\$	_	\$	1,583	\$	4,342	\$	_	\$	4,342
Operating expenses:												
Research and development	\$	8,663	\$	4,895	\$	3,768		22,819		13,539		9,280
General and administrative		2,622		925		1,697		6,995		2,590		4,405
Loss from operations		(9,702)		(5,820)		(3,882)		(25,472)		(16,129)		(9,343)
Other income, net		1,268		110		1,158		2,662		192		2,470
Net loss	\$	(8,434)	\$	(5,710)	\$	(2,724)	\$	(22,810)	\$	(15,937)	\$	(6,873)

# Revenue from Research and Development Arrangement

Revenue was \$1.6 million and \$0 million for the three months ended September 30, 2019 and 2018, respectively, and \$4.3 million and \$0 million for the nine months ended September 30, 2019 and 2018, respectively. The increase in 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.

# Research and Development Expenses

Research and development expenses for the three months ended September 30, 2019 increased by \$3.8 million to \$8.7 million compared to \$4.9 million for the three months ended September 30, 2018. The increase was driven primarily by \$1.5 million in personnel-related costs due to an increase in headcount. Other significant components of the increase in research and development expenses included \$1.1 million in lab supplies and services for NC318, NC410, other early-stage programs and discovery activities and \$0.5 million in clinical research costs related to advancing NC318.

Research and development expenses for the nine months ended September 30, 2019 increased by \$9.3 million to \$22.8 million compared to \$13.5 million for the nine months ended September 30, 2018. The increase was driven primarily by \$2.5 million in personnel-related costs due to an increase in headcount. Other significant components of the increase in research and development expenses included the following: \$2.3 million in lab supplies and services for NC318, NC410, other early-stage programs and discovery activities; \$1.9 million in clinical research costs related to advancing NC318; a \$0.5 million payment to Yale University in connection with the closing of our IPO; and \$0.6 million related to depreciation expense.

# General and Administrative

General and administrative expenses for the three months ended September 30, 2019 increased by \$1.7 million to \$2.6 million as compared to \$0.9 million for the three months ended September 30, 2018. The increase was driven primarily by increases, in connection with our IPO, of \$0.6 million for professional fees related to legal, finance and audit services, public relations, compensation and investor relations

support, \$0.5 million in insurance expenses and \$0.4 million in personnel-related costs due to an increase in headcount.

General and administrative expenses for the nine months ended September 30, 2019 increased by \$4.4 million to \$7.0 million as compared to \$2.6 million for the nine months ended September 30, 2018. The increase was driven primarily by increases, in connection with our IPO, of \$2.0 million for professional fees related to legal, finance and audit services, public relations, compensation and investor relations support, \$0.8 million in personnel-related costs due to an increase in headcount and \$0.8 million in insurance expenses in connection with our IPO as well as \$0.5 million for an unrestricted gift to an academic lab.

### Other Income, Net

Other income, net for the three months ended September 30, 2019 increased by \$1.2 million to \$1.3 million from \$110,000 for the three months ended September 30, 2018. The increase was driven primarily by interest income earned on higher cash balances, partially offset by interest expense related to the Term Loan.

Other income, net for the nine months ended September 30, 2019 increased by \$2.5 million to \$2.7 million from \$192,000 for the nine months ended September 30, 2018. The increase was driven primarily by interest income earned on higher cash balances, partially offset by interest expense related to the Term Loan.

# Comparison of the Years Ended December 31, 2018 and 2017

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

	Year I Decem			
	2018	2017	_(	Change
Operating expenses:				
Research and development	\$ 19,787	\$ 12,954	\$	6,833
General and administrative	3,409	2,595		814
Loss from operations	 (23,196)	(15,549)		(7,647)
Other income, net	397	80		317
Net loss	\$ (22,799)	\$ (15,469)	\$	(7,330)

# Research and Development Expenses

Research and development expenses for the year ended December 31, 2018 increased by \$6.8 million to \$19.8 million compared to \$13.0 million for the year ended December 31, 2017. The increase was driven primarily by \$2.7 million of increased expenses for product development and clinical research costs, which related to advancing NC318 through IND-enabling activities, the initiation of our Phase 1/2 clinical trial of NC318 in patients with advanced or metastatic solid tumors, clinical material production costs, commencement of NC410 preclinical studies and advancement of our other early-stage programs and discovery activities, including payments pursuant to the SRA and other sponsored research agreements. Other significant components of the increase in research and development expenses, each as a result of increased product development and clinical research costs, included the following: research and development compensation expense by \$2.0 million; reflecting higher headcount; depreciation and amortization expense by \$1.1 million; lab supplies and services by \$0.7 million; facility-related expenses by \$0.3 million; and research and development license costs by \$0.1 million.

# General and Administrative

General and administrative expenses for the year ended December 31, 2018 increased by \$0.8 million to \$3.4 million as compared to \$2.6 million for the year ended December 31, 2017. The increase was driven primarily by an increase of \$0.2 million in personnel-related costs due to an increase in headcount and an increase of \$0.3 million for professional fees related to legal and audit services.

Other Income, Net

Other income, net for the year ended December 31, 2018 increased by \$0.3 million to \$0.4 million from \$80,000 for the year ended December 31, 2017. The increase was driven primarily by interest income earned on the proceeds of our Series A and B Preferred Stock financing, partially offset by interest expense related to the Term Loan.

# **Liquidity and Capital Resources**

We have financed our operations primarily through private placements of preferred stock, proceeds pursuant to the Lilly Agreement and our IPO. 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 \$77.0 million after deducting underwriting discounts and commissions of \$6.0 million and offering expenses of \$3.4 million. 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 September 30, 2019, our principal source of liquidity was cash, cash equivalents and marketable securities of \$184.1 million. We believe that the net proceeds from this public offering, together with 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 the 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 September 30, 2019, our outstanding borrowings under the 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. We anticipate that we will need to raise substantial additional capital, the requirements of which 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 success of our collaboration with Lilly, including whether Lilly exercises its licensing options under its collaboration agreement with us, each of which would trigger additional payments to us;
- 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 our 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.

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 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):

		Nine Montl Septemb			Year I Decem		
	2019			2018	2018		2017
Net cash provided by (used in):							
Operating activities	\$	(25,632)	\$	(14,479)	\$ 7,992	\$	(12,514)
Investing activities	\$	(176,762)	\$	(1,159)	\$ (3,063)	\$	(8,652)
Financing activities	\$	81,735	\$	30,686	\$ 121,417	\$	24,860
Net (decrease) increase in cash and cash equivalents	\$	(120,659)	\$	15,048	\$ 126,346	\$	3,694

### Cash Used in Operating Activities

Net cash used in operating activities was \$25.6 million for the nine months ended September 30, 2019, which was primarily due to our net loss of \$22.8 million. Net cash used in operating activities was \$14.5 million for the nine months ended September 30, 2018, which was primarily due to our net loss of \$15.9 million in connection with our research and development activities, partially offset by timing of cash payments. The amount of cash used in operating activities in any period is influenced by the timing of cash payments for research-related expenses.

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. Net cash used in operating activities was \$12.5 million for the year ended December 31, 2017, which was primarily due to our net loss of \$15.5 million in connection with our research and development activities, partially offset by a \$1.6 million increase in accrued liabilities caused by the growth of our business as well as timing of cash payments. 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 nine months ended September 30, 2019 was \$176.8 million, which was primarily due to the purchase of marketable securities. Cash used in investing activities for the nine months ended September 30, 2018 was \$1.2 million, which consisted in each case primarily of purchases of property and equipment.

Cash used in investing activities for the years ended December 31, 2018 and 2017 was \$3.1 million and \$8.7 million, respectively, which consisted in each case primarily of purchases of laboratory equipment.

# Cash Provided by Financing Activities

Cash provided by financing activities was \$81.7 million for the nine months ended September 30, 2019, which consisted primarily of net proceeds from the Company's public offering. Cash provided by financing activities was \$30.7 million for the nine months ended September 30, 2018, which consisted of gross proceeds from the sale and issuance of shares of our Series A-3 Preferred Stock.

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

Cash provided by financing activities was \$24.9 million for the year ended December 31, 2017, which consisted primarily of net proceeds from the issuance and sale of shares of our Series A Preferred Stock, partially offset by payments under the Term Loan.

# **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of December 31, 2018 (in thousands):

	Payments Due by Period													
	Less than		1	1 - 3	3 - 5		M	ore Than						
	1	1 Year		1 Year		1 Year		Years		Years		5 Years		Total
Long-term debt obligations	\$	387	\$	73	\$	_	\$	_	\$	460				
Operating lease obligations		325		625		690		635		2,275				
Total	\$	712	\$	698	\$	690	\$	635	\$	2,735				

We had operating lease obligations consisting of an operating lease for our corporate headquarters, which includes both office and laboratory space, for approximately 25,000 square feet as of December 31, 2018. The term of the lease commenced in February 2016 and expires in August 2025. Under the terms of the lease as of December 31, 2018, we will have lease obligations aggregating \$2.3 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 agreements with Lilly and Yale and our 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.

There have been no material changes outside the ordinary course of business to our contractual obligations during the nine month period ended September 30, 2019, as compared to those set forth above. See Notes 6 and 7 to our unaudited condensed financial statements included elsewhere in this prospectus for a discussion of our leases and the Term Loan, respectively.

# Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles. 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

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.

### **Research and Development Expenses**

Expenditures, including payroll, contractor expenses and supplies, for research and development of product candidates are expensed as incurred. Development costs incurred by third parties 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.

### 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):

	N	ine Month Septemb			Year Ended December 31,			
	20	019	2	018	2	2018	2	017
Research and development expense	\$	182	\$	41	\$	85	\$	35
General and administrative expense	\$	342	\$	49	\$	178	\$	90
Total stock-based compensation expense	\$	524	\$	90	\$	263	\$	75

As of September 30, 2019, total unamortized stock-based compensation was \$7,365,199.

The intrinsic value of all outstanding stock options as of September 30, 2019 was \$55.3 million.

Common Stock Valuations

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.

# Income Taxes

We use 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 our property and

equipment and our 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, management concludes that it is more likely than not that the deferred tax assets will not be realized. In evaluating our ability to recover deferred tax assets, we consider all available positive and negative evidence, including our 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, we have recorded a full valuation allowance against our 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, we currently have no interest or penalties related to uncertain income tax benefits.

As of December 31, 2018, our gross deferred tax assets were \$15.8 million. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses, or NOLs. Utilization of NOLs may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code of 1986, as amended. Similar rules may apply under state tax laws. Our ability to use our remaining NOLs may be further limited if we experience an ownership change in connection with this offering, future offerings or as a result of future changes in our stock ownership.

# **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 U.S. 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 unaudited condensed financial statements included elsewhere in this prospectus.

### 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. 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. 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. We expect to submit an investigational new drug application, or IND, to the U.S.

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, 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 are seeking 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 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 antitumor 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. We are currently conducting IND-enabling studies for NC410 and expect to submit an IND and initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the first quarter of 2020. We are currently focused on opportunities for NC410 in ovarian cancer, NSCLC and renal cancer.

The advancement of cancer to late stages indicates a failure of the immune system to mount an effective anti-tumor immune response. Immuno-oncology, which focuses on stimulating the immune system to respond to cancer and includes checkpoint inhibitors targeting PD-L1, PD-1 and cytotoxic T-lymphocyte antigen-4, or CTLA-4, is one of the most significant advances in the history of cancer treatment. In 2011, the first checkpoint inhibitor was approved, and today, despite only a modest breadth of efficacy, this class of therapies is estimated to have had global sales of more than \$17 billion in 2018 and is predicted to reach more than \$33 billion in global sales by 2022. However, despite the recent success of 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. In addition, some patients develop resistance after initial treatment with these therapies. As a result, the standard of care in cancer today leaves many patients underserved. We believe broader efficacy and more meaningful clinical responses in oncology may be obtained by focusing on the TME.

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 Dr. 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.

In November 2018, we entered into a multi-year collaboration agreement with Eli Lilly and Company, or Lilly, focused on the discovery and development of immunomedicines for oncology using our FIND-IO platform. The collaboration seeks to discover novel cancer targets utilizing our platform and provides that we and Lilly will each receive options to exclusively develop antibodies resulting from the collaboration. In connection with the agreement, or the Lilly Agreement, we received an upfront payment of \$25.0 million in cash and an equity investment of \$15.0 million and are eligible to receive development and regulatory milestones and sales milestones in an aggregate of up to \$1.4 billion, as well as royalty payments.

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, our partnership with Lilly 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.

PROGRAMS	CELLS	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONE	WORLDWIDE RIGHTS
PRODUC	T CANDIDA	TES						
NC318 (S15)	Tumors and macrophages	ONCOLO	GY				Phase 2 data by end of 2020	<b>Next</b> Cure
NC410 (LAIR-1)	Dendritic & T cells	ONCOLO	GY				IND filing in Q1 2020	<b>Next</b> ©ure
DISCOVI	ERY AND RE	SEARCH F	PROGRAMS	3				
Multiple Programs	Immune cells						First IND filing in early 2021	<b>Next©</b> ure
FIND-IO Platform	Multiple cell types						First IND filing in late 2022	Next©ure Lilly

### **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 the first half of 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, we are currently conducting IND-enabling studies, with the expectation of submitting an IND and initiating a Phase 1/2 clinical trial in the first 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. We believe our relationship with Lilly will promote the efficient development of antibodies for novel cancer targets identified using our FIND-IO platform. 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, including through strategic partnerships. 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. We expect to explore a variety of alternatives for our platforms and future product candidates outside of oncology, including the pursuit of strategic partnerships.

# 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 protumorigenic 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**

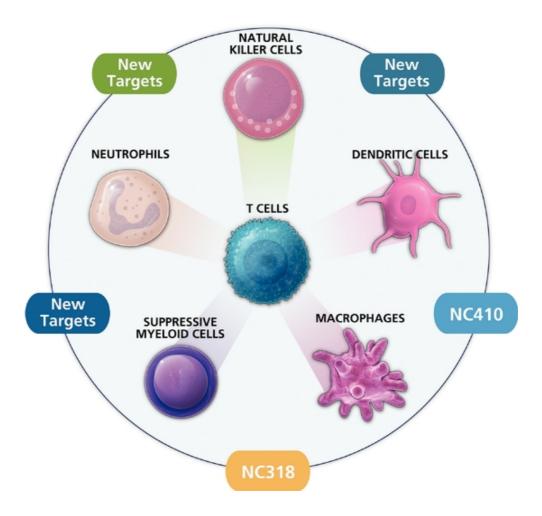
Our approach to identifying targets for new immunomedicines in cancer is based on the combination of our FIND-IO platform, our immunological expertise and our belief in the importance of understanding biological pathways and the normal function of the immune system in the TME. Rather than focusing on 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. NC410 targets the negative signaling of 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.

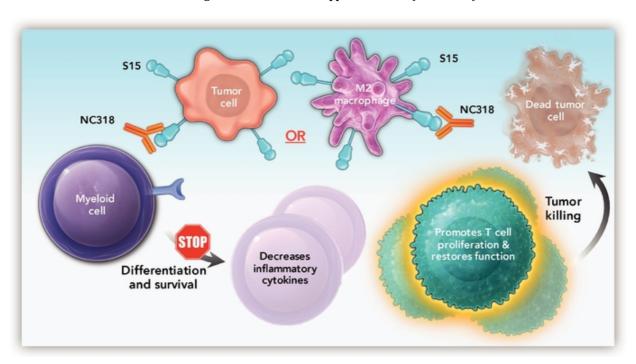
S15 molecules on M2 macrophages, as well as on tumors themselves, appear to interact with unidentified receptors on T cells and inhibit T cell proliferation and functions, leading to decreased anti-tumor immune response. It also appears that S15 interacts with myeloid cells to promote their survival and differentiation so that they contribute to the overall immunosuppressive tumor environment through production of cytokines, such as IL-6, IL-1b and TNF-a, 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.

# Myeloid cell Differentiation and survival Distinct S15-induced myeloid cell Immunosuppression and 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.

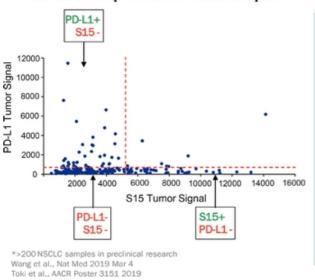
# NC318 is Designed to Block Immunosuppressive Activity Induced by S15

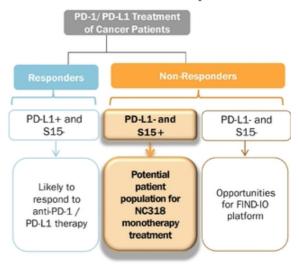


In preclinical studies, we have observed that S15 is highly expressed on both tumor cells and M2 macrophages in the TME in multiple tumor types, including human lung cancer, ovarian cancer, breast cancer and melanoma. In contrast, S15 expression on normal tissues is minimal. Our analysis shows that S15 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.

# S15 and PD-L1 Expression Generally Do Not Overlap in NSCLC Tumor Samples

# Potential New Treatment Options for PD-1/PD-L1 Non-Responders

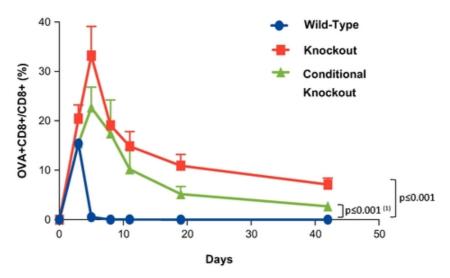




S15 Target Validation

We believe S15 represents a novel target for the treatment of cancer. We and others have conducted multiple preclinical studies in various animal models evaluating the effect of inhibiting S15 by knocking out the gene responsible for producing S15 in mice. Across these studies, we observed that mice in which S15 is absent have generally developed normally, suggesting that the inhibition of S15 is not associated with adverse effects on normal cells. In subsequent studies, we observed that S15 knockout mice mounted enhanced antigen-specific T cell responses *in vivo* as compared with wild-type mice, as shown in the following figure. In addition, when S15 was knocked out in myeloid-derived cells, reflected as conditional knockout in the figure below, the mice mounted an enhanced antigen-specific T cell response similar to that of the knockout mice, which suggests the key role that macrophages play in S15-mediated immunosuppression. The data show a statistically significant increase in antigen-specific T cells in knockout and conditional knockout mice as compared to wild-type mice, and the increase is prolonged and maintained over a longer period than in the wild-type mice. In addition, we observed a significant increase in antigen-specific T cells in the spleen, as measured by the percentage of OVA+ CD8+ cells among CD8+ cells. The knockout mice showed an increase of nearly 20% as compared to less than 2% in wild-type mice. This suggests that S15 plays a key role in mediating immune suppression and the absence or inhibition of S15 could restore normal immune function.

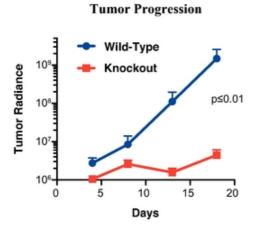
# Increase in T Cells Observed When S15 is Absent

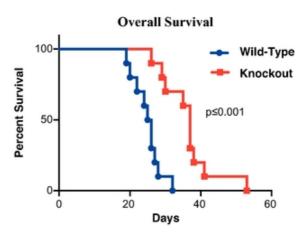


(1) The p-value, or probability value, cited in figures in this prospectus as "p," is the likelihood that an observed result occurred by chance. The smaller the p-value, the less likely that chance caused the result. A result that is sufficiently unlikely to have occurred by chance is referred to as 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 evaluated tumor progression in S15 knockout mice compared to wild-type mice in a glioma tumor model. As shown in the figures below, the knockout group showed delayed tumor progression as well as a corresponding increase in survival as compared to the wild-type group.

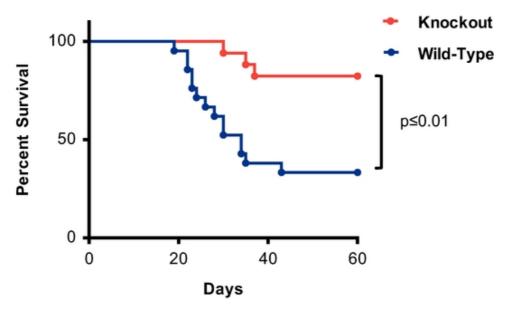
# Knocking Out S15 Delayed Tumor Progression and Prolonged Survival in Glioma Model





In order to study the potential benefit of S15 inhibition in non-responders to PD-1/PD-L1 therapies, we conducted a preclinical study evaluating S15 knockout mice in a frequently used melanoma model, the B16.GMCSF tumor model, which has been demonstrated to be resistant to PD-1/PD-L1 therapy. We observed that S15 knockout mice demonstrated greater anti-tumor effect and, as shown in the following figure, had better overall survival than wild-type mice. We believe that this study suggests NC318 may have therapeutic potential in patients who do not respond to checkpoint inhibitors.

Knocking Out S15 Prolonged Survival in PD-1/PD-L1 Resistant Tumor Model



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, 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 September 26, 2019, the cutoff date of the data presented by the NC318 trial investigator at SITC, tumor responses were evaluable in 45 patients, and four patients had not yet been assessed. Treatment-related adverse events experienced by more than 5% of patients as of September 26, 2019 were diarrhea (16%), infusion reactions (8%), fatigue (6%), headaches (6%), pruritis (6%), elevated amylase (8%) and elevated lipase (6%).

As of November 9, 2019, NC318 has 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, was observed. Treatment-related adverse events experienced by more than 5% of patients as of that date continued to be 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 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 remains ongoing at 55 weeks, and one partial response, which remains ongoing at 28 weeks, both in NSCLC patients, as well as 14 patients with stable disease, which remain 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) have 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

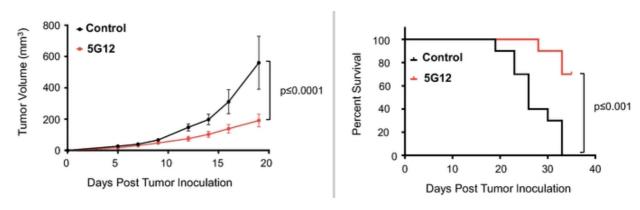
In the first half of 2020, we intend to initiate a Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors. This trial will be an open-label trial designed to assess the safety and tolerability of NC318 in combination 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

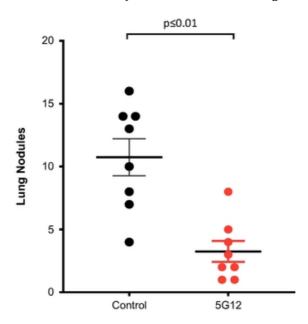
Most syngeneic mouse tumor cell lines, which are common mouse models used to test immunotherapies, do not express S15. In order to study the effects of our S15-targeted antibody, we generated a tumor model where the mouse expresses S15. The model was initiated by differentiating mouse bone marrow cells 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



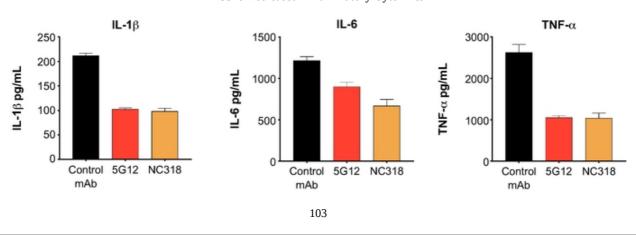
We also generated murine tumors expressing S15 on their surface. In our preclinical studies of an S15-positive murine colon cancer cell line, we observed that 5G12 delayed tumor growth and tumor metastasis, which was demonstrated by fewer lung nodules measured 28 days after treatment in the mice treated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

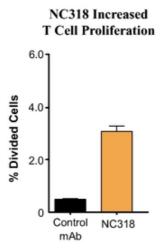
Treatment with 5G12 Delayed Tumor Metastasis in Lung Model

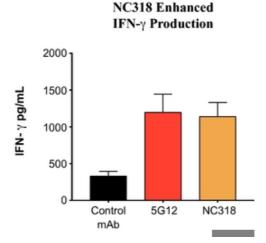


Based on *in vitro* studies, we understand that S15 drives an increase in pro-inflammatory and pro-tumorigenic cytokines, such as IL-1b, IL-6 and TNF-a. As indicated in the figure below, when human peripheral blood mononuclear cells, or PBMCs, which are blood cells that are critical components in the 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-g. 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. We are currently conducting IND-enabling studies and expect to file an IND and initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the first 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.

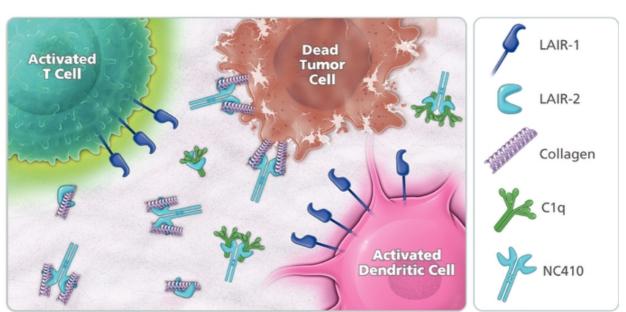
Under normal conditions, collagen forms a scaffold to provide strength and structure to tissues. C1q is part of the innate immune system to protect the host from infection and other foreign agents. Both collagen and C1q are highly upregulated and expressed under pathologic conditions, such as in the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



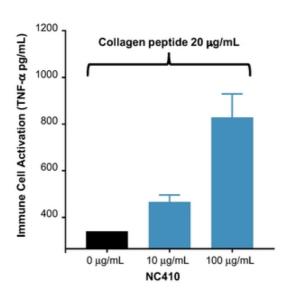
NC410 is Designed to Prevent Immune Suppression Caused by LAIR-1

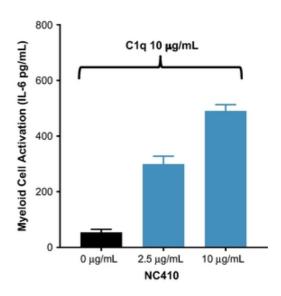
### Preclinical Data

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.

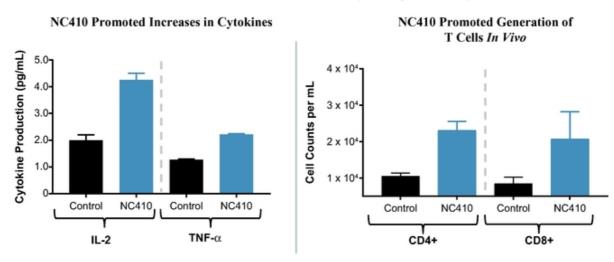
We have observed *in vitro* with human cells that using NC410 to block LAIR-1 from binding with collagen or C1q reverses immune suppression and restores normal immune cell function for both peripheral blood monocytes, including T cells, and myeloid cells. In one study of peripheral blood monocytes, we added 0  $\mu$ g/mL, 10  $\mu$ g/mL and 100  $\mu$ g/mL of NC410 to 20  $\mu$ g/mL of collagen peptide *in vitro*. Similarly, we also evaluated the addition of 0  $\mu$ g/mL, 2.5  $\mu$ g/mL and 10  $\mu$ g/mL of NC410 to 10  $\mu$ g/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



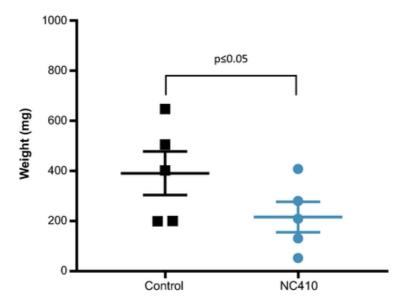


In another preclinical study with human cells, we observed that NC410 promoted increases in the cytokines IL-2 and TNF-a, as shown in the left-hand panel of the following figure, which is indicative of increased immune function. In addition, simultaneous *in vivo* injections of NC410 and human T cells 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.



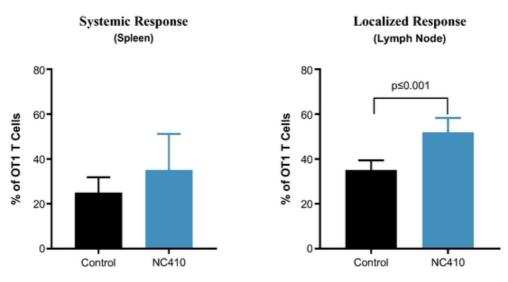
Through multiple preclinical studies in several additional tumor models, we observed that eliminating or blocking LAIR-1-mediated immune suppression prolonged survival. In addition, anti-tumor activity of NC410 correlated with a local increase in antigen-specific T cells in the TME *in vivo* using an 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

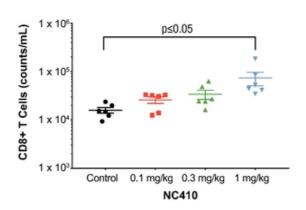


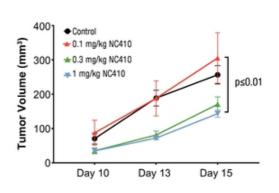
In addition, when human PBMCs were implanted into mice with mouse P815 mastocytoma tumor cells, we observed that NC410 mediated an increase in human T cells *in vivo* and that the increase in human T cells correlated with a delay in tumor growth. As shown in the figures below, NC410 increased the number 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

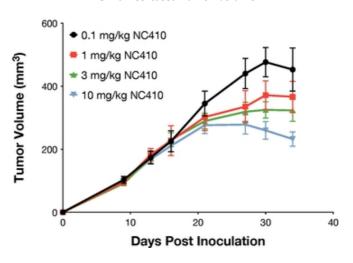
# NC410 Decreased Tumor Volume





### **Human HT29 Colon Adenocarcinoma Model**

### **NC410 Decreased Tumor Volume**



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.

We are currently conducting IND-enabling studies for NC410 and plan to file an IND and initiate a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors in the first quarter of 2020.

# **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.

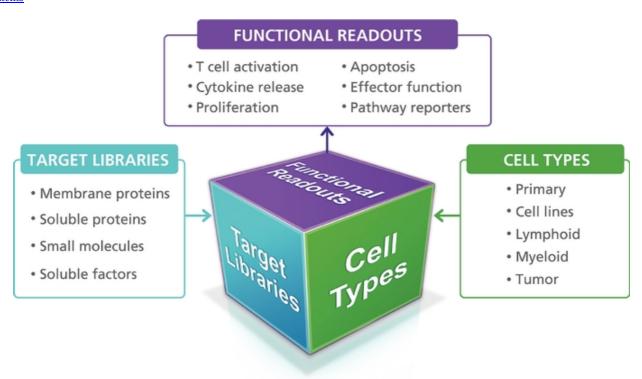
We also have an antibody in preclinical development targeting an immune modulator that is highly expressed in inflamed tissue and the TME in multiple tumor types. In our preclinical research, we observed that disrupting inhibitory signaling by this molecule with our antibody increased T cell and NK cell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

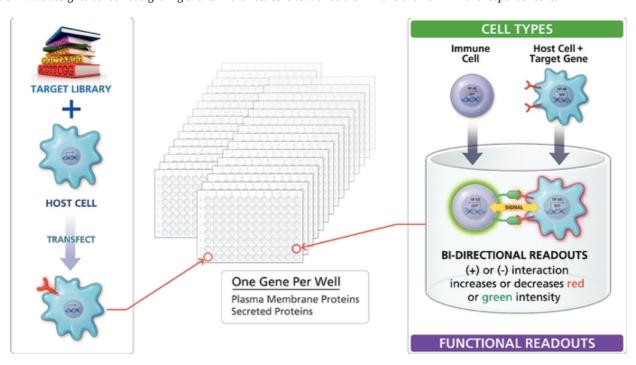
There are three integrated components to our FIND-IO platform. The first component consists of gene libraries, also called target libraries, comprising genes that are expressed and queried for immune or other functions. Our target libraries are composed of genes that encode a structurally diverse set 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 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.

### Research and Development Collaboration with Lilly

In November 2018, we entered into the Lilly Agreement, pursuant to which we will use our FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by us and Lilly. Under this 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. Lilly currently has all options remaining eligible for exercise. In addition, Lilly granted us the exclusive option to obtain worldwide exclusive licenses to research, develop, manufacture and commercialize an equal number of compounds and products directed to oncology targets for which Lilly does not exercise its option. We currently have all options remaining eligible for exercise. Under the Lilly Agreement, we retain all rights to our intellectual property outside of oncology for any targets that are not actively being researched and developed pursuant to the Lilly Agreement.

Under the Lilly Agreement, we and Lilly have agreed to engage in a multi-year research collaboration, which will be managed by a joint steering committee formed by an equal number of members from each party and expire upon the earlier of the exercise of all options granted to Lilly or four years from the date of the agreement, subject to certain extensions. We have granted Lilly exclusivity with respect to targets identified through our FIND-IO platform that can be used in the oncology field during the research term or until Lilly has exercised all of its options.

During the research term, as a part of target discovery, we will be responsible for providing Lilly with oncology targets identified using our FIND-IO platform. From the targets provided by us, Lilly may 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 may propose to advance that target to compound discovery. For each target that has been advanced to compound discovery, Lilly will have the option to obtain an exclusive license in all fields of use with respect to the compounds and products directed to the target. If Lilly does not exercise its option with respect to a given target that has advanced through compound discovery, or has previously exercised all of its options, we have the option to obtain licenses with respect to compounds and products directed to the target. Lilly and we may each exercise our respective options with respect to targets during the research term. Following option exercise by a party, the development and commercialization of any compounds and products directed to the target will be conducted by the exercising party. The exercising party must use commercially reasonable efforts to develop, seek regulatory approval for and commercialize any such products under mutually agreed work plans.

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 is also required to pay us quarterly research and development support payments in an aggregate in the mid single digit millions of dollars during a portion of the research term as well as option exercise fees in an aggregate of up to the high single digit millions of dollars upon the exercise of options by Lilly. For the first product directed to each target optioned by Lilly, Lilly will pay development and regulatory milestones. For the first additional indication in a different therapeutic area for such product, Lilly will pay regulatory milestones upon regulatory approval in each of the United States, European Union and Japan. Additionally, regardless of indication, Lilly will pay sales milestones as well as mid to high single-digit royalties on net sales for all products directed to each target optioned by Lilly. The milestone payments could amount to an aggregate of up to \$1.4 billion. This amount assumes that Lilly exercises all of the options available to it, as well as the successful achievement of all development and regulatory milestones and sales milestones for each target optioned by Lilly.

Upon our exercise of an option with respect to a given target, we will owe Lilly option exercise, milestone and royalty payments in amounts equivalent to a portion of the amounts payable by Lilly were Lilly to exercise an option, including an aggregate of up to \$710 million in development and regulatory milestones and sales milestones and low to mid single-digit royalties. Unless terminated earlier, the term of the Lilly Agreement will continue in effect, on a product-by-product and country-by-country basis, until the expiration of the applicable royalty term. Either party may terminate the agreement, in whole or in part, for the other's material breach that has not been cured within a certain period or general assignment for the benefit of creditors or in connection with the other's bankruptcy or insolvency. In addition, Lilly has the right to terminate the agreement in its entirety or with respect to one or more specified products or targets at any time with 60 days prior notice. To the extent that we terminate for Lilly's material breach or insolvency or Lilly terminates for convenience, all licenses and rights granted by us to Lilly will automatically terminates and the licenses and rights granted by Lilly to us will survive. Similarly, if Lilly terminates for our material breach or insolvency, all licenses and rights granted by Lilly to us will automatically terminate, and the licenses and rights granted by us to Lilly will survive. In such cases, all future royalties and milestones will be reduced in an amount to be reasonably agreed by the parties.

# 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 October 29, 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 chemically synthesized 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 any post-approval requirements, including the potential requirements to implement a Risk Evaluation and Mitigation Strategy, or REMS, and to complete 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 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 FDA 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 thereto 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 establishments with the FDA and certain state agencies. These establishments are subject to routine and periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP 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, or PDMA, 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 reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form and strength, and no clinically meaningful differences between the biological product 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. To date, a handful of biosimilar products and no interchangeable products have been approved under the BPCIA. 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. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. In July 2018, the FDA released its Biosimilars Action Plan to improve the efficiency of the biosimilar and interchangeable product development and approval process. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and impact of the BPCIA is subject to significant uncertainty.

## 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 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements 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. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new 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;
- 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, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives 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, substantially changing the way healthcare is financed by both governmental and private insurers and significantly impacting 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 now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. 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 repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain 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, or the BBA, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." 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 changes 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 entire ACA is invalid as a result of the tax penalty associated with the "individual mandate" being repealed by Congress as part of the Tax Act. This ruling is under appeal and stayed pending appeal. It is unclear how this decision, subsequent appeals and other efforts to repeal, replace or invalidate the ACA, regulations promulgated under the ACA or portions thereof, will impact the ACA and its implementation or our business.

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 Medicare; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. The Trump Administration's budget proposals for fiscal 2019 and 2020 contain drug price control measures, including measures to permit Medicare Part D plans to

negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has started soliciting feedback on some of these measures and, at the same, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or 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 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 October 23, 2019, we had 67 full-time employees, of which 52 were primarily engaged in research and development activities and 27 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.

#### **Facilities**

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 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.

# **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.

### MANAGEMENT

# **Executive Officers and Directors**

The following table sets forth the name and position of each of our executive officers and directors, and their ages as of November 12, 2019:

Name	Age	Position(s)
Executive Officers and Employee Directors		
Michael Richman	58	President, Chief Executive Officer and Director
Steven P. Cobourn, CPA	56	Chief Financial Officer
Kevin N. Heller, M.D.	48	Chief Medical Officer
James B. Bingham, Ph.D.	53	Chief Development Officer
Sol Langermann, Ph.D.	60	Chief Scientific Officer
Timothy Mayer, Ph.D.	55	Chief Operating Officer
Linda Liu, Ph.D.	53	Senior Vice President, Research
Non-Employee Directors		
David Kabakoff, Ph.D. <sup>(1)(2)</sup>	71	Chair of our Board of Directors
Elaine V. Jones, Ph.D. <sup>(3)</sup>	64	Director
Chau Q. Khuong <sup>(2)(3)</sup>	43	Director
Judith J. Li <sup>(1)</sup>	35	Director
Briggs Morrison, M.D. <sup>(2)</sup>	60	Director
Timothy M. Shannon, M.D. <sup>(2)(3)</sup>	60	Director
Stephen W. Webster <sup>(1)</sup>	58	Director
Stella Xu, Ph.D. <sup>(3)</sup>	49	Director

- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and corporate governance committee.

# **Executive Officers**

Michael Richman co-founded our company and has served as our President, Chief Executive Officer and a member of our board of directors since October 2015. Mr. Richman served as President and Chief Executive Officer of Amplimmune, Inc. (now MedImmune, LLC), a biopharmaceutical company focused on immuno-oncology, from 2007 to August 2015, including through Amplimmune's acquisition by AstraZeneca plc in October 2013. Before Amplimmune, Mr. Richman served as Executive Vice President and Chief Operating Officer of MacroGenics, Inc., a biopharmaceutical company focused on the treatment of cancer, from 2002 to 2007. Mr. Richman joined MacroGenics with approximately 20 years' experience in corporate business development within the biotechnology industry. Mr. Richman has served as a director of publicly traded Pieris Pharmaceuticals, Inc., a clinical-stage biotechnology company, since December 2014 and as a director of Madison Vaccines, Inc., a private company, since May 2014. Mr. Richman was previously a member of the board of directors of GenVec, Inc. from April 2015 until its acquisition by Intrexon Corporation in June 2017 and Opexa Therapeutics, Inc. from June 2006 until its acquisition by Acer Therapeutics in September 2017. Mr. Richman received a B.S. in genetics and molecular biology from the University of California at Davis and an M.S.B.A. in international business from San Francisco State University.

We believe that Mr. Richman is qualified to serve on our board of directors because of his service as our President and Chief Executive Officer, his service on the boards of other private and public life

sciences companies and his extensive knowledge of our company and industry, including comprehensive experience in financing, corporate management, research and business development.

Steven P. Cobourn, CPA has served as our Chief Financial Officer since January 2018. Previously, he served as Chief Financial Officer of Vaccinex, Inc., a biotechnology company, from May 2014 to January 2018. Prior to joining Vaccinex, Mr. Cobourn was the Vice President of Finance and Treasurer of Otsuka America Pharmaceutical, Inc., a private pharmaceutical company, from 2003 to April 2014, and served in other roles at Otsuka America Pharmaceutical from 1993 to 2003. Prior to joining Otsuka America Pharmaceutical, Mr. Cobourn was a Certified Public Accountant at Hass & Company LLC, an accounting firm. Mr. Cobourn received a B.S. in business administration from Drexel University and is a Certified Public Accountant.

*Kevin N. Heller, M.D.* has served as our Chief Medical Officer since April 2018. He has also served as an Adjunct Professor at the Yale University School of Medicine since October 2018. Dr. Heller served as head of antibody clinical development at Incyte Corporation, a biotechnology company, from May 2015 to April 2018 and as Global Medical Lead for the vandetanib program at AstraZeneca plc from May 2013 to May 2015. Prior to joining AstraZeneca plc, Dr. Heller served as an early clinical development lead for multiple programs, clinical strategy lead for ipilumumab and global lead for oncology search and evaluation in the business development group at Bristol-Meyers Squibb Company from 2007 to 2013. Dr. Heller received a B.S. in molecular biophysics and biochemistry from Yale University and an M.D. from George Washington University.

James B. Bingham, Ph.D. has served as our Chief Development Officer since December 2018 and previously served as our Senior Vice President, Development and Manufacturing from October 2015 to December 2018. Dr. Bingham has also served as President of MMG Biopharmaceuticals Consulting, LLC since November 2008. Prior to joining NextCure, Dr. Bingham held various positions at Amplimmune from 2007 to July 2015, including Senior Vice President of Development, Manufacturing and Quality from January 2013 to July 2015. Dr. Bingham served as Associate Director of Microbial Research & Development at Cambrex Corporation and, after its acquisition of Cambrex, Lonza Group AG from 2006 to 2007. Dr. Bingham also worked for Human Genome Sciences, Inc. (acquired by GlaxoSmithKline plc), or HGS, from 2000 to 2006. Prior to joining HGS, Dr. Bingham was also employed at MedImmune and Integrated Genetics (now part of Laboratory Corporation of America Holdings). Dr. Bingham received a B.S. in biology from St. Michael's College and a Ph.D. in biological chemistry from The Johns Hopkins University.

Sol Langermann, Ph.D. has served as our Chief Scientific Officer since December 2018 and previously served as our Senior Vice President, Research from October 2015 to December 2018. Prior to joining NextCure, Dr. Langermann served as Senior Vice President and Chief Scientific Officer of Amplimmune from 2007 to July 2015. Dr. Langermann previously served as Chief Scientific Officer at PharmAthene, Inc., which was later acquired by Altimmune, Inc., from 2004 to 2007. Prior to PharmAthene, he held several positions at MedImmune, LLC, including Senior Director of Cell Biology, Director of Immunology and Molecular Genetics and Research Scientist in Immunology. Dr. Langermann received a B.A. in philosophy of science from Columbia College, an M.L.A. in immunology from Harvard University and a Ph.D. in microbiology and molecular biology from Tufts University. He completed his postdoctoral fellowship in mucosal immunology at Harvard University.

*Timothy Mayer, Ph.D.* has served as our Chief Operating Officer since October 2019. He previously served as our Senior Vice President, Corporate Development from December 2018 to October 2019 and our Vice President, Business Development from February 2016 to December 2018. Prior to joining NextCure, Dr. Mayer held several positions at MacroGenics, Inc., a biopharmaceutical company focused on the treatment of cancer, from 2004 to February 2016, including Senior Director, Intellectual Property from 2009 to February 2016. Prior to that, Dr. Mayer worked on biotechnology and pharmaceutical patent matters as a Technical Specialist at Banner & Witcoff, Ltd., an intellectual property law firm, from 2000 to

2004. Dr. Mayer received a B.S. in microbiology and a B.S. in biochemistry from California Polytechnic State University and a Ph.D. in microbiology and immunology from the Pennsylvania State University College of Medicine.

Linda N. Liu, Ph.D. has served as our Senior Vice President, Research since December 2018 and previously served as our Vice President, Translational Research from October 2015 to December 2018. Prior to joining NextCure, Dr. Liu held several positions at Amplimmune from 2007 to August 2015, including Executive Director of Translational Science/Scientific Affairs and Vice President of New Product Development from January 2013 to August 2015. She served as a Senior Director of Biological Product Development at MaxCyte, Inc., a clinical stage biotechnology company aimed at commercializing cell loading technology, from 2000 to 2007 and as a Senior Scientist at Osiris Therapeutics, Inc. from 1999 to 2000. Dr. Liu received a B.S. in virology and molecular biology from Wuhan University in China and a Ph.D. in virology and cell biology from the University of Texas at Austin. She conducted her postdoctoral training in tumor cell biology at the St. Jude Children's Research Hospital.

#### **Non-Employee Directors**

David Kabakoff, Ph.D. has served as Chair of our board of directors since December 2015. Dr. Kabakoff has served as Executive Partner at Sofinnova Investments, Inc. since May 2007 and became a founding Partner of HealthQuest Capital in 2012. Dr. Kabakoff has served on the board of directors of Castle Biosciences, Inc., a publicly traded company that develops and commercializes diagnostic and prognostic tests for dermatologic cancers, since September 2017, and currently also serves on the board of directors of several privately held life sciences companies, including Lineagen, Inc., where he serves as chairman, Dauntless Pharmaceuticals, Inc., Rainier Therapeutics, Neurana Pharmaceuticals, bioTheranostics, Inc. and Antiva Biosciences, Inc. Dr. Kabakoff previously served as a director of several other publicly traded and privately held life sciences companies, including Principia Biopharma, Inc. from June 2016 to August 2018 in advance of Principia's September 2018 initial public offering, publicly traded InterMune, Inc. from November 2005 to September 2014 and Amplimmune. In 2001, Dr. Kabakoff co-founded Salmedix, Inc., a company that developed cancer drug treatments, and served as the company's Chairman and Chief Executive Officer and led its acquisition in June 2005 by Cephalon, Inc. Previously, Dr. Kabakoff held the positions of Executive Vice President of Dura Pharmaceuticals, Inc. and President and Chief Executive Officer of Spiros, both pharmaceutical companies, Chief Executive Officer of Corvas International, Inc., a developer of biotherapeutics, and held senior executive positions with Hybritech, a biotechnology company. Dr. Kabakoff received a B.A. in chemistry from Case Western Reserve University and a Ph.D. in chemistry from Yale University.

We believe Dr. Kabakoff is qualified to serve as a member of our board of directors due to his extensive experience in the biotechnology industry and his investing experience.

Elaine V. Jones, Ph.D. has served as a member of our board of directors since December 2015. Dr. Jones served as Vice President, Worldwide Business Development and Senior Partner at Pfizer Ventures, where she was responsible for making and managing venture investments of strategic interest to Pfizer Inc., from December 2008 to April 2019. Prior to joining Pfizer, Dr. Jones was a General Partner with EuclidSR Partners. She began her private equity career in 1999 at S.R. One, GlaxoSmithKline's venture fund. Before that, she was Director of Scientific Licensing for SmithKline Beecham and a research scientist for SmithKline Beecham Pharmaceutical R&D. Dr. Jones has served on the board of directors of publicly traded CytomX Therapeutics, Inc., a clinical-stage biopharmaceutical company, since May 2019 (she also previously served on CytomX's board from December 2014 to June 2016) and Gritstone Oncology, Inc., an immuno-oncology company, since September 2019 and currently serves on the board of directors for various privately held companies and as a trustee of Juniata College. Dr. Jones previously served on the boards of directors of several publicly traded healthcare companies, including Mersana Therapeutics, Inc. from February 2015 to June 2018, Mirna Therapeutics, Inc. from December 2012 to June 2016, Aquinox Pharmaceuticals, Inc. from June 2010 to February 2015 and Flexion Therapeutics, Inc. from December 2009 to June 2014. Dr. Jones received a B.S. in biology from Juniata College and a Ph.D. in microbiology from the University of Pittsburgh.

We believe that Dr. Jones is qualified to serve as a member of our board of directors due to her scientific and pharmaceutical industry background, as well as her extensive experience in the venture capital industry.

Chau Q. Khuong has served as a member of our board of directors since December 2015. Mr. Khuong has served as a Private Equity Partner at OrbiMed Advisors LLC, a venture capital and asset management firm, since 2003. Mr. Khuong currently serves as a director of several publicly traded life sciences companies, including BELLUS Health Inc. since December 2018, Synlogic, Inc. since February 2016, Inspire Medical Systems, Inc. since May 2014 and Aerpio Pharmaceuticals, Inc. since April 2014, and previously served as a director of Nabriva Therapeutics plc (formerly Nabriva Therapeutics AG) from April 2015 to August 2017, Otonomy, Inc. from August 2013 to July 2016 and as chairman of the board of directors of Pieris Pharmaceuticals, Inc. from December 2014 to November 2017. Mr. Khuong has also served on the board of directors for several privately held companies. Mr. Khuong received a B.S. in molecular biology with concentration in biotechnology and a M.P.H. with concentration in infectious diseases from Yale University.

We believe that Mr. Khuong is qualified to serve as a member of our board of directors due to his extensive directorship and healthcare industry experience.

*Judith J. Li* has served as a member of our board of directors since December 2015. Ms. Li has served as a Partner at Lilly Asia Ventures, which focuses on early- and growth-stage life sciences investments, since April 2015 and prior to that served as Principal at Lilly Asia Ventures from November 2013 to April 2015. Ms. Li has served as a director of Gritstone Oncology, Inc. since September 2017 and holds board appointments at a variety of Lilly Asia Ventures' private portfolio companies, including Just Biotherapeutics, Inc. and Veritas Genetics Inc. From April 2014 to December 2017, she served on the board of Crown BioScience Inc., a biotechnology company that was publicly listed on the Taiwan Stock Exchange until it was acquired in December 2017. Prior to joining Lilly Asia Ventures, Ms. Li served as a senior business analyst at McKinsey & Company, worked in hospital administration at Partners Healthcare, and co-founded an interventional nephrology medical device venture. Ms. Li received a B.A. in biology from Harvard University and an M.B.A. from Harvard Business School.

We believe that Ms. Li is qualified to serve on our board of directors due to her experience as a board member of biotechnology and pharmaceutical companies and her experience as an investor in early-stage life sciences companies.

Briggs Morrison, M.D. has served as a member of our board of directors since April 2019. Dr. Morrison has served as Executive Partner at MPM Capital, Inc. since June 2015 and as Chief Executive Officer and a member of the board of directors of Syndax Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, since June 2015. Dr. Morrison has served as a member of the board of directors of Arvinas, Inc., a publicly traded biopharmaceutical company focused on therapies to degrade disease-causing proteins, since June 2018 and prior to that as a member of its Scientific Advisory Board from August 2016 to June 2018. Before that, Dr. Morrison was the Chief Medical Officer and Head of Global Medicines Development at AstraZeneca plc from January 2012 to June 2015. Before joining AstraZeneca, Dr. Morrison held several positions at Pfizer Inc., including Head, Medical Affairs, Safety and Regulatory Affairs for Pfizer's human health business. Dr. Morrison also previously held several positions at Merck Research Laboratories, a division of Merck & Co., Inc., including Vice President, Clinical Sciences, Oncology. Dr. Morrison was a member of the executive committee of the Clinical Trials Transformation Initiative sponsored by the FDA and is on the board of the Alliance for Clinical Research Excellence and Safety. Dr. Morrison also serves on the board of directors for multiple private pharmaceutical companies. Dr. Morrison received a B.S. in biology from Georgetown University and an M.D. from the University of Connecticut Medical School. He completed residency training in internal medicine at Massachusetts General Hospital and a fellowship in medical oncology at the Dana-Farber Cancer Institute.

We believe Dr. Morrison is qualified to serve as a member of our board of directors due to his extensive executive leadership experience, his medical background and training and his service on the boards of other public and private biopharmaceutical and biotechnology companies.

Timothy M. Shannon, M.D. has served as a member of our board of directors since December 2015. Dr. Shannon has served as a General Partner at Canaan Partners since November 2009. Dr. Shannon has also served as the chairman of the board of directors at publicly traded Arvinas, Inc. since July 2013, and on the board of directors of IDEAYA Biosciences, Inc., a publicly traded oncology-focused precision medicine company, since March 2016. Dr. Shannon was the President and Chief Executive Officer of Aldea Pharmaceuticals, a biopharmaceutical company focused on the treatment of toxic aldehyde-related diseases, from November 2010 to September 2013. Dr. Shannon also served as Chief Executive Officer of CuraGen Corporation from 2007 to 2009 and as CuraGen's Chief Medical Officer from 2004 to 2007. From 1992 to 2002, Dr. Shannon served in various senior research and development roles at Bayer Healthcare, including Senior Vice President of Worldwide Clinical Development. Dr. Shannon previously served as a member of the boards of directors of publicly traded CytomX Therapeutics, Inc. from July 2012 to March 2017, Celldex Therapeutics, Inc. from October 2009 to December 2014 and CuraGen Corporation from September 2007 until its acquisition by Celldex in October 2009. Dr. Shannon received a B.A. in chemistry from Amherst College and an M.D. from the University of Connecticut.

We believe Dr. Shannon is qualified to serve on our board of directors due to his extensive experience in the venture capital industry, his executive leadership experience, his medical background and training and his service on the boards of other public and private biopharmaceutical companies.

Stephen W. Webster has served as a member of our board of directors since April 2019. Mr. Webster has served as the Chief Financial Officer of Spark Therapeutics, Inc., a publicly traded biotechnology company, since July 2014. He was previously Senior Vice President and Chief Financial Officer of Optimer Pharmaceuticals, Inc., a publicly traded biotechnology company, from July 2012 until its acquisition by Cubist Pharmaceuticals, Inc. in October 2013. Prior to joining Optimer, Mr. Webster served as SVP and Chief Financial Officer of Adolor Corporation, a biopharmaceutical company, from 2008 until its acquisition by Cubist Pharmaceuticals, Inc. in 2011. From 2007 until joining Adolor Corporation in 2008, Mr. Webster served as Managing Director, Investment Banking Division, Health Care Group for Broadpoint Capital Inc. (formerly First Albany Capital). Mr. Webster served as co-founder, President and Chief Executive Officer for Neuronyx, Inc., a biopharmaceutical company, from 2000 to 2006. Mr. Webster previously served in positions of increased responsibility, including as Director, Investment Banking Division, Health Care Group for PaineWebber Incorporated. Mr. Webster has served as a director of Nabriva Therapeutics AG (formerly Nabriva Therapeutics plc), a publicly traded biopharmaceutical company, since August 2016 and Viking Therapeutics, Inc., a publicly traded biopharmaceutical company, since May 2014. Mr. Webster received an A.B. in economics from Dartmouth College and an M.B.A. in finance from The Wharton School of the University of Pennsylvania.

We believe that Mr. Webster is qualified to serve as a member of our board of directors due to his extensive experience in the biopharmaceutical industry, particularly his service as chief financial officer and on the boards of other public companies.

Stella Xu, Ph.D. has served as a member of our board of directors since November 2018. Dr. Xu has served as Managing Director of Quan Capital, a life sciences venture fund with offices in China and the United States, since August 2017. Prior to joining Quan Capital, Dr. Xu served as Vice President and site head of Roche Innovation Center Shanghai, and a member of the global management team for Roche's Immunology, Inflammation & Infectious Diseases Discovery and Translation Area, from September 2012 to August 2017. Dr. Xu joined Roche from McKinsey & Company. Dr. Xu has served as a director of Centrexion Therapeutics Corporation, a biopharmaceutical company focused on the treatment of chronic pain, since January 2018 and previously served as a director of ARMO BioSciences, Inc., a publicly traded late-stage biopharmaceutical company focused on immuno-oncology, from August 2017 to July 2018 when

it was acquired by Eli Lilly and Company. Dr. Xu received a B.S. in biophysics from Peking University and a Ph.D. in immunology from Northwestern University.

We believe that Dr. Xu is qualified to serve on our board of directors due to her extensive, global experience in the development and commercialization of innovative therapies.

#### **Board Composition and Diversity**

Our board of directors currently consists of nine members. Each of our current directors will continue to serve until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

Our nominating and corporate governance committee is responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including but not limited to the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly traded company;
- experience in the industries in which we compete;
- experience as a board member or executive officer of another publicly traded company;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to race, gender or national origin;
- · conflicts of interest; and
- practical and mature business judgment.

We have no formal policy regarding board diversity. Our board of directors evaluates each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

# Director Independence

Our board of directors has determined that none of our directors other than Mr. Richman has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Nasdaq rules. There are no family relationships among any of our directors or executive officers. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related Party Transactions."

### **Board Leadership Structure**

Dr. Kabakoff currently serves as Chair of our board of directors. Our board of directors believes that separation of the positions of Chair and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole, and has concluded that our current board leadership structure is appropriate at this time. However, our amended and restated bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chair and Chief Executive Officer and to appoint a lead director in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. Our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

### Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- the Class I directors are Ms. Li, Dr. Shannon and Dr. Xu, and their terms will expire at the annual meeting of stockholders to be held in 2020;
- the Class II directors are Dr. Jones, Mr. Khuong and Dr. Morrison, and their terms will expire at the annual meeting of stockholders to be held in 2021; and
- the Class III directors are Dr. Kabakoff, Mr. Richman and Mr. Webster, and their terms will expire at the annual meeting of stockholders to be held in 2022.

Our amended and restated certificate of incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company.

## Role of the Board in Risk Oversight

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also monitors compliance with legal and regulatory requirements and considers and approves or disapproves

any related person transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices and of our board of directors. Our compensation committee assesses and monitors whether any of our compensation policies and programs have the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed about such risks through committee reports.

#### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees operates under a written charter approved by our board of directors that satisfies applicable SEC and Nasdaq standards. From time to time, our board of directors may establish other committees to facilitate the management of our business. Each committee's charter is available under the Governance section of our website at <a href="https://www.nextcure.com">www.nextcure.com</a>. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website.

#### **Audit Committee**

The primary function of our audit committee is to oversee our corporate accounting and financial reporting process. Our audit committee's responsibilities include:

- appointing and retaining, approving the compensation of, overseeing and evaluating the independence, qualification and performance of our independent registered public accounting firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and the prompt reporting of violations of our code of business conduct and ethics
- reviewing our critical accounting policies and estimates;
- · discussing our risk management policies;
- · reviewing and approving or ratifying any related person transaction; and
- preparing the audit committee report required to be included in our annual proxy statement

The members of our audit committee are Dr. Kabakoff, Ms. Li and Mr. Webster and Mr. Webster serves as the chair of the committee. Our board of directors has determined that each of the members of our audit committee satisfies the financial literacy and sophistication requirements of the SEC and the Nasdaq listing rules. In addition, our board of directors has determined that Mr. Webster qualifies as an audit committee financial expert under SEC rules, members of our audit committee must also meet heightened independence standards. Our board of directors has determined that each of the members of our audit committee is independent under the applicable SEC and Nasdaq listing rules.

## **Compensation Committee**

Our compensation committee oversees policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and approves or recommends corporate goals and objectives relevant to compensation of our executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves or makes recommendations to our board of directors regarding the issuance of stock options and other awards to our executive officers. The

compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter. The members of our compensation committee are Dr. Shannon, Mr. Khuong, Dr. Kabakoff and Dr. Morrison and Dr. Shannon serves as chair of the committee. Each of the members of our compensation committee is independent under the applicable Nasdaq listing rules and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

### Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, our nominating and corporate governance committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our board of directors concerning governance matters. The members of our nominating and corporate governance committee are Dr. Jones, Mr. Khuong, Dr. Shannon and Dr. Xu and Dr. Jones serves as chair of the committee. Each of the members of our nominating and corporate governance committee is independent under the applicable Nasdaq listing rules.

# **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has ever served as one of our officers or employees. None of our executive officers serves, or has served during the last three fiscal years, as a member of the board of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving as one of our directors or on our compensation committee.

### **Code of Business Conduct and Ethics**

We adopted a code of business conduct and ethics that applies to all of our directors, officers and employees, including those officers responsible for financial reporting. A current copy of the code of business conduct and ethics is available under the Corporate Governance section of our website. We intend to disclose future amendments to the code or any waivers of its requirements on our website. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website.

### **Limitation on Liability and Indemnification Matters**

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the duty of loyalty to us or our stockholders;
- any act or omission not in good faith that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also obligate us to advance expenses incurred by a director or officer in advance of the final disposition of

any action or proceeding and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of such person's actions in that capacity regardless of whether we would otherwise be permitted to indemnify such person under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. These indemnification agreements generally require us, among other things, to indemnify our directors, executive officers and these employees against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors, executive officers and employees as a result of any proceeding against them as to which they could be indemnified. We believe that these provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage.

### **Non-Employee Director Compensation**

In the year ended December 31, 2018, we did not pay any fees to, or make any equity or non-equity awards to, or pay any other compensation to the non-employee members of our board of directors for their services as directors, except that we granted Dr. Kabakoff an option to purchase 37,342 shares of our common stock at an exercise price of \$7.63 per share. Prior to our IPO, we did not compensate any of our other non-employee directors for service on our board of directors. We did reimburse our non-employee directors for travel and other necessary business expenses incurred in the performance of their service as directors.

In connection with our IPO, our board of directors approved a compensation program for our non-employee directors, or the Non-Employee Director Compensation Program. Pursuant to this program, our non-employee directors receive annual cash compensation as follows:

- the Chair of our board of directors receives a \$65,000 annual retainer and each other non-employee director receives \$35,000;
- the chair of our audit committee receives a \$15,000 annual retainer and each other member receives \$7,500;
- the chair of our compensation committee receives a \$10,000 annual retainer and each other member receives \$5,000; and
- the chair of our nominating and corporate governance committee receives a \$8,000 annual retainer and each other member receives \$4,000.

All fees under the Non-Employee Director Compensation Program are paid quarterly in arrears and are pro-rated for any partial quarters of service, and no per meeting fees are paid, except that we reimburse non-employee directors for reasonable expenses incurred in connection with attending board and committee meetings.

Under the Non-Employee Director Compensation Program, each non-employee director is also entitled to receive an annual stock option award to purchase 11,000 shares of our common stock that vests on the earlier of one year from the grant date of the award or the date of the next annual meeting of the

stockholders, subject to continued service through the vesting date. Annual stock option grants for non-employee directors who were initially elected in the 12 months preceding the annual grant date will be pro-rated on a monthly basis for time in service. In addition, each non-employee director who is elected or appointed to our board of directors is entitled to receive an initial stock option award to purchase 22,000 shares of our common stock that vests in three equal annual installments commencing on the grant date of the award, subject to continued service through the applicable vesting date. All stock options granted pursuant to the Non-Employee Director Compensation Program are subject to the terms and provisions of the 2019 Plan.

### **Director Compensation Table**

As described above, we did not pay any cash or grant any stock awards or other compensation to our non-employee directors during 2018 for their services as non-employee directors, except for the option granted to Dr. Kabakoff. Except as described below for Dr. Kabakoff, there were no outstanding stock awards or option awards held by our non-employee directors as of December 31, 2018. The table below sets forth information on the compensation of all our non-employee directors for the year ended December 31, 2018. Michael Richman, our President and Chief Executive Officer, is also a member of our board of directors, but did not receive any additional compensation for his service as a director.

	Stock Awards	Option Awards	Total	
Name	(\$)	(\$) <sup>(1)</sup>	(\$)	
David Kabakoff, Ph.D.	<u>—</u> (2)	182,888(3)	182,888	
All other non-employee directors	_	_	_	

- (1) Amounts in this column reflect the full grant date fair value of stock option awards granted during the year as measured pursuant to Financial Accounting Standards Board Accounting Standards Codification Topic 718 and do not correspond to the actual value that may be recognized by the director in connection with the applicable awards. See Note 11 to our audited financial statements included elsewhere in this prospectus regarding assumptions underlying the valuation of equity awards.
- (2) As of December 31, 2018, Dr. Kabakoff held 62,237 shares of restricted common stock that were purchased in May 2016 and are subject to repurchase following termination, of which 10,372 shares were unvested and will vest in equal monthly installments through December 29, 2019, subject to Dr. Kabakoff's continued service with us through the applicable vesting date.
- (3) As of December 31, 2018, Dr. Kabakoff held an option to purchase 37,342 shares of our common stock. The option vests 25% on December 21, 2019 and, thereafter, <sup>1</sup>/<sub>36th</sub> of the remaining option will vest on each monthly anniversary of the grant date.

#### **EXECUTIVE COMPENSATION**

This section discusses the material components of the executive compensation program for our named executive officers, or NEOs, who are named in the "Summary Compensation Table" below. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies. In 2018, our NEOs and their positions were as follows:

- Michael Richman, President and Chief Executive Officer;
- Steven P. Cobourn, Chief Financial Officer; and
- Sol Langermann, Ph.D., Chief Scientific Officer.

## **Summary Compensation Table**

The following table sets forth information concerning the compensation of our NEOs for the year ended December 31, 2018:

Name and Principal Position Michael Richman President and Chief Executive Officer	<u>Year</u> 2018	Salary (\$) 383,400	Bonus (\$)	Option Awards (\$) <sup>(1)</sup> 1,963,224	Inc	ton-Equity centive Plan empensation (\$) 154,480	All Other Compensation (\$) 493	Total (\$) 2,501,597
Steven P. Cobourn, CPA Chief Financial Officer	2018	239,583(2)\$	58,800	694,465		_	493	993,341
Sol Langermann, Ph.D.  Chief Scientific Officer	2018	340,976	_	455,022	\$	85,800	493	882,291

- (1) Amounts in this column reflect the full grant date fair value of stock option awards granted during the year as measured pursuant to Financial Accounting Standards Board Accounting Standards Codification Topic 718 and do not correspond to the actual value that may be recognized by the director in connection with the applicable awards. See Note 11 to our audited financial statements included elsewhere in this prospectus regarding assumptions underlying the valuation of equity awards.
- (2) Mr. Cobourn's employment commenced with us on January 22, 2018. The 2018 salary reported reflects the pro rata portion of Mr. Cobourn's annual salary of \$250,000 earned during 2018 from commencement of his employment through December 31, 2018.

## **Narrative to Summary Compensation Table**

## **Annual Base Salary**

We have entered into employment agreements with each of our NEOs that establish annual base salaries, which are generally determined, approved and reviewed periodically by our board of directors in order to compensate our NEOs for services rendered to our company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries for our NEOs have generally been set at levels deemed necessary to attract and retain individuals with superior talent. In March 2018, the annual base salaries of Mr. Richman and Dr. Langermann were increased by 3% and 2.5% to \$386,200 and \$343,050, respectively. Mr. Cobourn's annual base salary for 2018 was \$250,000.

#### Annual Bonus and Non-Equity Incentive Plan Compensation

Our NEOs are eligible to receive annual bonuses, which are determined at the discretion of our board of directors based upon, among other things, the achievement of pre-determined performance milestones. For 2018, Mr. Richman and Dr. Langermann were each eligible to receive a target bonus of up to 35% and 25%, respectively, of his base salary. Our board of directors reviewed performance for the fiscal year 2018 and based on the level of achievement of performance milestones determined to pay these bonuses at target with the exception of Mr. Richman, who received a bonus of 40% of his base salary, which was above his target. At the time Mr. Cobourn joined our company in 2018, our board of directors did not set a target bonus percentage for Mr. Cobourn. Mr. Cobourn's bonus was determined by our board of directors using the same pre-determined performance milestones used for our other NEOs and represented 25% of his base salary pro-rated to reflect his start date of January 22, 2018.

#### **Equity Awards**

Although we do not have a formal policy with respect to the grant of equity incentive awards to our NEOs, we believe that equity grants provide our NEOs with a strong link to our long-term performance, create an ownership culture and help to align the interests of our NEOs and our stockholders. Our board of directors and compensation committee has historically been responsible for approving NEO equity grants, Our compensation committee is generally responsible for approving NEO equity grants. Vesting of equity awards is generally tied to continuous service with us and serves as an additional retention measure. Our NEOs generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain goals or to reward NEOs for exceptional performance. Prior to our IPO, we granted all awards pursuant to our 2015 Omnibus Incentive Plan, or the 2015 Plan, the terms of which are described below under "—Equity Compensation Plans—2015 Omnibus Incentive Plan."

In August 2018, our board of directors awarded Mr. Richman an option to purchase 118,249 shares of our common stock, Mr. Cobourn an option to purchase 74,684 shares of our common stock, and Mr. Langermann an option to purchase 24,894 shares of our common stock, each at an exercise price of \$1.77 per share. In December 2018, our board of directors awarded Mr. Richman an option to purchase 373,422 shares of our common stock, Mr. Cobourn an option to purchase 124,474 shares of our common stock and Dr. Langermann an option to purchase 87,131 shares of our common stock, each at an exercise price of \$7.63 per share. With respect to each of the grants disclosed above, 25% vest on the one-year anniversary of the grant date, and, thereafter,  $^{1}$ /36th of the remaining options vest on each monthly anniversary of the grant date.

## **Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding equity awards held by our NEOs that were outstanding as of December 31, 2018. All of the awards listed in this table were granted under the 2015

Plan, the terms of which are described below under "—Equity Compensation Plans—2015 Omnibus Incentive Plan."

		Option Awards			Stock Awards		
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$/sh)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested (\$)
Michael Richman	3/15/2017	43,565	56,014(1)	1.21	3/15/2027	_	
	8/27/2018	_	118,249(2)	1.77	8/27/2028	_	
	12/21/2018	_	373,422(1)	7.63	12/21/2028	_	
						64,311(3)	964,665(4)
Steven P. Cobourn, CPA	8/27/2018	_	74,684(5)	1.77	8/27/2028	_	
	12/21/2018	_	124,474(1)	7.63	12/21/2028	_	
Sol Langermann, Ph.D.	9/1/2016	14,003	10,891(1)	0.48	9/1/2026	_	
	3/15/2017	10,891	14,003(1)	1.21	3/15/2027	_	
	8/27/2018	_	24,894(2)	1.77	8/27/2028	_	
	12/21/2018	_	87,131(1)	7.63	12/21/2028	_	

- (1) On the one-year anniversary of the grant date, 25% of these options vest or vested and, thereafter, <sup>1</sup>/<sub>36th</sub> of the remaining options vest on each monthly anniversary of the grant date.
- On March 15, 2019, one quarter of the options vested and, thereafter, <sup>1</sup>/36th of the remaining options vest on each monthly anniversary thereof
- (3) Represents unvested restricted common stock purchased by the NEO on October 1, 2015 in connection with our founding. On December 29, 2015, the NEO entered into a stock restriction agreement pursuant to which 25% of the stock vested on the agreement date, 25% vested on the one-year anniversary of the agreement date and, thereafter, <sup>1</sup>/36th of the remaining shares vest on each monthly anniversary of the agreement date.
- (4) The market value of the stock award is based on our IPO price of \$15.00 per share.
- On January 22, 2019, one quarter of the options vested and, thereafter, <sup>1</sup>/<sub>36th</sub> of the remaining options vest on each monthly anniversary thereof.

### Employment Agreements with Named Executive Officers and Potential Payments Upon Termination or Change in Control

We have entered into employment agreements with each of our NEOs, as described below.

We entered into a letter agreement with Michael Richman, our President and Chief Executive Officer, in August 2016 that governs the current terms of his employment with us. Pursuant to that agreement, Mr. Richman (i) was entitled to an initial annual base salary of \$375,000, which has since increased, (ii) is eligible to receive an annual bonus of up to 35% of his base salary, (iii) in our board of directors' sole discretion, from time to time, is entitled to equity compensation awards under the 2015 Plan and (iv) receives health insurance benefits and other benefits approved by our board of directors.

We entered into a letter agreement with Steven P. Cobourn, our Chief Financial Officer, in December 2017 that governs the current terms of his employment with us. Pursuant to that agreement, Mr. Cobourn (i) was entitled to an initial annual base salary of \$250,000, (ii) received an option to purchase 74,684

shares of our common stock under the 2015 Plan and (iii) receives health insurance benefits and other benefits approved by our board of directors.

We entered into a letter agreement with Sol Langermann, Ph.D., our Chief Scientific Officer, in August 2016 that governs the current terms of his employment with us. Pursuant to that agreement, Dr. Langermann (i) was entitled to an initial annual base salary of \$325,000, which has since increased, (ii) is eligible to receive an annual bonus of up to 25% of his base salary, (iii) received an option to purchase 24,894 shares of our common stock under the 2015 Plan and (iv) receives health insurance benefits and other benefits approved by our board of directors.

In the event Mr. Richman or Dr. Langermann's employment with us is terminated by us for any reason other than Cause (as defined in the employment agreements) or by the NEO for Good Reason (as defined in the employment agreements), then he will be entitled to: (i) any unpaid salary for services rendered prior to the date of termination of employment; (ii) any earned but unpaid annual bonus for any fiscal year prior to the year in which termination of employment occurs; (iii) reimbursement of any unreimbursed business expenses; (iv) accrued but unused vacation; (v) any other payments, benefits or fringe benefits to which the NEO is entitled under the terms of any applicable compensation arrangement or benefit, equity, program or grant; (vi) 12 months' base salary, in the case of Mr. Richman, and six months' base salary, in the case of Dr. Langermann, subject to certain conditions and terms set forth in the employment agreement, including the execution of a release of claims; and (vii) health insurance coverage until the earlier of (a) six months following the effective termination date or (b) the date upon which the NEO commences full-time employment.

#### Other Agreements

We have also entered into standard confidentiality and proprietary rights agreements with each of our NEOs pursuant to which each NEO has agreed to protect our confidential, proprietary information and trade secret information indefinitely. Pursuant to these agreements, each NEO has agreed not to compete with us during his employment and for a period of one year after the termination of his employment and not to solicit our employees during his employment and for a period of one year after the termination of his employment. In addition, each NEO has agreed that there is a presumption that we own all inventions or works created by the NEO (i) using our facilities, supplies, information, trade secrets or time, (ii) that are indirectly related to or arise out of our actual or proposed business, (iii) that relate to any task assigned or performed by the NEO on our behalf or (iv) that are based on our confidential information.

#### **Equity Compensation Plans**

#### 2015 Omnibus Incentive Plan

Our board of directors adopted, and our stockholders approved the 2015 Plan on December 29, 2015, which was subsequently amended to increase the number of shares issuable under the 2015 Plan. The 2015 Plan is intended to enhance our company's ability to attract and retain highly qualified officers, directors, key employees and other persons, and to motivate such persons to serve us and our affiliates and to expend maximum effort to improve the business results and our earnings, by providing to such persons an opportunity to acquire or increase a direct proprietary interest in our operations and our future success. The 2015 Plan provides for the grant of stock options, restricted stock and stock units. No further awards will be made under the 2015 Plan; however, awards outstanding under the 2015 Plan will continue to be governed by their existing terms.

## **Outstanding Awards**

As of September 30, 2019, options to purchase 2,001,678 shares of our common stock and 2,593 unvested shares of restricted stock were outstanding under the 2015 Plan. If any shares covered by an award granted under the 2015 Plan are not purchased or are forfeited, expire or otherwise terminate

without delivery of any shares subject to the award, or are settled in cash in lieu of shares, then the number of shares subject to such award will, to the extent of any such forfeiture, termination, expiration or settlement, again be available for future issuance under the 2019 Plan.

#### Administration

The compensation committee of our board of directors generally administers the 2015 Plan. The administrator has complete discretion to make all decisions relating to the 2015 Plan and outstanding awards.

## Changes in Capitalization

In the event of a recapitalization, reclassification, stock split, reverse stock split, spin-off, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, or other increase or decrease in our shares of common stock effected without the receipt of consideration by us, then the number and kind of shares for which grants of options and other awards may be made under the 2015 Plan will be adjusted proportionately and accordingly by the administrator of the 2015 Plan. In addition, the number and kind of shares for which awards are outstanding, as well as the exercise price of outstanding options will be adjusted proportionately and accordingly by the administrator of the 2015 Plan.

#### Corporate Transaction

Our board of directors has the discretion to determine the effect of a "corporate transaction" (as defined in the 2015 Plan) on any outstanding awards. Without limiting the generality of the foregoing, in connection with a corporate transaction, our board of directors may elect, in its sole discretion, to:

- cancel any outstanding awards and pay or deliver, or cause to be paid or delivered, to the holder of the award an amount in cash or securities having a value (as determined by our board of directors acting in good faith) equal to the product of the number of shares subject to the award, or the Grant Shares, multiplied by, (i) in the case of options, the amount, if any, by which (a) the formula or fixed price per share paid to holders of shares of our common stock pursuant to such transaction exceeds (b) the exercise price applicable to such Grant Shares and (ii) in the case of restricted stock and stock units, the formula or fixed price per share paid to holders of shares of our common stock pursuant to the transaction;
- provide in connection with such corporate transaction for the assumption or continuation of the options previously granted, or for the substitution for such awards for new common stock options relating to the stock of a successor entity, or a parent or subsidiary thereof, with appropriate adjustments as to the number of shares (disregarding any consideration that is not common stock) and exercise prices, such that awards previously granted will continue in the manner and under the terms so provided;
- cancel any outstanding awards that are unvested (or any unvested portion thereof) without payment to the holders of such awards; or
- cancel any outstanding awards to the extent the exercise price applicable to the Grant Shares issuable under such awards is greater than the formula or fixed price per share paid to holders of shares of our common stock pursuant to such transaction, with or without any payment to the holders of such awards.

If we establish an exercise window in connection with a scheduled consummation of a corporate transaction, any exercise of an option during such period will be conditioned upon the consummation of the event and will be effective only immediately before the consummation of the event. Upon the consummation of any corporate transaction, the 2015 Plan and all outstanding but unexercised options will terminate. Our board of directors will send written notice of an event that will result in such a termination

to all individuals who hold options not later than the time at which we give notice of the event to the holders of our common stock.

Our board of directors may, in its sole discretion, provide for the accelerated vesting or lapse of restrictions of awards at any time.

#### Plan Amendment and Termination

Our board of directors may amend or terminate the 2015 Plan or any outstanding award under the 2015 Plan at any time; provided that no amendment may adversely impair a participant's rights under outstanding awards without his or her consent. Our stockholders must approve any amendment if such approval is required under applicable law or Nasdaq listing rules. Unless terminated sooner by our board of directors or extended with stockholder approval, the 2015 Plan will terminate on December 29, 2025.

#### 2019 Omnibus Incentive Plan

Our board of directors adopted our 2019 Omnibus Incentive Plan, or the 2019 Plan, in April 2019 and our stockholders approved the 2019 Plan in May 2019. The 2019 Plan became effective on May 8, 2019 upon the effectiveness of the registration statement for our IPO. The purpose of the 2019 Plan is to provide eligible individuals with an incentive to contribute to our success and to operate and manage our business in a manner that will provide for our long-term growth and profitability and that will benefit our stockholders and other important stakeholders, including our employees and customers. The 2019 Plan is also intended to provide a means of recruiting, rewarding and retaining key personnel. The 2019 Plan provides for the grant 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. The 2019 Plan replaces the 2015 Plan; however, awards outstanding under the 2015 Plan will continue to be governed by their existing terms.

#### Share Reserve

The number of shares of our common stock reserved for issuance under the 2019 Plan is equal to the sum of (i) 2,900,000 shares plus (ii) any shares related to awards outstanding under the 2015 Plan on May 8, 2019 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 1st of each year during the term of the 2019 Plan, by a number equal to 4% of the shares of common stock outstanding on December 31st of the prior calendar year; however, our board of directors may provide that there will be no increase, or a smaller increase, in the share reserve for a given calendar year. As of September 30, 2019, options to purchase 247,275 shares of our common stock were outstanding under the 2019 Plan and 2,653,969 additional shares of our common stock remained available for future issuance.

If any shares covered by an award granted under the 2019 Plan are not purchased or are forfeited or expire or otherwise terminate without delivery of any shares subject to the award, or are settled in cash in lieu of shares, then the number of shares subject to such award will, to the extent of any such forfeiture, termination, expiration or settlement, again be available for future issuance under the 2019 Plan. In addition, if shares subject to an award are applied to the exercise price or tax withholding obligations related to the award, such shares will again be available for future issuance under the 2019 Plan.

#### Administration

The 2019 Plan is administered by our board of directors or a committee of our board of directors to which our board of directors delegates such administration (as applicable, the administrator). Subject to the terms of the 2019 Plan, the administrator has the complete discretion to determine the eligible individuals who are to receive awards under the 2019 Plan, to determine the terms and conditions of

awards granted under the 2019 Plan and to make all decisions related to the 2019 Plan and awards granted thereunder. The administrator also interprets the provisions of the 2019 Plan. Our board of directors has delegated full authority to administer the 2019 Plan to its compensation committee.

**Eligibility** 

All of our employees and the employees of our affiliates are eligible to receive awards under the 2019 Plan. In addition, our non-employee directors and certain consultants and advisors who perform services for us and our affiliates may receive awards under the 2019 Plan. However, only our employees and our subsidiaries are eligible to receive incentive stock options.

Stock Options

The 2019 Plan authorizes our compensation committee to grant incentive stock options (under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code) and stock options that do not qualify as incentive stock options, or non-qualified stock options. The maximum number of shares that may be issued under the 2019 Plan pursuant to the exercise of incentive stock options is 8,700,000. The compensation committee will determine the exercise price of each stock option, provided that the price must be equal to at least the fair market value of our shares of common stock on the date on which the stock option is granted. If we were to grant incentive stock options to any 10% stockholder, the exercise price may not be less than 110% of the fair market value of our shares of common stock on the date of grant.

The term of a stock option cannot exceed 10 years from the date of grant. If we were to grant incentive stock options to any 10% stockholder, the term cannot exceed five years from the date of grant. The compensation committee will determine at what time or times each stock option may be exercised and the period of time, if any, after death, disability or termination of employment during which stock options may be exercised. Stock options may be made exercisable in installments. The compensation committee may accelerate the exercisability of stock options.

The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options that are exercisable for the first time by a grantee during any calendar year under all of our stock plans may not exceed \$100,000. We will generally treat stock options or portions thereof that exceed such limit as non-qualified stock options.

Stock Appreciation Rights

The 2019 Plan authorizes our compensation committee to grant stock appreciation rights that provide the recipient with the right to receive, upon exercise of the stock appreciation right, cash, shares of our common stock or a combination of the two. The amount that the recipient will receive upon exercise of the stock appreciation right generally will equal the excess of the fair market value of our common stock on the date of exercise over the shares' fair market value on the date of grant. Stock appreciation rights will become exercisable in accordance with terms determined by our compensation committee. Stock appreciation rights may be granted in tandem with a stock option grant or independently from a stock option grant. The term of a stock appreciation right cannot exceed 10 years from the date of grant.

Restricted Stock, Restricted Stock Units and Deferred Stock Units

The 2019 Plan authorizes our compensation committee to grant restricted stock, restricted stock units and deferred stock units. Restricted stock is an award of our common stock on which vesting restrictions are imposed that subject such shares of our common stock to a substantial risk of forfeiture, as defined in Section 83 of the Code. A restricted stock unit is an award that represents the right to receive a compensation amount, based on the value of our shares of common stock, if vesting criteria established by the compensation committee are met. If the vesting criteria are met, we will settle restricted stock units in

cash, shares of our common stock or a combination of the two. A deferred stock unit is a restricted stock unit that may be settled at some point in the future at a time or times consistent with the requirements of Section 409A of the Code.

Subject to the provisions of the 2019 Plan, our compensation committee will determine the terms and conditions of each award of restricted stock, restricted stock units and deferred stock units, including the restricted period for all or a portion of the award, the restrictions applicable to the award and the purchase price, if any, for the shares of our common stock subject to the award. A grantee of restricted stock will have all the rights of a stockholder, including the right to vote the shares and receive dividends, except to the extent limited by our compensation committee. However, all cash dividends declared or paid on shares of restricted stock will not vest or become payable unless and until the shares of restricted stock to which the dividends apply become vested and nonforfeitable. In addition, all stock dividend payments or distributions, if any, received by a grantee with respect to shares of restricted stock as a result of any stock split, stock dividend, combination of stock or other similar transaction will be subject to the same vesting conditions and restrictions as applicable to such underlying shares of restricted stock.

Grantees of restricted stock units and deferred stock units will have no voting or dividend rights or other rights associated with stock ownership, although our compensation committee may award dividend equivalent rights on such units. Dividend equivalent rights granted as a component of another award will not vest or become payable unless and until the award to which the dividend equivalent rights correspond becomes vested and settled.

#### Dividend Equivalent Rights

The 2019 Plan authorizes our compensation committee to grant dividend equivalent rights in connection with the grant of any equity-based award other than stock options and stock appreciation rights. Dividend equivalent rights entitle the grantee to receive, or to receive credits for the future payment of, cash, shares of our common stock or other property equal in value to dividend payments or distributions declared or paid by us with respect to a number of shares of our common stock specified in such dividend equivalent right (or other award to which such right relates), as if such shares had been issued to and held by the grantee as of the record date of such dividend or distribution. Dividend equivalent rights may be paid currently or may be deemed to be reinvested in additional shares of stock, which may thereafter accrue additional dividend equivalent rights and may be payable in cash, shares of our common stock or a combination of the two; however, dividend equivalent rights granted as a component of another award will not vest or become payable unless and until the award to which the dividend equivalent rights correspond becomes vested and settled. Our compensation committee will determine the terms of any dividend equivalent rights.

## Other Equity-Based Awards

The 2019 Plan authorizes our compensation committee to grant other types of equity-based awards under the 2019 Plan. Other equity-based awards may be granted with vesting, value and/or payment contingent upon the achievement of one or more performance goals or other vesting conditions, and may be payable in cash, shares of our common stock or a combination thereof. The terms and conditions that apply to other equity-based awards will be determined by our compensation committee.

## Non-Employee Director Compensation Limitation

The 2019 Plan provides that the aggregate value of all awards granted under the plan and all other cash compensation paid by us to any of our non-employee directors in any calendar year may not exceed \$750,000; however, such amount will be \$1.0 million for the calendar year in which the non-employee director is initially elected or appointed to our board of directors. Our board of directors may make exceptions to these limitations for individual non-employee directors in extraordinary circumstances,

provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving non-employee directors.

#### Changes in Capitalization

In the event of a recapitalization, reclassification, stock split, reverse stock split, spin-off, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, or other increase or decrease in our shares of common stock effected without the receipt of consideration by us, then the number and kind of shares for which grants of options and other awards may be made under the 2019 Plan, including the maximum number of shares that may be issued upon the exercise of incentive stock options, will be adjusted proportionately and accordingly by our compensation committee. In addition, the number and kind of shares for which awards are outstanding, as well as the exercise price of outstanding options and stock appreciation rights, will be adjusted proportionately and accordingly by our compensation committee.

## Change in Control

Except as otherwise provided in the applicable award agreement, in another agreement with a grantee, or as otherwise set forth in writing, upon the occurrence of a "change in control" (as defined in the 2019 Plan) in which outstanding awards are not being assumed, continued or substituted for, the following provisions will apply to the awards: (i) except for performance-based awards, all shares of restricted stock, restricted stock units, deferred stock units and dividend equivalent rights will be deemed to have vested and any underlying shares of our common stock will be deemed delivered immediately before the change in control; and (ii) at our compensation committee's discretion, either all options and stock appreciation rights will become exercisable 15 days before the change in control (with any exercise of an option or stock appreciation right during such 15 day period to be contingent upon the consummation of the change in control) and terminate upon the change in control to the extent not exercised, or all options, stock appreciation rights, shares of restricted stock units, deferred stock units and/or dividend equivalent rights will be canceled and cashed out in connection with the change in control.

In the case of performance-based awards, if less than half of the performance period has lapsed, the award will be treated as though target performance has been achieved. If at least half of the performance period has lapsed, actual performance to date will be determined as of a date reasonably proximal to the date of the consummation of the change in control, as determined by our compensation committee in its sole discretion, and that level of performance will be treated as achieved immediately prior to the occurrence of the change in control. If our compensation committee determines that actual performance is not determinable, the award will be treated as though target performance has been achieved. Any awards that arise after performance is determined in accordance with this paragraph will be treated as set forth in the preceding paragraph. Other equity-based awards will be governed by the terms of the applicable award agreement.

If we experience a change in control in which outstanding awards will be assumed, continued or substituted for by the surviving entity, then, except as otherwise provided in the applicable award agreement, in another agreement with a grantee, or as otherwise set forth in writing, upon the occurrence of the change in control, the 2019 Plan and the awards granted under the 2019 Plan will continue in the manner and under the terms so provided in the event of the change in control to the extent that provision is made in writing in connection with such change in control for the assumption or continuation of such awards, or for the substitution for such awards with new awards, with appropriate adjustments as to the number of shares (disregarding any consideration that is not common stock) and exercise prices of options and stock appreciation rights.

Except as otherwise provided in the applicable award agreement, in another agreement with a grantee, or as otherwise set forth in writing, in the event a grantee's award is assumed, continued, or substituted upon the consummation of any change in control and the service of such grantee with us or an affiliate of ours is terminated without "cause" (as defined in the 2019 Plan) within 12 months following the consummation of such change in control, such award will become fully vested and may be exercised in full, to the extent applicable, beginning on the date of such termination and for the one-year period, or such longer period as may be determined by our compensation committee, immediately following such termination.

### Clawback; Transferability

All awards will be subject to mandatory repayment to us by a grantee to the extent the grantee is, or in the future becomes, subject to (i) any "clawback" or recoupment policy by us or any of our affiliates that is adopted to comply with the requirements of any applicable laws, or (ii) any applicable laws which impose mandatory recoupment, under circumstances set forth in such applicable laws. Except in limited circumstances, awards granted under the 2019 Plan may generally not be transferred in any manner prior to vesting other than by will or by the laws of descent and distribution.

#### Plan Amendment and Termination

Our compensation committee may amend or terminate the 2019 Plan at any time; provided that no amendment may materially impair a participant's rights under outstanding awards without his or her consent. Our stockholders must approve any amendment if such approval is required under applicable law or Nasdaq listing rules. Unless terminated sooner by our board of directors or extended with stockholder approval, the 2019 Plan will terminate on the day before the tenth anniversary of the effective date of the registration statement of which this prospectus is a part.

## No Repricing without Stockholder Approval

Except in connection with certain corporate transactions, we may not, without obtaining stockholder approval: (i) amend the terms of outstanding options or stock appreciation rights to reduce the applicable exercise price; (ii) cancel outstanding options or stock appreciation rights in exchange for or substitution of options or stock appreciation rights with an exercise price that is less than the exercise price of the original options or stock appreciation rights; or (iii) cancel outstanding options or stock appreciation rights with an exercise price above the current stock price in exchange for cash or other securities.

### 2019 Employee Stock Purchase Plan

Our board of directors adopted the ESPP in April 2019 and our stockholders approved the ESPP in May 2019. The ESPP became effective on May 8, 2019 upon the effectiveness of the registration statement for our IPO. The purpose of the ESPP is to encourage and to enable eligible employees to acquire proprietary interests in our company through the purchase and ownership of shares of our common stock. The ESPP is intended to benefit us and our stockholders by incentivizing participants to contribute to our success and to operate and manage our business in a manner that will provide for our long-term growth and profitability and that will benefit our stockholders and other important stakeholders. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

## Share Reserve

The ESPP authorizes the issuance of up to 240,000 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our participating affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1st of each year, commencing on January 1, 2020 and continuing until the expiration of the ESPP, in an amount equal to the

least of (i) 1% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (ii) 480,000 shares of our common stock (subject to adjustment as provided in the ESPP) and (iii) a number of shares of our common stock determined by our board of directors or our compensation committee, as applicable; however, our board of directors or our compensation committee, as applicable, may act prior to the first day of any calendar year to provide that there will be no increase in the share reserve for such calendar year.

#### Administration

The ESPP is administered under the direction of our board of directors, our compensation committee, or any other committee designated by our board of directors. Our board of directors has delegated full authority to administer the ESPP to its compensation committee. Among other things, the compensation committee has the authority to determine eligibility for participation in the ESPP, designate separate offerings under the plan and construe, interpret and apply the terms of the plan.

#### Eligibility

All of our employees who are employed by us or our participating affiliates may be eligible to participate in the ESPP, provided that the following employees are among those that are ineligible under the ESPP: (i) employees whose customary employment is 20 hours or less per week; (ii) employees whose customary employment is for not more than five months in any calendar year; and (iii) employees who, after exercising their rights to purchase our common stock under the ESPP, would own 5% or more of our total combined voting power.

No employee may purchase shares of our common stock in any calendar year under the ESPP and under all other employee stock purchase plans having an aggregate fair market value in excess of \$25,000, determined as of the first trading day of the offering period. In addition, unless otherwise determined by our compensation committee, no employee may purchase more than 5,000 shares of our common stock in any one offering period.

## Offering Periods

The ESPP is being implemented through a series of offerings under which eligible employees are granted purchase rights to purchase our common stock on specified dates during such offerings. Our compensation committee will determine offering periods of not more than 27 months and may permit periodic purchases of our common stock within a single offering period. Unless otherwise established by our compensation committee prior to the start of an offering period, the plan will have two offering periods (with concurrent purchase periods) that commence each calendar year, and each offering period will be of approximately six months' duration, with the first such offering period beginning on the first trading day of April and ending on the last trading day of the immediately following September, and the second such offering period beginning on the first trading day of October and ending on the last trading day of the immediately following March.

#### Payroll Deductions and Purchase Price

Generally, all employees, including executive officers, employed by us or by any of our participating affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their eligible compensation for the purchase of our common stock under the ESPP. Unless otherwise determined by our compensation committee, the purchase price per share of our common stock under the ESPP will be 85% of the lesser of the average of the high and low sales price of our common stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period).

#### Limitations on the Sale of Shares

Our compensation committee has the right to (i) require that an employee not request that all or a part of the shares of our common stock purchased by the employee be reissued in the employee's own name and shares be delivered to the employee until two years have elapsed since the offering date of the offering period in which the shares of our common stock were purchased and one year has elapsed since the day the shares of our common stock were purchased, or the holding period, (ii) require that any sales of our common stock during the holding period be performed through a licensed broker acceptable to us and (iii) limit sales or other transfers of shares of our common stock for up to two years from the date the employee purchases shares of our common stock under the ESPP.

#### Corporate Transactions

In the event that there occurs a change in our capital structure through such actions as a recapitalization, stock split, reverse stock split, spin-off, combination of shares, exchange of shares, stock dividend or other distribution payable in capital stock, our compensation committee will make appropriate adjustments to the number and kind of shares that may be purchased, and the number and kind of shares for which options are outstanding, under the ESPP.

In the event of certain significant corporate transactions, including (i) a dissolution or liquidation, (ii) a merger, consolidation or reorganization where we are not the surviving entity, (iii) a sale of all or substantially all of our assets, or (iv) a merger or consolidation resulting in any person or entity owning more than 50% of the combined voting power of all classes of our capital stock, the ESPP and all elections outstanding under the ESPP will terminate, except for certain situations where, for instance, the parties make arrangements for the continuation or assumption of the ESPP. In the event of any such termination of the ESPP, the offering period and the purchase period will be deemed to have ended on the last trading day prior to such termination, and the options of each participant then outstanding will be deemed to be automatically exercised on such last trading day.

## Amendment, Suspension, or Termination

The ESPP will terminate on the day before the 10th anniversary of the date of adoption of the ESPP by our board of directors, unless earlier terminated. Our compensation committee may amend, suspend, or terminate the ESPP; however, any such amendment, suspension, or termination may not impair any vested rights without the employee's consent. Our compensation committee may not increase the number of shares reserved for issuance under the ESPP without stockholder approval.

#### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2016 to which we have been or are to be a participant, in which the amount exceeds \$120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of any class of our voting securities, or any immediate family member of or person sharing a household with any of the foregoing persons, had or will have a direct or indirect material interest, other than employment relationships with our executive officers and compensation to our directors. Employment relationships with and compensation paid to our NEOs are described under the section entitled "Executive Compensation" and compensation to our directors is described in "Management—Non-Employee Director Compensation."

#### Our Relationships with Yale University and Dr. Lieping Chen

## Consulting Agreement with Lieping Chen, M.D., Ph.D.

In December 2015, we entered into a consulting agreement for advisory services with our scientific founder, Dr. Lieping Chen, who beneficially owned more than 5% of our outstanding common stock at the time of the transaction. The term of the consulting agreement expires December 31, 2020. Under the agreement, Dr. Chen receives \$5,000 per month in consulting fees until the expiration of the agreement.

## Yale License Agreement and Sponsored Research Agreement

In December 2015, we entered into a license agreement with Yale University, which beneficially owned more than 5% of our outstanding common stock at the time of the transaction. Under the Yale Agreement, we obtained a 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 in an aggregate amount of up to approximately \$3.0 million.

In connection with the Yale Agreement, we also entered into 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.

Dr. Chen 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 the Yale Cancer Center. For more information about the Yale Agreement and the SRA, see "Business—Our Collaboration Agreements—Agreements with Yale University."

### Gift to Yale University

In March 2016, we made a charitable contribution to Dr. Chen at Yale University of \$500,000 to be used at Dr. Chen's discretion to support research activities.

## Our Relationship with Eli Lilly

In November 2018, we entered into the Lilly Agreement, which is focused on the discovery and development of immunomedicines for oncology using our FIND-IO platform. At the time of the transaction, Lilly beneficially owned more than 5% of our outstanding common stock. 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 are eligible for support, option exercise and milestone payments of

an aggregate of up to \$1.4 billion, as well as mid to high single-digit royalties under the Lilly Agreement. Upon our exercise of an option with respect to a given target, we will owe Lilly option exercise, milestone and royalty payments in amounts equivalent to a portion of the amounts payable by Lilly were Lilly to exercise an option. For more information on the Lilly Agreement, see "Business—Our Collaboration Agreements—Research and Development Collaboration with Lilly."

## **Sales and Purchases of Securities**

## Series A-2 and Series A-3 Preferred Stock Financings

In January 2017, we issued and sold an aggregate of 25,000,000 shares of our Series A-2 Preferred Stock, at a purchase price of \$1.00 per share, for aggregate proceeds to us of \$25 million. In April 2018, we issued and sold an aggregate of 28,181,819 shares of our Series A-3 Preferred Stock, at a purchase price of \$1.10 per share, for aggregate proceeds to us of approximately \$31 million. Each share of Series A-2 and Series A-3 Preferred Stock was converted into 0.1245 shares of common stock upon the closing of our IPO.

Certain owners of 5% or more of a class of our voting stock and entities that may have been deemed to beneficially own 5% or more of a class of our voting stock purchased shares of our Series A-2 and Series A-3 Preferred Stock in these financings. The following table summarizes those purchases:

Participants	Shares of Series A-2 Preferred Stock	Shares of Series A-3 Preferred Stock	Purchase Price
OrbiMed Private Investments VI, LP <sup>(1)</sup>	5,970,000	5,861,455	\$ 12,417,601
Canaan X L.P. <sup>(2)</sup>	5.970,000	5,861,455	\$ 12,417,601
Sofinnova Venture Partners IX, L.P. <sup>(3)</sup>	3,732,500	7,301,000	\$ 11,763,600
Pfizer Inc. <sup>(4)</sup>	4,477,500	4,396,091	\$ 9,313,200
Entities associated with Lilly Asia Ventures <sup>(5)</sup>	4,477,500	4,396,091	\$ 9,313,200
Alexandria Venture Investments, LLC	372,500	365,727	\$ 774,780

- (1) Chau Q. Khuong, a member of our board of directors, is a Partner at OrbiMed Advisors LLC, which is associated with OrbiMed Private Investments VI, LP.
- (2) Timothy M. Shannon, M.D., a member of our board of directors, is a managing member of Canaan Partners X LLC, the general partner of Canaan X L.P.
- (3) David Kabakoff, Ph.D., the Chair of our board of directors, is an Executive Partner at Sofinnova Investments, Inc., the management company of Sofinnova Venture Partners IX, L.P.
- (4) These shares are directly owned by Pfizer Ventures (US) LLC, or Pfizer Ventures. Pfizer Inc. is the parent company of Pfizer Ventures and may be deemed to beneficially own the shares directly owned by Pfizer Ventures. Elaine V. Jones, a member of our board of directors, was Vice President, Worldwide Business Development and Senior Partner at Pfizer Ventures, which is associated with Pfizer Inc., when these shares were issued.
- (5) Consists of 1,492,500 shares of Series A-2 Preferred Stock and 1,465,364 shares of Series A-3 Preferred Stock purchased by Lilly Asia Ventures Fund III, L.P. and 2,985,000 shares of Series A-2 Preferred Stock and 2,930,727 shares of Series A-3 Preferred Stock purchased by LAV Biosciences Fund III, L.P. Judith J. Li, a member of our board of directors, is a Partner at Lilly Asia Ventures, which is associated with Lilly Asia Ventures Fund III, L.P. and LAV Biosciences Fund III.

#### Series B Preferred Stock Financing

In November 2018, we issued and sold an aggregate of 15,052,117 shares of our Series B-1 Preferred Stock at a purchase price of \$1.59 per share, 34,276,734 shares of our Series B-2 Preferred Stock at a purchase price of \$1.59 per share and 7,500,000 shares of our Series B-3 Preferred Stock at a purchase price of \$2.00 per share. We received aggregate gross proceeds of approximately \$93.4 million for the sale of our Series B Preferred Stock. Each share of Series B Preferred Stock was converted into 0.1245 shares of common stock upon the closing of our IPO.

Certain owners of 5% or more of a class of our voting stock and entities that may have been deemed to beneficially own 5% or more of a class of our voting stock purchased shares of our Series B-1, B-2 and B-3 Preferred Stock in these financings. The following table summarizes that participation:

	Shares of Series B-1 Preferred	Shares of Series B-2 Preferred	Shares of Series B-3 Preferred	Purchase
Participants (1)	Stock	Stock	Stock	Price
OrbiMed Private Investments VI, LP <sup>(1)</sup>	3,554,466			\$ 5,651,601
Canaan X L.P. <sup>(2)</sup>	2,296,605			\$ 3,651,602
Sofinnova Venture Partners IX, L.P. <sup>(3)</sup>	3,773,585			\$ 6,000,000
Pfizer Inc. <sup>(4)</sup>	2,665,850			\$ 4,238,702
Entities associated with Lilly Asia Ventures <sup>(5)</sup>	2,132,680			\$ 3,390,961
Alexandria Venture Investments, LLC	628,931			\$ 1,000,000
HH NCure Holdings LLC <sup>(6)</sup>		7,861,636		\$ 12,500,001
Quan Venture Fund II, L.P. <sup>(7)</sup>		7,861,636		\$ 12,500,001
Bay City Capital GF Xinde International Life Sciences USD				
Fund, L.P.		4,716,982		\$ 7,500,000
Citadel Multi-Strategy Equities Master Fund Ltd.		3,144,655		\$ 5,000,001
Taiho Ventures, LLC		3,144,655		\$ 5,000,001
Ling Tong Investment Limited		3,144,654		\$ 5,000,000
Entities associated with ArrowMark Partners		2,515,723		\$ 4,000,000
Entities associated with NS Investment		1,886,793		\$ 3,000,000
Eli Lilly and Company			7,500,000	\$ 15,000,000

- (1) Chau Q. Khuong, a member of our board of directors, is a Partner at OrbiMed Advisors LLC, which is associated with OrbiMed Private Investments VI, LP.
- (2) Timothy M. Shannon, M.D., a member of our board of directors, is a managing member of Canaan Partners X LLC, the general partner of Canaan X L.P.
- (3) David Kabakoff, Ph.D., the Chair of our board of directors, is an Executive Partner at Sofinnova Investments, Inc., the management company of Sofinnova Venture Partners IX, L.P.
- (4) Elaine V. Jones, a member of our board of directors, was Vice President, Worldwide Business Development and Senior Partner at Pfizer Ventures, which is associated with Pfizer Inc., when these shares were issued.
- (5) Consists of 710,893 shares of Series B-1 Preferred Stock purchased by Lilly Asia Ventures Fund III, L.P. and 1,421,787 shares of Series B-1 Preferred Stock purchased by LAV Biosciences Fund III, L.P. Judith J. Li, a member of our board of directors, is a Partner at Lilly Asia Ventures, which is associated with Lilly Asia Ventures Fund III, L.P. and LAV Biosciences Fund III.
- (6) Qingqing Yi, a former member of our board of directors, is a Partner at Hillhouse Capital Group, which is associated with HH NCure Holdings LLC.
- (7) Stella Xu, a member of our board of directors, is a Managing Director at Quan Capital, which is associated with Quan Venture Fund II. L.P.

In connection with the Series B Preferred Stock financing, we reimbursed (i) counsel for HH NCure Holdings LLC in the amount of \$150,000, (ii) counsel for Quan Venture Fund II, L.P., in the amount of \$10,000 and (iii) counsel for Pfizer Inc., OrbiMed Private Investments VI, LP, Lilly Asia Ventures and Sofinnova Venture Partners IX, L.P., collectively, in an aggregate amount of \$45,000 for legal fees incurred by them.

## Amended and Restated Investors' Rights Agreement

In connection with our Series B Preferred Stock financing in November 2018, we entered into an amended and restated investors' rights agreement with the holders of our preferred stock. One stockholders is entitled to rights with respect to the registration of its shares under the Securities Act in certain circumstances. For a more detailed description of these registration rights, see the section entitled "Description of Capital Stock—Registration Rights."

#### **Voting Agreement**

In connection with our Series A Preferred Stock financing, we entered into a voting agreement with the holders of our preferred stock and the holders of our common stock with respect to election of our directors and certain other matters, which voting agreement was amended and restated in connection with our Series B Preferred Stock financing in November 2018. The agreement terminated upon the closing of our IPO.

#### **Management Rights Letters**

In connection with our preferred stock financings, we entered into management rights letters with purchasers of our preferred stock with which certain of our directors are affiliated, pursuant to which such purchasers were granted certain management rights, including the right to consult with and advise our management on significant business issues, review our operating plans, examine our books and records and inspect our facilities. These management rights terminated upon the closing of our IPO.

## Participation in our Initial Public Offering

In connection with our IPO, certain of our 5% stockholders and funds associated with certain of our directors purchased shares of our common stock from the underwriters at the IPO price of \$15.00 per share, and on the same terms as other investors in our IPO. The following table summarizes those purchases:

Participants	Shares of Common Stock	Purchase Price
Sofinnova Ventures, Inc. <sup>(1)</sup>	400,000	\$ 6,000,000
OrbiMed Advisors, New York <sup>(2)</sup>	350,000	\$ 5,250,000
Pfizer Inc. <sup>(3)</sup>	200,000	\$ 3,000,000
Quan Venture Fund II, L.P. <sup>(4)</sup>	125,000	\$ 1,875,000
Canaan X LP <sup>(5)</sup>	50,000	\$ 750,000

- (1) David Kabakoff, Ph.D., the Chair of our board of directors, is an Executive Partner at Sofinnova Investments, Inc., which is associated with Sofinnova Ventures, Inc.
- (2) Chau Q. Khuong, a member of our board of directors, is a Partner at OrbiMed Advisors LLC, which is associated with OrbiMed Advisors, New York.
- (3) These shares are directly owned by Pfizer Ventures.

- (4) Stella Xu, a member of our board of directors, is a Managing Director at Quan Capital, which is associated with Quan Venture Fund II, L.P.
- (5) Timothy M. Shannon, M.D., a member of our board of directors, is a managing member of Canaan Partners X LLC, which is associated with Canaan X LP.

## **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and executive officers. These indemnification agreements generally require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors and executive officers as a result of any proceeding against them as to which they could be indemnified. For more information regarding these agreements, see "Management—Limitation on Liability and Indemnification Matters."

#### **Policies and Procedures Regarding Transactions with Related Persons**

Our board of directors adopted a written related person transaction policy, effective upon the closing of the IPO, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest. Types of transactions covered by this policy include, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth information relating to the beneficial ownership of our common stock as of November 11, 2019, by:

- · each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our NEOs; and
- all of our directors and executive officers as a group.

The number of shares beneficially owned prior to this offering by each entity, person, director or executive officer is determined in accordance with SEC rules, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of November 11, 2019 through the exercise of any stock option or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 22,753,960 shares of our common stock outstanding on November 11, 2019. The percentage of beneficial ownership after this offering in the table below is based on 25,953,960 shares of common stock assumed to be outstanding after the closing of this offering, assuming no exercise of the underwriters' option to purchase additional shares. Shares of our common stock that a person has the right to acquire within 60 days of November 11, 2019 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but not for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Except as set forth

below, the address for each beneficial owner listed is c/o NextCure, Inc., 9000 Virginia Manor Road, Suite 200, Beltsville, Maryland 20705.

	Number of Shares	Percenta Shares Ben Own	eficially
Name of Beneficial Owner	Beneficially Owned	Before Offering	After Offering
5% Stockholders:			
OrbiMed Advisors LLC <sup>(1)</sup>	2,711,013	11.91%	10.45%
Sofinnova Venture Partners IX, L.P. <sup>(2)</sup>	2,521,856	11.08%	9.72%
Canaan X L.P. <sup>(3)</sup>	2,254,442	9.91%	8.69%
Pfizer Inc. <sup>(4)</sup>	1,970,759	8.66%	7.59%
Entities associated with Lilly Asia Ventures <sup>(5)</sup>	1,704,391	7.49%	6.57%
Named Executive Officers and Directors:			
Michael Richman <sup>(6)</sup>	599,420	2.61%	2.31%
Steven P. Cobourn, CPA <sup>(7)</sup>	66,905	*	*
Sol Langermann, Ph.D. <sup>(8)</sup>	107,876	*	*
David Kabakoff, Ph.D. <sup>(9)</sup>	71,573	*	*
Elaine V. Jones, Ph.D.	_	_	_
Chau Q. Khuong	_	_	_
Judith J. Li	_	_	_
Briggs Morrison, M.D. (10)	5,290	*	*
Timothy M. Shannon, M.D.		_	_
Stephen W. Webster	_		_
Stella Xu, Ph.D. <sup>(11)</sup>	1,103,570	4.85%	4.25%
All executive officers and directors as a group (15 persons) <sup>(12)</sup>	2,314,074	9.90%	8.92%

<sup>\*</sup> Indicates beneficial ownership of less than 1% of the total outstanding common stock.

- (1) Based solely on a Schedule 13D filed by OrbiMed Advisors LLC and OrbiMed Capital GP VI LLC on May 21, 2019. OrbiMed Advisors LLC is the general partner of OrbiMed Capital GP VI LLC, the general partner of OrbiMed Private Investments VI, LP, which directly owns the shares. OrbiMed Advisors LLC and OrbiMed Capital GP VI LLC may be deemed to have shared voting and dispositive power over the shares. Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein as members of OrbiMed Advisors LLC's management committee share voting and dispositive power over the shares. The address for OrbiMed Advisors LLC is 601 Lexington Ave, 54th Floor, New York, NY 10022.
- (2) Based solely on a Schedule 13D filed by Sofinnova Venture Partners IX, L.P. and Sofinnova Management IX, L.L.C. on May 17, 2019. Sofinnova Management IX, L.L.C., or SM IX, the general partner of Sofinnova Venture Partners IX, L.P., may be deemed to have sole voting and dispositive power with respect to, and Dr. Michael F. Powell, Dr. James I. Healy and Dr. Anand Mehra, the managing members of SM IX, may be deemed to have shared power to vote and dispose of, the shares owned by Sofinnova Venture Partners IX, L.P. The address for Sofinnova Venture Partners IX, L.P. is 3000 Sand Hill Rd., Bldg. 4, Suite 250, Menlo Park, CA 94025.
- (3) Canaan Partners X LLC is the sole general partner of Canaan X L.P. and may be deemed to have sole voting and dispositive power over the shares held by Canaan X L.P. Investment, voting and dispositive decisions with respect to the shares held by Canaan X L.P. are made by the managers of Canaan Partners X LLC, collectively. None of the managers of Canaan Partners X LLC has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by Canaan X L.P. The address for Canaan X L.P. is 285 Riverside Ave., Suite 250, Westport, CT 06880.

- (4) Based solely on a Schedule 13G filed by Pfizer Inc. and Pfizer Ventures (US) LLC on May 22, 2019. Pfizer Inc. has sole voting and dispositive power with respect to 331,829 shares and shared voting and dispositive power with respect to 1,638,930 shares. As of October 28, 2019, the board of directors of Pfizer Inc. was comprised of the following individuals: Ronald E. Blaylock, Albert Bourla, W. Don Cornwell, Joseph J. Echevarria, Scott Gottlieb, Helen H. Hobbs, James M. Kilts, Dan R. Littman, Shantanu Narayen, Suzanne Nora Johnson, Ian C. Read and James C. Smith. Pfizer Inc. is a publicly traded company. The address for Pfizer Inc. is 235 East 42nd St., New York, NY 10017.
- (5) LAV GP III, L.P. is the General Partner of LAV Biosciences Fund III, L.P. and Lilly Asia Ventures Fund III, L.P. The Managing Partner of LAV GP III, L.P. is Yi Shi, Ph.D. Dr. Shi may be deemed to have voting and dispositive power over the shares owned by LAV Biosciences Fund III, L.P. and Lilly Asia Ventures Fund III, L.P. The address for Lilly Asia Ventures is Unit 902-904, Two Chinachem Central, 26 Des Voeux Road Central, Hong Kong.
- (6) Consists of (a) 385,869 shares of common stock, including up to 10,718 shares of restricted common stock subject to repurchase by us upon certain terminations, and (b) 213,551 shares of common stock issuable upon the exercise of stock options within 60 days of November 11, 2019. Our right of repurchase lapses in equal monthly installments through December 29, 2019.
- (7) Consists of 66,905 shares of common stock issuable upon the exercise of stock options within 60 days of November 11, 2019.
- (8) Consists of (a) 37,342 shares of common stock, including up to 1,555 shares of restricted common stock subject to repurchase by us upon certain terminations, and (b) 70,534 shares of common stock issuable upon the exercise of stock options within 60 days of November 11, 2019. Our right of repurchase lapses in equal monthly installments through December 29, 2019.
- (9) Consists of (a) 62,237 shares of restricted common stock subject to repurchase following termination, 1,729 of which are unvested and subject to forfeiture following termination for any reason other than death or disability prior to December 29, 2019 and (b) 9,336 shares of common stock issuable upon the exercise of stock options within 60 days of November 11, 2019. The unvested restricted common stock will vest in equal monthly installments through December 29, 2019, subject to Dr. Kabakoff's continued service with us.
- (10) Consists of 5,290 shares of common stock issuable upon the exercise of stock options within 60 days of November 11, 2019.
- (11) Consists of 1,103,570 shares of common stock directly owned by Quan Venture Fund II, L.P. Dr. Xu is a Managing Director and has voting and dispositive power over the shares directly owned by Quan Venture Fund II, L.P.
- (12) Consists of (a) 1,697,931 shares of common stock, including 78,140 shares subject to repurchase or forfeiture, and (b) 616,143 shares of common stock issuable upon the exercise of stock options within 60 days of November 11, 2019.

#### DESCRIPTION OF CAPITAL STOCK

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws and of 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 and amended and restated bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

#### General

Our amended and restated certificate of incorporation authorizes 100,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share, all of which shares of preferred stock are undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of September 30, 2019, there were outstanding:

- 22,739,345 shares of our common stock held by approximately 40 stockholders of record; and
- 2,248,953 shares of our common stock issuable upon exercise of outstanding stock options.

#### Common Stock

#### Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the 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 the 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.

## 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, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

#### **Stock Options**

As of September 30, 2019, options to purchase 2,001,678 shares of our common stock were outstanding under the 2015 Plan, with a weighted average exercise price of \$4.83 per share. No further awards will be made under the 2015 Plan. For additional information regarding the terms of the 2015 Plan, see "Executive Compensation—Equity Incentive Plans—2015 Omnibus Incentive Plan." As of September 30, 2019, options to purchase 247,275 shares of our common stock were outstanding under the 2019 Plan, with a weighted average exercise price of \$18.18 per share, and 2,653,969 additional shares of our common stock remained available for future issuance thereunder. For additional information regarding the terms of the 2019 Plan, see "Executive Compensation—Equity Incentive Plans—2019 Omnibus Incentive Plan."

#### 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. 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. In addition, the issuance of our preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. No shares of preferred stock are currently outstanding, and we have no present plan to issue any shares of preferred stock.

## **Registration Rights**

Under the terms of our amended and restated investors' rights agreement, the holders of 6,336,439 shares of common stock, or their transferees, have the right to require us to register their shares, or the registrable shares, under the Securities Act so that those shares may be publicly resold, and the right to include their shares in any registration statement we file, in each case as described below.

#### **Demand Registration Rights**

The holders of the registrable shares are entitled to certain demand registration rights. Beginning on November 8, 2019, the holders of at least 20% of these shares can, on not more than two occasions, request that we register all or a portion of their shares if the aggregate offering price of the shares would exceed \$10 million (after deductions of underwriters' commissions and expenses).

## Piggyback Registration Rights

In the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the holders of the registrable shares will be entitled to certain "piggyback" registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, registration on a form that does not include substantially the same information as would be required to be included in a registration statement covering the registrable

shares, a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities also being registered, or corporate reorganizations or certain other transactions, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the underwriters have the right, subject to specified conditions, to exclude or limit the number of shares such holders may include.

#### Form S-3 Registration Rights

If we become and are eligible to file a registration statement on Form S-3, the holders of the registrable shares can make a written request that we register their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate offering price of the shares is at least \$1 million (after deductions of underwriters' commissions and expenses). These stockholders may make an unlimited number of requests for registration on Form S-3, but in no event shall we be required to file more than two registrations on Form S-3 in any given 12-month period.

#### **Expenses of Registration**

We will pay the registration expenses of the holders of the shares registered pursuant to the demand, piggyback and Form S-3 registration rights described above, including the reasonable expenses of one counsel for the selling holders.

#### **Expiration of Registration Rights**

The demand, piggyback and Form S-3 registration rights described above 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 the 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 impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

## Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our board of directors, our Chair, President or Chief Executive Officer.

#### 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 the board of directors or a committee of the 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 will 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 will be 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 <sup>2</sup>/3% of the voting power of the then outstanding voting stock. For more information on the classified board, see "Management—Classified Board of Directors." Any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. Furthermore, the authorized number of directors may be changed only by a resolution of the board of directors. This system of electing and removing directors, filling vacancies and fixing the size of the 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  $66^2/3\%$  of the voting power of the 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.

## **Limitation of Liability and Indemnification Matters**

For a discussion of liability and indemnification, see "Management—Limitation on Liability and Indemnification Matters."

#### 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.

#### MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by a Non-U.S. Holder (as defined below). For purposes of this discussion, a Non-U.S. Holder is a beneficial owner of our common stock that is not a "U.S. person" or partnership, including any entity or arrangement treated as a partnership and the equity holders therein, for U.S. federal income tax purposes.

A U.S. person is any of the following:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

If you are an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and your activities. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors as to particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

This discussion is based on the Code, administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations, changes to any of which subsequent to the date of this prospectus supplement may affect the tax consequences described herein, possibly with retroactive effect. We have not sought and will not seek any rulings from the Internal Revenue Service, or IRS, regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including, without limitation, certain former citizens or long-term residents of the United States, a person who holds or receives our common stock pursuant to the exercise of an employee stock option or otherwise as compensation, partnerships (or arrangements classified as partnerships for U.S. federal income tax purposes) or other pass-through entities and the equity holders therein, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities, tax-exempt organizations, tax-qualified retirement plans or foreign pension funds, persons subject to the alternative minimum tax, persons subject to special tax accounting rules under Section 451(b) of the Code, persons that own, or have owned, actually or constructively, more than 5% of our common stock and persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy.

This discussion does not describe all of the U.S. federal income tax consequences that may be relevant to you in light of your particular circumstances, and does not address the potential application of the alternative minimum tax, Medicare contribution tax, estate or gift taxes and does not address any aspect of

state, local or non-U.S. taxation, or any taxes other than income taxes. You should consult your tax adviser with regard to the application of the U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or non-U.S. taxing jurisdiction.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR NON-U.S. TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

#### **Distributions**

Distributions of cash or other property paid on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, they will constitute a return of capital, which will first reduce your basis in our common stock, but not below zero, and any excess will be treated as gain from the sale or other disposition of our common stock, as described below under "—Gain on Disposition of Our Common Stock."

Dividends paid to you generally will be subject to withholding tax at a 30% rate or a reduced rate specified by an applicable income tax treaty. In order to obtain a reduced rate of withholding, subject to the discussion below under "—FATCA," you will be required to provide to us or our paying agent a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying your entitlement to benefits under a treaty. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. If you hold our common stock through a financial institution or other agent acting on your behalf, you will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

If you do not timely provide the required certification, but qualify for a reduced treaty rate, you may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to you are effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained by you in the United States), you will generally be taxed on the dividends on a net income basis in the same manner as a U.S. person. If you are a foreign corporation you also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of your effectively connected earnings and profits for the taxable year, as adjusted for certain items.

If dividends paid to you are effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained by you in the United States), you will be exempt from the withholding tax discussed in the preceding paragraph, although you will be required to provide a properly executed IRS Form W-8ECI in order to claim an exemption from withholding. You should consult your tax advisors regarding any applicable income tax treaties that may provide for different rules.

#### Gain on Disposition of Our Common Stock

Subject to the discussions below under "—Information Reporting and Backup Withholding" and "—FATCA," you generally will not be subject to U.S. federal income or withholding tax on gain realized on a sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- we are or have been a "United States real property holding corporation," as defined in the Code, or a USRPHC, at any time within the five-year period ending on the date of the taxable disposition or your holding period for such common stock, whichever period is shorter, and our common stock is not regularly traded on an established securities market or you hold more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the taxable disposition or the holding period for such common stock.

You will generally be taxed on the gain described in the first bullet above in the same manner as a U.S. person. If you are a foreign corporation, you also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of your effectively connected earnings and profits for the taxable year, as adjusted for certain items.

You will generally be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty) on gain described in the second bullet point above; however, such gain may be offset by certain U.S.-source capital losses (even though you are not considered a resident of the United States), provided that you have timely filed U.S. federal income tax returns with respect to such losses.

Generally, a corporation is a USRPHC only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus any of its assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a UPRHC, or that we are likely to become one in the future. Even if we are a USRPHC, for so long as our common stock is regularly traded on an established securities market, sales of our common stock generally will not be subject to tax if you have not held more than 5% of our common stock, actually or constructively, during the five-year period preceding such sale or other disposition of our common stock (or your holding period, if shorter). If we are a USRPHC and either our common stock is not regularly traded on an established securities market or you hold, or are treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, you will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. No assurance can be provided that our common stock will continue to be regularly traded on an established securities market for purposes of the rules described above. You are encouraged to consult your own tax advisors regarding the possible consequences to you if we are, or were to become, a USRPHC.

#### **Information Reporting and Backup Withholding**

Information returns are required to be filed with the IRS in connection with payments of dividends on our common stock. Unless you comply with certification procedures to establish that you are not a U.S. person, information returns may also be filed with the IRS in connection with the proceeds from a sale or other disposition of our common stock. You may be subject to backup withholding on payments on our common stock or on the proceeds from a sale or other disposition of our common stock unless the

applicable withholding agent does not have actual knowledge or reason to know that you are a U.S. person and you comply with certification procedures to establish that you are not a U.S. person or otherwise establish an exemption. Your provision of a properly executed applicable IRS Form W-8 certifying your non-U.S. status will permit you to avoid backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know that you are a U.S. person. Amounts withheld under the backup withholding rules are not additional taxes and may be refunded or credited against your U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

#### **FATCA**

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, require withholding of 30% on payments of dividends on our common stock, and, subject to the discussion of certain proposed Treasury Regulations below, gross proceeds of dispositions of our common stock, to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied, or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, you may be eligible for refunds or credits of such taxes. The U.S. Treasury recently released proposed Treasury Regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In its preamble to such proposed Treasury Regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. You should consult your tax adviser regarding the effects of FATCA on your investment in our common stock.

#### **UNDERWRITERS**

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, BofA Securities, Inc. and Piper Jaffray & Co. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<u>Name</u>	Number of Shares
Morgan Stanley & Co. LLC	
BofA Securities, Inc.	
Piper Jaffray & Co.	
Needham & Company, LLC	
BTIG, LLC	
Total	3,200,000

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to an additional shares of our common stock. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 480,000 shares of common stock.

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	Per Share	No Exercise	Full Exercise
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$0.9 million. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority of up to \$35,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "NXTC."

We and all directors and officers and certain stockholders have agreed that, without the prior written consent of the representatives, on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus, or the restricted period:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of the representatives, on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock. None of our other stockholders is subject to any such restrictions and, accordingly, common stock or other securities held by these other stockholders may be transferred or disposed of, to or through any broker-dealer, at any time during or following this offering, subject to such stockholder's compliance with applicable securities laws.

The restrictions described in the immediately preceding paragraph to do not apply to:

- the sale of shares to the underwriters;
- the issuance by us of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- transactions by any person other than us relating to shares of common stock or other securities acquired in open market transactions after the closing of this offering; provided that no filing under Section 16(a) of the Exchange Act is required or voluntarily made in connection with subsequent sales of the common stock or other securities acquired in such open market transactions;
- transfers of shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock (i) as a bona fide gift or (ii) to any corporation, partnership, limited liability company, investment fund or other entity controlled or managed, or under common control or management by, the holder, provided that, (a) each transferee shall sign and deliver a lock-up agreement and (b) no filing under Section 16(a) of the Exchange Act reporting a reduction in the beneficial ownership of shares of common stock shall be required or shall be voluntarily made during the restricted period; or
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing
- under the Exchange Act, if any, is required or voluntarily made regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

The representatives, in their joint discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the option. The underwriters can close out a covered short sale by exercising the option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the option. The underwriters may also sell shares in excess of the option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

#### **Selling Restrictions**

# Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or each, a Relevant Member State, an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (i) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- (iii) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

## **United Kingdom**

Each underwriter has represented and agreed that:

- (i) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity within the meaning of Section 21 of the Financial Services and Markets Act 2000, or FSMA, received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (ii) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

#### Hong Kong

Shares of our common stock may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to shares of our common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

## Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended), or the FIEL, has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors, or QII

Please note that the solicitation for newly issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "QII only private placement" or a "QII only secondary distribution" (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "small number private placement" or a "small number private secondary distribution" (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

## Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an

institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where shares of our common stock are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired shares of our common stock under Section 275 except: (a) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (b) where no consideration is given for the transfer; or (c) by operation of law.

#### **LEGAL MATTERS**

The validity of the shares of our common stock to be issued in this offering will be passed upon for us by our counsel, Hogan Lovells US LLP, Baltimore, Maryland. As of the date of this prospectus, a partner of Hogan Lovells US LLP owns 37,342 shares of our common stock. Cooley LLP, New York, New York, is acting as counsel for the underwriters in connection with this offering.

#### **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2018 and 2017, and for each of the two years in the period ended December 31, 2018, as set forth in their report. We have included our financial statements in this prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

We are subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information are available for inspection and copying at the website of the SEC referred to above. We maintain a website at www.nextcure.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.

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#### 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, 2018 and 2017, the related statements of operations and comprehensive loss, preferred stock and stockholders' equity 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, 2018 and 2017, 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 2017.

Tysons, VA

March 5, 2019, except as to the fourth paragraph of Note 16, as to which the date is May 3, 2019.

# BALANCE SHEETS

# (in thousands, except share and per share amounts)

	December 31,			
Assets	_	2018		2017
Current assets:				
Cash and cash equivalents	\$	135,173	\$	8,427
Restricted cash	Ψ	460	Ψ	860
Prepaid expenses and other current assets		152		133
Total current assets	_	135,785	_	9,420
Property and equipment, net		11,407		10,021
Other assets		436		26
Total assets	\$	147,628	\$	19,467
Liabilities, Preferred Stock and Stockholders' Deficit	-		_	
Current liabilities:				
Accounts payable	\$	2,483	\$	1,141
Accrued liabilities		2,411		1,564
Deferred rent, current portion		28		19
Term loan, current portion		387		400
Deferred revenue from related party, current portion		4,989		_
Total current liabilities		10,298		3,124
Deferred rent, net of current portion		242		295
Term loan, net of current portion		73		460
Deferred revenue from related party, net of current portion		21,736		_
Total liabilities		32,349		3,879
Commitments and contingencies (Note 7)	_			
Preferred stock:				
Series A Preferred Stock, par value of \$0.001 per share; 68,181,819 and 64,545,455 shares authorized at December 31, 2018 and 2017, respectively, 68,181,819 and 40,000,000 shares issued and outstanding at December 31, 2018 and 2017, respectively		71,000		40,000
Series B Preferred Stock, par value \$0.001 per share; 56,828,852 and 0 shares authorized at		/1,000		40,000
December 31, 2018 and 2017, respectively, 56,828,851 and 0 shares issued and outstanding at				
December 31, 2010 and 2017, respectively. 30,020,031 and 0 shares issued and outstanding at December 31, 2018 and 2017, respectively.		91,223		_
Total Preferred Stock	_	162,223	_	40,000
Stockholders' deficit:	_	102,225		40,000
Common stock, par value of \$0.001 per share; 158,745,671 and 84,045,455 shares authorized as of December 31, 2018 and 2017, respectively, 1,374,812 and 1,369,212 shares issued and				
outstanding at December 31, 2018 and 2017, respectively		11		11
Additional paid-in capital		342		75
Accumulated deficit		(47,297)		(24,498)
Total stockholders' deficit	_	(46,944)	_	(24,412)
Total liabilities, preferred stock and stockholders' deficit	\$	147,628	\$	19,467

# STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

	Year Ended December 31,				
		2018	ber .	2017	
Operating expenses:	_	2010		2017	
Research and development	\$	19,787	\$	12,954	
General and administrative		3,409		2,595	
Total operating expenses		23,196		15,549	
Loss from operations		(23,196)		(15,549)	
Other income, net		397		80	
Net loss		(22,799)		(15,469)	
Other comprehensive income		_			
Total comprehensive loss	\$	(22,799)	\$	(15,469)	
Net loss per share attributable to common stockholders—basic and diluted	\$	(16.64)	\$	(11.30)	
Weighted average common shares outstanding—basic and diluted		1,369,846		1,369,212	

# STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

# (in thousands, except share data)

	Preferred Stock				Stockholders' Deficit				
	Series	s A	Series	s B	Commo	n Stock	Additional Paid-in	Stockholders'	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of December 31, 2016	15,000,000	\$ 15,000	_	\$ —	1,369,212	\$ 11	\$ —	\$ (9,029)	\$ (9,018)
Stock-based compensation	_	_	_	_	_	_	75	_	75
Issuance of Series A-2 preferred stock, net of issuance costs of \$0	25,000,000	25,000	_	_	_	_	_	_	_
Net loss								(15,469)	(15,469)
Balance as of December 31, 2017	40,000,000	40,000	_	_	1,369,212	11	75	(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,	60 404 040	# F1 000	FC 000 054	ф. 04.222	4 254 042		ф. 343.	ф (4E 20E)	
2018	68,181,819	\$ 71,000	56,828,851	\$ 91,223	1,374,812	\$ 11	\$ 342	\$ (47,297)	\$ (46,944)

# STATEMENTS OF CASH FLOWS

# (in thousands)

	Year Ended December 31,			
		2018		2017
Cash flows from operating activities:				
Net loss	\$	(22,799)	\$	(15,469)
Adjustments to reconcile net loss to net cash provided by (used) in operating activities:				
Depreciation and amortization		1,677		582
Stock-based compensation		263		75
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(19)		(89)
Other assets				21
Accounts payable		1,342		767
Accrued liabilities		847		1,557
Deferred rent		(44)		42
Deferred revenue from related party	_	26,725		
Net cash provided by (used) in operating activities	_	7,992	_	(12,514)
Cash flows from investing activities:				
Purchase of property and equipment	_	(3,063)		(8,652)
Net cash used in investing activities		(3,063)		(8,652)
Cash flows from financing activities:				
Proceeds from issuance of preferred stock, net of issuance costs		122,223		25,000
Proceeds from issuance of common stock		4		
Payments of the term loan		(400)		(140)
Deferred financing costs	_	(410)		_
Net cash provided by financing activities		121,417		24,860
Net increase in cash, cash equivalents and restricted cash		126,346		3,694
Cash, cash equivalents and restricted cash—beginning of year		9,287		5,593
Cash, cash equivalents and restricted cash—end of year	\$	135,633	\$	9,287
Supplemental disclosures of cash flow information:				
Cash paid for interest	\$	25	\$	30
Cash paid for income taxes	\$		\$	
Supplemental disclosures of noncash investing and financing activities:	_			
Purchase of property and equipment included in accrued liabilities	\$	_	\$	515
Deferred financing costs in accrued liabilities	\$	284	\$	_
	_			

#### 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.

#### 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; our 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 our 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.

# Liquidity

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, 2018, 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 is dependent on its ability to raise additional capital to finance its operations. On April 5, 2018, the Company issued 28,181,819 shares of Series A-3 Preferred Stock at an issuance price of \$1.10 per share for cash proceeds of \$31.0 million (Note 9). On November 5, 2018, the Company entered into a Series B Preferred Stock Purchase Agreement and issued 15,052,117 shares of Series B-1 Preferred Stock at an issuance price of \$1.59 per share, 34,276,734 shares of Series B-2 Preferred Stock at an issuance price of \$1.59 per share and 7,500,000

# NOTES TO FINANCIAL STATEMENTS (Continued)

#### 1. Nature of the Business and Basis of Presentation (Continued)

shares of Series B-3 Preferred Stock at an issuance price of \$2.00 per share for aggregate cash proceeds of \$93.4 million (Note 9).

The Company plans to seek additional funding through public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. 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.

# **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").

# Reverse Stock Split

On May 3, 2019, the Company effected a 1-for-8.0338 reverse stock split of its 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.

# 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. On an ongoing basis, management evaluates its estimates, including those related to accrued expenses, revenue recognition, the valuation of equity-based compensation, including incentive stock options, common stock and restricted common stock, as well as income taxes. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

# 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 Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies

# 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.

#### Restricted Cash

The Company is required to maintain cash collateral on deposit in a segregated money market bank account, as a condition of its Term Loan (Note 8) equal to the principal portion on a quarterly basis. The bank may restrict withdrawals or transfers by, or on behalf of, the Company. The required reserve totaled \$460,000 as of December 31, 2018. This amount is presented as restricted cash on the accompanying balance sheet.

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

	December 31,		
	2018		2017
Cash and cash equivalents	\$ 135,173	\$	8,427
Restricted cash	460		860
Total	\$ 135,633	\$	9,287

# 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 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.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

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.

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 recorded at cost. Depreciation is computed over the estimated useful lives of the related assets using the straight-line method. 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

#### **Construction in Progress**

Construction in progress (Note 4) 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.

# Impairment of Long-Lived Assets

The Company reviews the recoverability of its long-lived asset group when events or changes in circumstances occur that indicate that the carrying value of the asset group may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the asset group from the expected future cash flows (undiscounted and without interest expense) of the related operations. If these cash flows are less than the carrying value of such asset group, an impairment loss for the difference between the estimated fair value and carrying value is recorded. There was no impairment loss recognized during the years ended December 31, 2018 or 2017.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

#### Preferred Stock

The Company's preferred stock is classified outside of stockholders' deficit because the shares contain deemed liquidation rights that are a contingent redemption feature not solely within the control of the Company.

#### Research and Development Costs

Expenditures, including payroll, contractor expenses and supplies, for research and development of products are expensed as incurred. Development costs incurred by third parties 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.

#### **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 Company recognizes forfeitures as they occur as allowed by ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09").

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

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

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 as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

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, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale.

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 property and equipment 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 has adopted 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 which 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

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

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 entity will collect consideration it is entitled to 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 or dependent to other goods or services in the contract.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services 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 which 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 will re-evaluate 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 or (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

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

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 consolidated 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

The Company did not have any other comprehensive income or loss for any of the periods presented and, therefore, comprehensive loss did not differ from net loss.

# Net Loss per Share

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company considers its Series A Preferred Stock and Series B Preferred Stock to be participating securities because in the event a dividend is paid on common stock, the holders of Series A Preferred Stock and Series B Preferred Stock would be 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.

# **Recently Adopted Accounting Pronouncements**

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) ("ASU 2016-08"), which clarified the revenue recognition implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing ("ASU 2016-10"), which clarified the revenue recognition

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

guidance regarding the identification of performance obligations and the licensing implementation. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), which narrowly amended the revenue recognition guidance regarding collectability, noncash consideration, presentation of sales tax and transition. ASU No. 2016-08, ASU No. 2016-10 and ASU 2016-12 are effective during the same period as ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which is effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2014-09 as of January 1, 2018 on a retrospective basis. There was no revenue in previous years and the adoption of ASC 606 did not have any impact on prior year financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero-coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. The retrospective transition method, requiring adjustment to all comparative periods presented, is required unless it is impracticable for some of the amendments, in which case those amendments would be prospectively applied as of the earliest date practicable. ASU 2016-15 is effective for the Company for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted ASU 2016-15 as of January 1, 2018.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which requires that a statement of cash flows explain the change during the period in the total cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning and ending balances shown on the statement of cash flows. The guidance is effective for the Company for fiscal years beginning after December 15, 2019 and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted ASU 2016-18 as of January 1, 2017.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions of the agreement. The standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company adopted ASU 2017-09 as of the required effective date of January 1, 2018. In June 2018, the FASB issued ASU No. 2018-07 *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU No. 2018-07"). ASU No. 2018-07 expands the guidance in ASC718 to include share-based payments for goods and services to non-employees and generally aligns it with the guidance for share-based payments to employees. The amendments are effective for the Company for fiscal years beginning after December 15, 2019 and interim periods within

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 2. Summary of Significant Accounting Policies (Continued)

fiscal years beginning after December 15, 2020, with early adoption permitted for entities that have adopted ASC 606. The Company adopted this new standard on January 1, 2018.

# **Recently Issued Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). The new guidance requires 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 for fiscal years beginning after December 15, 2019 and interim periods fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the effect of this standard on its financial statements.

# 3. Fair Value of Financial Instruments

The following table sets forth the fair value of the Company's financial assets by level within the fair value hierarchy (in thousands):

			As of December 3	1, 2018	
			Fair Valu	ie Measurement	Based on
Assets	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds (cash equivalents)	\$ 5,000	\$ 5,000	\$ 5,000	\$ —	\$ —
			As of December 3:	, -	
			Fair Valu	ie Measurement	Based on
	Carrying	Fair	Quoted Prices in Active Markets	Significant Other Observable Inputs	Significant Unobservable Inputs
Assets	Amount	Value	(Level 1)	(Level 2)	(Level 3)
Money market funds (cash equivalents)	\$ 1,000	\$ 1,000	\$ 1,000	\$ —	\$ —

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1 during the years ended December 31, 2018 and 2017.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 4. Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	December 31,	
	2018	2017
Research equipment	\$ 7,787	\$ 6,213
Leasehold improvements	4,825	564
Computer equipment	167	111
Furniture and fixtures	70	33
Construction in progress	1,027	3,892
Property and equipment, gross	13,876	10,813
Less: accumulated depreciation and amortization	(2,469)	(792)
Property and equipment, net	\$ 11,407	\$ 10,021

Construction in progress at December 31, 2018 consists of the costs incurred for research equipment.

Depreciation and amortization expense was \$1.7 million and \$582,000 for the years ended December 31, 2018 and 2017, respectively.

# 5. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2018	2017
Accrued construction in progress	\$ —	\$ 515
Accrued payroll and related benefits	1,008	493
Accrued clinical trial costs	271	_
Accrued operating expenses	719	450
Accrued financing costs	284	_
Accrued office lease	127	104
Accrued interest	2	2
Total accrued liabilities	\$ 2,411	\$ 1,564

# 6. 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 will 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 have 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. Both Lilly and the Company each have all options remaining eligible for exercise. The research collaboration with Lilly will be managed by a joint steering committee formed by an equal number of members from the Company and Lilly and will expire upon the earlier of the exercise of all options granted to Lilly or four years from the date of the agreement, subject to certain extensions.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 6. Agreement with Eli Lilly and Company (Continued)

During the research term under the Lilly Agreement, as a part of target discovery, the Company will be responsible for providing Lilly with oncology targets identified using the Company's FIND-IO platform. From the targets provided by the Company, Lilly may 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 may propose to advance that target to compound discovery. For each target that has been advanced to compound discovery, Lilly will have the option to obtain an exclusive license with respect to the compounds and products directed to the target. If Lilly does not exercise its option with respect to a given target or has previously exercised all of its options, the Company will have the option to obtain licenses with respect to compounds and products directed to that target. Following option exercise by a party, the development and commercialization of any products directed to the target will be conducted by the exercising party. The exercising party must use commercially reasonable efforts to develop, seek regulatory approval for and commercialize any such products under mutually agreed upon work plans.

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 9). In addition, the Company will receive quarterly research and development support payments during a portion of the research term as well as option exercise fees upon option exercises by Lilly.

Pursuant to the Lilly Agreement, Lilly will owe an aggregate of up to \$1.4 billion in development and regulatory milestones and sales milestones. Additionally, Lilly will pay mid to high single-digit royalties on net sales for all products directed to each target optioned by Lilly. Upon the Company's exercise of an option with respect to a given target, the Company will pay Lilly option exercise, milestone and royalty payments. The company will owe an aggregate of up to \$710.0 million in development and regulatory milestones and sales milestones.

The company has evaluated the Lilly Agreement under ASC 606. Two performance obligations were identified as follows:

- research and development services; and
- material right related to an optional term extension by Lilly.

The Lilly Agreement was executed in November 2018, however, the performance obligations were initiated in January 2019; accordingly no revenue was recorded under the Lilly Agreement in 2018. As of December 31, 2018, deferred revenue included in the Company's balance sheets in connection with the Lilly Agreement was \$26.7 million, which consisted of the \$25.0 million upfront payment plus \$1.7 million attributed as a premium on the proceeds from Lilly's equity investment in the Company (Note 9).

# 7. Commitments and Contingencies

# **Operating Leases**

The Company subleases its facilities under a non-cancelable operating sublease agreement. The sublease commenced on February 9, 2016 and expires on August 31, 2025. The Company is also responsible for its prorated share of the sublandlord's operating expense.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 7. Commitments and Contingencies (Continued)

The future minimum payments for the operating leases are as follows (in thousands):

Year Ending December 31,	
2019	\$ 325
2020	308
2021	317
2022	355
2023	335
Thereafter	635
Total future minimum payments	2,275

Rent expense incurred under operating leases was approximately \$420,000 and \$376,000 for the years ended December 31, 2018 and 2017, respectively.

# Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

In the normal course of business, the Company may become involved in legal proceedings. The Company will accrue a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within this range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. As of December 31, 2018 and 2017, the Company was not involved in any material legal proceedings.

#### 8. Term Loan

In April 2016, the Company entered into a \$1.0 million term loan (the "Term Loan"). The Term Loan bears interest at the prime rate less 1%. The interest rate in effect was 4.5% and 3.5% for the years ended December 31, 2018 and 2017, respectively. The Term Loan is secured by all certificates of deposit, money market accounts, cash, securities, investment property and deposit or investment accounts. The Term Loan requires monthly payments of interest only before May 2017, and equal monthly payments of principal and interest thereafter, as defined in the agreement. Interest expense under the Term Loan was approximately \$25,000 and \$30,000 for the years ended December 31, 2018 and 2017, respectively. The outstanding balance on the Term Loan totaled \$460,000 as of December 31, 2018.

Future maturities of the Term Loan as of December 31, 2018 are as follows (in thousands):

2019	\$ 387
2020	73
Total	460
Less: current portion of term loan	387
Term loan, net of current portion	\$ 73

# NOTES TO FINANCIAL STATEMENTS (Continued)

#### 9. Preferred Stock

As of December 31, 2018, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 125,010,671 shares of \$0.001 par value preferred stock. The Company's preferred stock is classified outside of stockholders' deficit because the shares contain deemed liquidation rights that are a contingent redemption feature not solely within the control of the Company.

# Series A Preferred Stock

As of December 31, 2018, the Company has issued 68,181,819 shares of Series A Preferred Stock as follows:

In December 2015, the Company issued 15,000,000 shares of Series A-1 Preferred Stock at an issuance price of \$1.00 per share for cash proceeds of \$15.0 million.

In January 2017, the Company issued 25,000,000 shares of Series A-2 Preferred Stock at an issuance price of \$1.00 per share for cash proceeds of \$25.0 million.

In April 2018, the Company issued 28,181,819 shares of Series A-3 Preferred Stock at an issuance price of \$1.10 per share for cash proceeds of approximately \$31.0 million.

# Series B Preferred Stock

As of December 31, 2018, the Company has issued 56,828,851 shares of Series B Preferred Stock as follows:

In November 2018, the Company issued 15,052,117 and 34,276,734 shares of Series B-1 Preferred Stock and Series B-2 Preferred Stock, respectively, at an issuance price of \$1.59 per share for aggregate cash proceeds of approximately \$78.4 million.

Concurrent with the issuance of the Series B-1 Preferred Stock and Series B-2 Preferred Stock, in November 2018, the Company issued 7,500,000 shares of Series B-3 Preferred Stock at an issuance price of \$2.00 per share for cash proceeds of \$15.0 million in connection with the execution of the Collaboration Agreement with Lilly. The Company allocated \$13.3 million of the proceeds to Series B-3 Preferred Stock and \$1.7 million to deferred revenue. The \$1.7 million was determined to be a premium over the fair value of the Series B-3 Preferred Stock and attributed as additional consideration of the Collaboration Agreement (Note 6).

The Company estimated the premium of the Series B-3 Preferred Stock based on 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 \$1.7 million premium on the Series B-3 Preferred Stock will be recognized as revenue on a proportional performance basis over the term of the Collaboration Agreement.

The Company's Preferred Stock has the following rights and preferences, privileges and restrictions:

# Dividends

The holders of Preferred Stock are entitled to receive annual noncumulative dividends at an annual rate of 8% in preference to any declaration or payment of any dividend on the common stock, on an

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 9. Preferred Stock (Continued)

as-converted basis when, as and if declared by the Board of Directors. As of December 31, 2018, no dividends have been declared.

#### **Voting Rights**

Each share of Preferred Stock represents such number of votes as is equal to the number of shares of common stock into which such share is convertible. The holders of Preferred Stock vote together with the holders of common stock on an as-converted basis on all matters in which stockholders are entitled to vote. The holders of Series A Preferred Stock, exclusively and as a separate class, are entitled to elect five directors, the holders of the Series B Preferred Stock, exclusively and as a separate class, are entitled to elect two directors of the Company as of December 31, 2018.

# Conversion Rights

The holders of the Preferred Stock are entitled to convert each share into 0.1245 shares of common stock on demand. The Preferred Stock is mandatorily convertible upon the closing of a qualified public offering in which gross proceeds to the Company of not less than \$75.0 million or on the date specified by a majority vote of the outstanding shares of Preferred Stock voting on an as-converted basis.

# Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of the Company's Series B Preferred Stock are entitled to receive, before any payment of any of the assets of the Company to the holders of the Series A Preferred Stock and holders of common stock, \$12.77 per share with respect to shares of Series B-1 Preferred Stock and Series B-2 Preferred Stock and \$16.07 per share with respect to shares of Series B-3 Preferred Stock (as adjusted for any stock dividend, stock split, combination or other similar transactions, plus any declared but unpaid dividends). After payment of the above but before any payment of any of the assets of the Company to the holders of common stock, the holders of Series A Preferred Stock are entitled to receive \$8.03 per share with respect to shares of Series A-1 Preferred Stock and Series A-2 Preferred Stock and \$8.84 per share with respect to shares of Series A-3 Preferred Stock (as adjusted for any stock dividend, stock split, combination or other similar transactions, plus any declared but unpaid dividends).

#### 10. Common Stock

As of December 31, 2018, the Company's Certificate of Incorporation, as amended and restated, authorized the Company to issue 158,745,671 shares of \$0.001 par value common stock, of which 1,374,812 were issued and outstanding.

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 the preferred stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of preferred stock equivalent to the dividend amount they would receive if each share of preferred stock was converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the preferred stock have been paid in full. No dividends have been declared or paid by the Company through December 31, 2018.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 10. Common Stock (Continued)

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 the preferred stock.

# 11. Stock-Based Compensation

#### 2015 Omnibus Incentive Plan

The NextCure, Inc. 2015 Omnibus Incentive Plan (the "2015 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards, unrestricted stock awards or 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. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors or its committee if so delegated, except that the exercise price per share of the stock options may not be less than 100% of the fair market value of a share of the Company's common stock on the date of grant and the term of the stock options may not be greater than 10 years.

Under the 2015 Plan, the Company had initially reserved on December 29, 2015, 311,185 shares of common stock, which number of shares was automatically increased pursuant to the terms of the 2015 Plan by 373,422 as of the second closing of the Series A Preferred Stock financing on January 24, 2017. The total number of shares of common stock that may be issued under the 2015 Plan was 2,824,317 as of December 31, 2018. As of December 31, 2018, there were 2,056,891 stock options and 62,237 shares of registered stock outstanding and 699,590 shares of common stock available for future issuance under the 2015 Plan.

Stock options granted under the 2015 Plan generally vest over four years and expire after 10 years.

The exercise price for stock options granted is not less than the fair value of common shares as determined by the board of directors as of the date of grant. The board of directors determines the value the Company's common stock taking into consideration the most recently available third-party valuation of common shares, as well as additional factors, which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 11. Stock-Based Compensation (Continued)

A summary of stock option activity for awards under the 2015 Plan is presented below:

	0	Options Outstanding and Exercisable							
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value <sup>(1)</sup> (in thousands)					
Outstanding as of January 1, 2017	189,189	\$ 0.48	8.6	\$ 137					
Granted	317,397	1.21							
Outstanding as of December 31, 2017	506,586	0.94	9.0	137					
Granted	1,570,136	5.92	9.9	2,684					
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					
Vested and expected to vest as of December 31, 2018	2,056,891	4.74	9.4	5,946					
Exercisable as of December 31, 2018	242,079	0.88	7.9	1,634					

<sup>(1)</sup> 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, 2018 and 2017.

The weighted average grant date fair value per share of stock options granted during the years ended December 31, 2018 and 2017 was \$3.80 and \$0.80, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017 was \$38,000 and \$0, respectively.

The aggregate grant date fair value of stock options and restricted stock vested during the year ended December 31, 2018 and 2017 was approximately \$157,000 and \$29,000, respectively.

# Stock-Based Compensation

The Company recorded stock-based compensation expense of \$263,000 and \$75,000 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, there was \$6.0 million of unrecognized compensation cost related to unvested stock-based compensation arrangements granted under the 2015 Plan. This remaining compensation expense is expected to be recognized over a weighted average period of three years as of December 31, 2018.

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

		Decemi	oer 3	<i>.</i> 1,
	2	018	2	017
Research and development	\$	85	\$	35
General and administrative		178		40
Total stock-based compensation expense	\$	263	\$	75

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 11. Stock-Based Compensation (Continued)

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

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

# Restricted Common Stock

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

# 12. Net Loss Per Share Attributable to Common Stockholders

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

	December 31,			
	2018	2017		
Numerator:				
Net loss	\$ (22,799)	(15,469)		
Denominator:				
Weighted average number of common shares, basic and diluted	1,369,846	1,369,212		
Net loss per common share attributable to common stockholders, basic and				
diluted	\$ (16.64)	\$ (11.30)		

The Company's potential dilutive securities, which include preferred stock and common stock options, 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:

	Decemb	er 31,
	2018	2017
Preferred stock	15,560,569	4,978,957
Options to purchase common stock	242,079	64,783
Total	15,802,648	5,043,746

# NOTES TO FINANCIAL STATEMENTS (Continued)

#### 13. Income Taxes

# 2017 U.S. Tax Reform

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. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs".

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.

# **Income Taxes**

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

	Decembe	r 31,
	2018	2017
Expected income tax benefit at the federal statutory rate	21.0%	34.0%
State taxes, net of federal benefit	6.5	6.5
Research and development credit, net	7.2	4.7
Non-deductible items	(2.2)	(5.3)
Prior year provision to return adjustments	(7.7)	4.1
Tax rate reduction due to the Tax Act		(15.6)
Other	0.3	(2.9)
Change in valuation allowance	(25.1)	(25.5)
Total	<u> </u>	<u> </u>

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.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 13. Income Taxes (Continued)

The principal components of the Company's deferred tax assets consisted of the following as of December 31, 2018 and 2017 (in thousands):

	Decemb	er 3	1,
	2018		2017
Deferred tax assets:			
Federal and state net operating loss carryforwards	\$ 11,946	\$	6,176
Research and development tax credits	3,393		1,283
Charitable contribution carryforwards	165		153
Accruals	290		135
Other	23		4
Gross deferred tax assets	15,817		7,751
Less: valuation allowance	(15,525)		(7,491)
Total deferred tax assets	\$ 292	\$	260
Deferred tax liabilities:			
Depreciation and amortization	\$ (292)	\$	(260)
Gross deferred tax liabilities	\$ (292)	\$	(260)
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, 2018. The Company increased its valuation allowance by approximately \$8.0 million for the year ended December 31, 2018. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2018, the Company had federal and state net operating loss carryforwards of \$43.5 million and \$43.0 million, respectively, some of which begin to expire in the year ending December 31, 2036. Approximately \$20.8 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 \$2.5 million and \$1.1 million, respectively, as of December 31, 2018. The federal 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"), net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC. Future owner or equity shifts, including an initial public offering, 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 2015 to 2017 remain open to examination by the major jurisdictions in which the Company are 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.

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 13. Income Taxes (Continued)

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, 2018, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized.

# 14. 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, 2018, the Company has not provided any contributions to this plan.

# 15. Related Party Transactions

#### Lilly Agreement

In November 2018, the Company entered into the Lilly Agreement with a stockholder of the Company, Lilly, pursuant to which the Company will use its proprietary FIND-IO platform to identify novel oncology targets for additional collaborative research and drug discovery by the Company and Lilly. Lilly provided to the Company a cash upfront payment of \$25.0 million upon entering into the Collaboration Agreement and made a concurrent \$15.0 million equity investment in the Company (Note 6 and Note 9).

# Consulting Agreement with Scientific Founder

In December 2015, the Company entered into a consulting agreement for scientific advisory services with a founder of the Company (the "Scientific Founder"), who is also a stockholder of the Company. The term of the consulting agreement expires December 31, 2020. Under the agreement, the Scientific Founder is entitled to receive \$5,000 per month in consulting fees until the expiration of the agreement. As of December 31, 2018, the amount due under this agreement is \$120,000.

# Yale License Agreement and Sponsored Research Agreement

In December 2015, the Company entered into a license agreement with Yale University (the "Yale Agreement"), which is also a stockholder of the Company. Under the Yale Agreement, the Company obtained a license to products that either incorporate certain licensed patents used in the discovery of targets or arise out of research and development of the Scientific Founder's laboratory at Yale, including a proprietary target. The Company is obligated to pay Yale low single-digit royalties on sales of products that are either covered by the patents licensed to the Company under the Yale Agreement or arise out of the Scientific Founder's laboratory, subject to minimum annual royalty payments in the low to mid hundreds of thousands of dollars, an annual license maintenance fee in the mid to high tens of thousands of dollars and milestone payments of up to \$3.0 million per product.

In connection with the Yale Agreement, the Company also entered into the Corporate Sponsored Research Agreement with Yale (the "SRA"), in which the Company 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 the Scientific Founder. As of December 31,

# NOTES TO FINANCIAL STATEMENTS (Continued)

# 15. Related Party Transactions (Continued)

2018, the Company has made payments in an aggregate of \$7.4 million under the SRA, including \$2.5 million and \$2.1 million in the years ended December 31, 2018 and 2017, respectively.

# 16. Subsequent Events

On January 25, 2019, the Company amended its Term Loan to an aggregate principal amount of \$5.0 million, which 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%. Under the agreement, 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.

On January 30, 2019, the Company entered into a new lease for 14,075 square feet to be used for office, manufacturing and laboratory space, which the Company expects to take possession of in June 2019. The new lease is expected to expire in March 2030 and will also cover the Company's existing space after expiration of the Company's current lease. Base rent for the first 10 months is abated, after which the base rent of the lease is \$19,650 per month, with an increase in annual rent of 3.0% in each subsequent year of the lease term.

On March 15, 2019, the Company entered into an amended and restated lease that covers the Company's existing space plus additional square footage to be used as office space, which the Company took possession of upon entering into the amended and restated lease. The amended and restated lease expires in August 2025. The total remaining commitment under the amended and restated lease is approximately \$3.0 million.

On May 3, 2019, the Company effected a 1-for-8.0338 reverse stock split of its 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.

# CONDENSED BALANCE SHEETS

# (unaudited, in thousands, except share and per share amounts)

	Se	September 30, 2019		ecember 31, 2018
Assets				
Current assets:				
Cash and cash equivalents	\$	9,935	\$	135,173
Marketable securities		174,147		_
Restricted cash		1,289		460
Prepaid expenses and other current assets		3,777		152
Total current assets		189,148		135,785
Property and equipment, net		12,031		11,407
Other assets		3,945		436
Total assets	\$	205,124	\$	147,628
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	\$	2,576	\$	2,483
Accrued liabilities		2,582		2,411
Deferred rent, current portion		_		28
Term loan, current portion		1,250		387
Deferred revenue, current portion		6,199		4,989
Total current liabilities		12,607		10,298
Deferred rent, net of current portion		434		242
Term loan, net of current portion		3,750		73
Deferred revenue, net of current portion		17,684		21,736
Total liabilities		34,475		32,349
Commitments and contingencies (Note 7)				
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 September 30, 2019 and December 31, 2018, respectively		_		71,000
Series B Preferred Stock, par value \$0.001 per share; 0 and 56,828,852 shares authorized at				
September 30, 2019 and December 31, 2018, respectively, 0 and 56,828,851 shares issued				
and outstanding at September 30, 2019 and December 31, 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				
September 30, 2019 and December 31, 2018. No shares issued and outstanding at				
September 30, 2019 and December 31, 2018, respectively		_		_
Common stock, par value of \$0.001 per share; 100,000,000 and 158,745,671 shares				
authorized at September 30, 2019 and December 31, 2018, respectively, 22,739,345, and				
1,374,812 shares issued and outstanding at September 30, 2019 and December 31, 2018,		20		
respectively		23		1
Additional paid-in capital		240,791		352
Accumulated other comprehensive loss  Accumulated deficit		(58)		(47.207)
		(70,107)		(47,297)
Total stockholders' equity (deficit)	φ	170,649	¢.	(46,944)
Total liabilities, preferred stock and stockholders' equity (deficit)	\$	205,124	\$	147,628

# CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

# (unaudited, in thousands, except share and per share amounts)

	Three Mont Septemb			Nine Months September				
	2019		2018	2019			2018	
Revenue:								
Revenue from research and development arrangement	\$ 1,583	\$		\$	4,342	\$	_	
Operating expenses:								
Research and development	8,663		4,895		22,819		13,539	
General and administrative	2,622		925		6,995		2,590	
Total operating expenses	11,285		5,820		29,814		16,129	
Loss from operations	(9,702)		(5,820)		(25,472)		(16,129)	
Other income, net	1,268		110		2,662		192	
Net loss	(8,434)		(5,710)		(22,810)		(15,937)	
Comprehensive loss:								
Unrealized loss on marketable securities	(58)		_		(58)		_	
Total comprehensive loss	\$ (8,492)	\$	(5,710)	\$	(22,868)	\$	(15,937)	
Net loss per common share—basic and diluted	\$ (0.37)	\$	(4.17)	\$	(1.81)	\$	(11.64)	
Weighted average number of common shares—basic and diluted	22,715,567		1,369,212		12,609,219		1,369,212	

# CONDENSED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

# (unaudited, in thousands, except share data)

				Nin	e Months End	ded Senter	nher 30 201	q					
		Preferre	d Stock	1111	Stockholders' Equity (Deficit)								
	Series A Shares Amount		Series B Shares Amount		Common	Stock Additional		Accumulated Other Comprehensive Loss		Stockholders' Equity (Deficit)			
Balance as of December 31, 2018 Stock-based compensation	68,181,819	\$ 71,000	56,828,851		1,374,812			\$ <u> </u>	\$ (47,297)	\$ (46,944)			
Issuance of common stock Net loss			<u> </u>		4,697		4		(6,155)	(6,155)			
Balance as of March 31, 2019	68,181,819	71,000	56,828,851	91,223	1,379,509	1	739		(53,452)	(52,712)			
Initial public offering, net of issuance costs of \$9.4M	_	_	_	_	5,750,000	6	76,848	_	_	76,854			
Conversion of preferred stock to common stock	(68,181,819)	(71,000)	(56,828,851)	(91,223)	15,560,569	15	162,208	_	_	162,223			
Stock-based compensation expense	_	_	_	_	_	_	412	_	_	412			
Issuance of common stock upon exercise of vested options, \$0.001 par value	_	_	_	_	24,687	1	38	_		39			
Net loss Balance as of June 30, 2019					22,714,765	23	240,245		(8,221)	178,595			
Stock-based compensation Issuance of common stock	_ _	_		_	24,580	_	524 22	_ _	_ _	524 22			
Unrealized loss on marketable securities Net loss	_	_	_	_	_	_	_	(58)	(8,434)	(58) (8,434)			
Balance as of September 30, 2019		<u>\$</u>		<u>\$</u>	22,739,345	\$ 23	\$ 240,791	\$ (58)					

		Nine Months Ended September 30, 2018										
		Preferred	Stock		Stockholders' Deficit							
	Serie Shares	s A Amount	Ser Shares	ies B Amount	Common	1 Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Deficit		
Balance as of December 31, 2017	40,000,000	\$ 40,000		s —	1,369,212	<b>\$</b> 1	\$ 84	\$ —	\$ (24,498)			
Stock-based compensation		_	_		_	_	24	_		24		
Net loss									(4,996)	(4,996)		
Balance as of March 31, 2018	40,000,000	40,000			1,369,212	1	108		(29,494)	(29,385)		
Issuance of Series A-3 preferred stock, net of issuance costs of \$0	28,181,819	31,000	_	_	_	_	_	_	_	_		
Stock-based compensation			_	_	_	_	24	_	_	24		
Net loss									(5,231)	(5,231)		
Balance as of June 30, 2018	68,181,819	71,000	_		1,369,212	1	132	_	(34,725)	(34,592)		
Stock-based compensation							90			90		
Issuance of common stock	_	_	_	_	_	_	_	_	_	_		
Net loss									(5,710)	(5,710)		
Balance as of September 30, 2018	68,181,819	\$ 71,000		<u>s – </u>	1,369,212	\$ 1	\$ 222	<u>\$</u>	\$ (40,435)	\$ (40,212)		

# CONDENSED STATEMENTS OF CASH FLOWS

# (unaudited, in thousands)

		Nine Months Ende September 30,		
Cash flaves from apprecting activities.	_	2019	-	2018
Cash flows from operating activities:  Net loss	\$	(22 010)	¢	(15,937)
Adjustments to reconcile net loss to net cash used in operating activities:	Ф	(22,010)	Ф	(13,937)
Depreciation and amortization		1,933		1,159
Stock-based compensation		1,319		138
Changes in operating assets and liabilities:		1,515		150
Prepaid expenses and other assets		(3,660)		(89)
Accounts payable		93		776
Accrued liabilities and other current liabilities		335		(526)
Deferred revenue		(2,842)		(520)
Net cash used in operating activities	_	(25,632)		(14,479)
Cash flows from investing activities:	<u> </u>	(23,032)	-	(14,473)
Purchase of property and equipment		(2,557)		(1,159)
Purchase of marketable securities		(174,205)		(1,155)
Net cash used in investing activities	_	(176,762)	_	(1,159)
Cash flows from financing activities:		(170,702)	_	(1,100)
Proceeds from initial public offering, net of issuance costs		77,264		_
Proceeds from issuance of preferred stock, net of issuance costs				31,000
Proceeds from issuance of common stock		65		_
Proceeds from the term loan		4,540		_
Deferred financing costs		(134)		(14)
Payments of the term loan				(300)
Net cash provided by financing activities		81,735		30,686
Net (decrease) increase in cash, cash equivalents and restricted cash		(120,659)		15,048
Cash, cash equivalents and restricted cash—beginning of year		135,633		9,287
Cash, cash equivalents and restricted cash—end of period	\$	14,974	\$	24,335
Supplemental disclosures of cash flow information:	_			
Cash paid for interest	\$	137	\$	18
Supplemental disclosures of noncash investing and financing activities:	_		_	
Purchase of property and equipment included in accrued liabilities	\$	73	\$	76
Deferred financing costs included in accrued liabilities	\$	134	\$	
Conversion of convertible preferred stock into common stock	\$	162,223	\$	
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#### 1. Nature of the Business

# 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.

# **Initial Public Offering**

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 \$77.0 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.

# 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 September 2019, the Company has funded its operations primarily with proceeds from the sale of preferred stock and proceeds from the Company's agreement with Eli Lilly and Company (Note 6) and proceeds from the IPO. The Company expects to incur additional operating losses and negative operating cash flows for the foreseeable future.

#### 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

The accompanying unaudited condensed financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 have been prepared by the Company in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto as of and for the year ended December 31, 2018, which are included in the Company's final prospectus that forms a part of the Company's Registration Statement on Form S-1 (Reg. No. 333-230837) (the "Registration Statement"), as filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on May 9, 2019.

The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements. In the opinion of management, the accompanying unaudited interim condensed financial statements contain all adjustments necessary for a fair statement of the Company's financial position as of September 30, 2019 and condensed results of operations and cash flows for the three and nine months ended September 30, 2019 and 2018. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

# 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. On an ongoing basis, management evaluates its estimates, including those related to accrued expenses, revenue recognition, the valuation of equity-based compensation, including incentive stock options, common stock and restricted common stock, as well as income taxes. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Although actual results could differ from those estimates, management does not believe that such differences would be material.

#### Restricted Cash

The Company is required, as a condition of its Term Loan (Note 8), to maintain cash collateral on deposit in a segregated money market bank account equal to the principal portion of the Term Loan, as determined on a quarterly basis. The bank may restrict withdrawals or transfers by or on behalf of the Company that would violate this requirement. The required reserve totaled \$5.0 million as of September 30, 2019. This amount is presented in part as restricted cash and in part as other assets on the accompanying balance sheet.

# 2. Summary of Significant Accounting Policies (Continued)

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

	Sep	September 30, 2019		December 31, 2018	
Cash and cash equivalents	\$	9,935	\$	135,173	
Restricted cash (including \$3,750 in other assets)		5,039		460	
Total	\$	14,974	\$	135,633	

# Marketable Securities

Our investments primarily consist of government debt securities, corporate bonds and agency bonds. These marketable securities are classified as available-for-sale, and as such, are reported at fair value on our condensed balance sheets. 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, together with interest on securities, are included in other income, net, on our condensed statements of operations.

If a decline in the fair value of a marketable security below our 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 cost of securities sold is based on the specific identification method.

# Revenue Recognition

The Company has adopted Accounting Standards Codification 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

# 2. Summary of Significant Accounting Policies (Continued)

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 promised goods or services 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

#### 2. Summary of Significant Accounting Policies (Continued)

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 condensed 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.

#### **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, 2020. 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

#### 2. Summary of Significant Accounting Policies (Continued)

amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements in ASC 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.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-18"). ASU 2018-18 clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation and disclosure requirements. The amendment also adds unit of account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. Lastly, ASU 2018-18 provides that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 will be precluded if the collaborative arrangement participant is not a customer. ASU 2018-18 will be effective for non-emerging growth companies 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 these clarifications for the accounting and presentation for its collaborative arrangements within the scope of Topic 808, but does not expect that the adoption of ASU 2018-18 will have any impact.

#### 3. Investments

Investments consist of the following (in thousands):

	September 30, 2019					
	Amortized Cost	Gross Gross Unrealized Gain Loss		Estimated Fair Value		
U.S. treasury securities	\$ 19,982	\$ 1	\$ —	\$ 19,983		
Agency bonds	47,178	_	(17)	47,161		
Corporate bonds	107,045	20	(62)	107,003		
Total	\$ 174,205	\$ 21	\$ (79)	\$ 174,147		

As of September 30, 2019, no investments are considered to be other-than-temporarily impaired. The Company uses the specific identification method when calculating realized gains and losses. For the three and nine months ended September 30, 2019, the Company recorded no realized gains and losses on available-for-sale securities.

#### 4. Fair Value of Financial Instruments

The Company has certain financial assets recorded at fair value, which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- 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.

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.

The following tables set forth the fair value of the Company's financial assets by level within the fair value hierarchy (in thousands):

	September 30, 2019																																											
		arrying Amount	Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Fair Value		Level 1		Level 1			Level 2	Lev	vel 3
Cash equivalents:																																												
Money market	\$	5,465	\$	5,465	\$	5,465	\$	_	\$	_																																		
Marketable securities:																																												
U.S. treasury securities		19,982		19,983		_		19,983		_																																		
Agency bonds		47,178		47,161		_		47,161		_																																		
Corporate bonds		107,045		107,003		_		107,003		_																																		
Total	\$	179,670	\$	179,612	\$	5,465	\$	174,147	\$	_																																		

		Dece	mber 31, 2018	}	
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:					
Money market	\$ 5,000	\$ 5,000	\$ 5,000	_	

The Company did not transfer any assets measured at fair value on a recurring basis between levels during the three and nine months ended September 30, 2019.

#### 5. Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	Sep	tember 30, 2019	December 31, 2018		
Research equipment	\$	9,746	\$	7,787	
Leasehold improvements		5,365		4,825	
Computer equipment		441		167	
Furniture and fixtures		94		70	
Construction in progress		787		1,027	
Property and equipment, gross		16,433		13,876	
Less: accumulated depreciation and amortization		(4,402)		(2,469)	
Property and equipment, net	\$	12,031	\$	11,407	

Construction in progress at September 30, 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 \$788,000 and \$1,933,000 for the three and nine months ended September 30, 2019, respectively, and \$396,000 and \$1,159,000 for the three and nine months ended September 30, 2018, respectively.

#### 6. 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 will 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 have 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. Both Lilly and the Company have all options remaining eligible for exercise. The research collaboration with Lilly will be managed by a joint steering committee formed by an equal number of members from the Company and Lilly and will expire upon the earlier of the exercise of all options granted to Lilly or four years from the date of the agreement, subject to certain extensions. The Company considers Lilly to be a related party based on Lilly's equity investment in the Company as discussed below.

During the research term under the Lilly Agreement, as a part of target discovery, the Company will be responsible for providing Lilly with oncology targets identified using the Company's FIND-IO platform. From the targets provided by the Company, Lilly may 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 may propose to advance that target to compound discovery. For each target that has been advanced to compound discovery, Lilly will have the option to obtain an exclusive license with respect to the compounds and products directed to the target. If Lilly does not exercise its option with respect to a given target or has previously exercised all of its options, the Company will have the option to obtain licenses with respect to compounds and products directed to that target. Following option exercise by a party, the development and commercialization of any products directed to the target

#### 6. Agreement with Eli Lilly and Company (Continued)

will be conducted by the exercising party. The exercising party must use commercially reasonable efforts to develop, seek regulatory approval for and commercialize any such products under mutually agreed upon work plans.

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. In addition, the Company will receive quarterly research and development support payments during a portion of the research term as well as option exercise fees upon option exercises by Lilly.

Pursuant to the Lilly Agreement, Lilly may owe an aggregate of up to \$1.4 billion in development and regulatory milestones and sales milestones. Additionally, Lilly will pay mid to high single-digit royalties on net sales for all products directed to each target optioned by Lilly. Upon the Company's exercise of an option with respect to a given target, the Company will pay Lilly an option exercise payment and may become obligated to milestone and royalty payments. The company may owe an aggregate of up to \$710.0 million in development and regulatory milestones and sales milestones.

Upon the adoption of ASC 606, the Company evaluated the Lilly Agreement under the provisions of ASC 606 and concluded that Lilly is 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 that has been 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 the 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 is being recognized as the research and development services are provided using an input method according to research and development costs incurred to date compared to estimated total research and development

#### 6. Agreement with Eli Lilly and Company (Continued)

costs. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. Revenue allocated to Lilly's right related to an optional term extension is deferred until the right is exercised or lapses, and will subsequently be recognized accordingly.

While the Lilly Agreement was executed in November 2018, the Company's performance initiated in January 2019. Under the Lilly Agreement, the Company recognized revenue of \$1.6 million and \$4.3 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, deferred revenue included in the Company's balance sheets comprised the following (in thousands):

	Sep	tember 30, 2019	Dec	cember 31, 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		1,500		_
Revenue from research and development arrangement recognized		(4,342)		_
Total deferred revenue, end of period		23,883		26,725
Less: Deferred revenue, current portion		(6,199)		(4,989)
Deferred revenue, non-current portion	\$	17,684	\$	21,736

#### 7. 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

#### 7. Commitments and Contingencies (Continued)

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.

The future minimum payments for the operating leases are as follows (in thousands):

Remainder of the year	\$ 97
2020	566
2021	692
2022	742
2023	733
Thereafter	6,088
Total future minimum payments	\$ 8,918

Rent expense incurred under operating leases was approximately \$252,000 and \$442,000 for the three and nine months ended September 30, 2019, respectively, and \$107,000 and \$308,000 for the three and nine months ended September 30, 2018, respectively.

#### 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.

#### 8. Term Loan

In April 2016, the Company entered into a \$1.0 million term loan with a commercial bank (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 4.33% and 4.44% for the three and nine months ended September 30, 2019, respectively. The effective interest rate was 4.18% and 3.84% for the three and nine months ended September 30, 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.

#### 8. Term Loan (Continued)

Future maturities of the Term Loan as of September 30, 2019 are as follows (in thousands):

Remainder of the year	\$ _
2020	1,528
2021	1,667
2022	1,667
2023	138
Total	5,000
Less: current portion of term loan	(1,250)
Term loan, net of current portion	\$ 3,750

Interest expense under the Term Loan was approximately \$56,000 and \$155,000 for the three and nine months ended September 30, 2019, respectively, and \$7,000 and \$20,000 for the three and nine months ended September 30, 2018, respectively.

#### 9. Stock-Based Compensation

#### **Employee Equity Plans**

The NextCure, Inc. 2015 Omnibus Incentive Plan (the "2015 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards, unrestricted stock awards or 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. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors or its committee if so delegated, except that the exercise price per share of the stock options may not be less than 100% of the fair market value of a share of the Company's common stock on the date of grant and the term of the stock options may not be greater than 10 years.

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 Registration Statement was declared effective (the "Effective Date"). The 2019 Plan replaces the 2015 Plan as 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 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 September 30, 2019, 2,653,969 shares were reserved for future grant under the 2019 Plan.

#### 9. Stock-Based Compensation (Continued)

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

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

	Options Outstanding and Exercisable						
	Number of Shares	A	Veighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)		Aggregate Intrinsic Value <sup>(1)</sup> 1 thousands)	
Outstanding as of December 31, 2018	2,056,891	\$	4.74	9.4	\$	5,946	
Granted	247,275	\$	18.18	10.0			
Exercised	(53,963)	\$	1.20	8.1			
Forfeitures	(1,250)	\$	7.63	9.5			
Outstanding as of September 30, 2019	2,248,953	\$	6.30	9.1	\$	55,305	
Vested and expected to vest as of September 30, 2019	2,248,953	\$	6.30		\$	55,305	
Exercisable as of September 30, 2019	450,866	\$	1.15		\$	12,335	

<sup>(1)</sup> 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 September 30, 2019 and December 31, 2018.

The weighted-average grant date fair value of stock options granted to employees for the nine months ended September 30, 2019 was \$11.48. The aggregate intrinsic value of stock options exercised during the nine months ended September 30, 2019 was \$1,600,000.

The Company's potential dilutive securities, which as of September 30, 2019 include common stock options, 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 used to calculate both basic and diluted net loss per common share is the same. The Company excluded 2,248,953 potential shares of common stock, presented based on amounts outstanding at three and nine periods ended September 30, 2019, from the computation of diluted net loss per common share for the period 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.

#### 9. Stock-Based Compensation (Continued)

#### **Stock-Based Compensation**

The Company recorded stock-based compensation expense of \$524,000 and \$1,319,000 for the three and nine months ended September 30, 2019, respectively, and \$90,000 and \$138,000 for the three and nine months ended September 30, 2018, respectively.

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

		Thi Mon End Septem	ths led	0,		Nine M End Septeml	led	ed	
	2	2019 2018		018	2019		2	2018	
Research and development	\$	182	\$	41	\$	482	\$	62	
General and administrative		342		49		837		76	
Total stock-based compensation expense	\$	524	\$	90	\$	1,319	\$	138	

#### 10. Income Taxes

The Company did not record a provision or benefit for income taxes during the nine months ended September 30, 2019. The Company continues to maintain a full valuation allowance against its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize its deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of any commercially ready products. It has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Management reevaluates the positive and negative evidence at each reporting period.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code, certain substantial changes in the Company's ownership may have limited, or may limit in the future, the amount of net operating loss and research and development credit carryforwards that can be used to reduce future income taxes.

### 11. Subsequent Events

The Company has evaluated subsequent events through the issuance date of these interim condensed financial statements.

### 3,200,000 Shares



Common Stock

**PROSPECTUS** 

Joint Book-Running Managers

**MORGAN STANLEY** 

**BofA SECURITIES** 

PIPER JAFFRAY

Co-Managers

NEEDHAM & COMPANY

**BTIG** 

, 2019

#### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by us in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

	Amount to be Paid
SEC registration fee	\$ 18,638.45
FINRA filing fee	22,039.04
Printing and engraving expenses	120,000.00
Legal fees and expenses	475,000.00
Accounting fees and expenses	225,000.00
Transfer agent and registrar fees and expenses	5,000.00
Miscellaneous expenses	34,322.51
Total	\$ 900,000.00

#### Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the duty of loyalty to us or our stockholders;
- any act or omission not in good faith that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that:

- we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we will advance expenses to our directors in connection with legal proceedings to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our amended and restated bylaws are not exclusive.

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Our amended and restated certificate of incorporation, attached as Exhibit 3.1 hereto, and our amended and restated bylaws, attached as Exhibit 3.2 hereto, provide for the indemnification provisions described above and elsewhere herein.

We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. These indemnification agreements generally require us, among other things, to indemnify our directors, executive officers and these employees against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors, executive officers and employees as a result of any proceeding against them as to which they could be indemnified. We also maintain directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances.

The form of Underwriting Agreement, attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters named in this registration statement of our executive officers, directors and us, and by us of the underwriters named in this registration statement, for specified liabilities, including liabilities arising under the Securities Act. Our amended and restated investors' rights agreement with certain stockholders, attached as Exhibit 4.2 hereto, also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

See the undertakings set forth in response to Item 17 herein.

#### Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all securities sold or granted by us within the last three years that were not registered under the Securities Act and the consideration, if any, received by us for such securities.

#### **Issuances of Capital Stock**

- (1) In January 2017, we issued an aggregate of 25,000,000 shares of our Series A-2 Preferred Stock to seven accredited investors at a price per share of \$1.00 for aggregate proceeds of \$25 million. Upon the closing of our IPO, each share of Series A-2 Preferred Stock converted into 0.1245 shares of our common stock.
- (2) In April 2018, we issued an aggregate of 28,181,819 shares of our Series A-3 Preferred Stock to seven accredited investors at a price per share of \$1.10 for aggregate proceeds of \$31 million. Upon the closing of our IPO, each share of Series A-3 Preferred Stock converted into 0.1245 shares of our common stock.
- (3) In November 2018, we issued an aggregate of 15,052,117 shares of our Series B-1 Preferred Stock to seven accredited investors at a price per share of \$1.59 for aggregate proceeds of approximately \$23.9 million. Upon the closing of our IPO, each share of Series B-1 Preferred Stock converted into 0.1245 shares of our common stock.
- (4) In November 2018, we issued an aggregate of 34,276,734 shares of our Series B-2 Preferred Stock to 14 accredited investors at a price per share of \$1.59 for aggregate proceeds of approximately \$54.5 million. Upon the closing of our IPO, each share of Series B-2 Preferred Stock converted into 0.1245 shares of our common stock.
- (5) In November 2018, we issued an aggregate of 7,500,000 shares of our Series B-3 Preferred Stock to Eli Lilly and Company at a price per share of \$2.00 for aggregate proceeds of \$15 million. Upon the closing of our IPO, each share of Series B-3 Preferred Stock converted into 0.1245 shares of our common stock.

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#### **Grants of Stock Options and Restricted Stock**

- (6) Since November 12, 2016, we have granted to our directors, officers, employees, consultants and other service providers stock options to purchase an aggregate of 2,139,164 shares of our common stock under the 2015 Plan or the 2019 Plan at exercise prices ranging from \$0.48 to \$15.57 per share. Of these, stock options covering an aggregate of 15,476 shares were cancelled without being exercised.
- (7) From November 12, 2016 through the filing of our registration statement on Form S-8 on May 13, 2019, we issued an aggregate of 34,984 shares of our common stock to our directors, officers and employees pursuant to the exercise of stock options under the 2015 Plan at exercise prices ranging from \$0.48 to \$1.76 per share for aggregate proceeds of approximately \$48,431.

We deemed the offers, sales and issuances of the securities described in paragraphs (1) through (5) above to be exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rules 504 and 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

We deemed the issuance of restricted common stock and grants and exercises of stock options described in paragraphs (6) and (7) above to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing securities issued in the transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

#### Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

See the Index to Exhibits attached to this registration statement, which is incorporated by reference herein.

(b) Financial Statement Schedules

No financial statement schedules are provided, because the information called for is not required or is shown either in the financial statements or the notes thereto.

### Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the

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registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

#### INDEX TO EXHIBITS

Exhibit Exhibit Description Numbe 1.1 Form of Underwriting Agreement. 3.1\* Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 filed with Registrant'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 Registrant'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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 5.1 Opinion of Hogan Lovells US LLP. 10.1<sup>†\*</sup> 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 Registrant'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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 10.3<sup>†\*</sup> Research and Development Collaboration Agreement, dated as of November 2, 2018, by and between the Company and Eli Lilly and Company (incorporated by reference to Exhibit 10.3 filed with Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 10.5<sup>+\*</sup> 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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). NextCure, Inc. 2015 Omnibus Incentive Plan, as amended (incorporated by reference to Exhibit 10.6 filed with Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 10.7<sup>+\*</sup> Form of Stock Option Agreement under the NextCure, Inc. 2015 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.7 filed with Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).

Exhibit **Exhibit Description** Numbe 10.8+\* 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)). Forms of Stock Option Agreement under the NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by  $10.9^{+*}$ reference to Exhibit 10.9 filed with Registrant's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)). 10.10<sup>+\*</sup> Form of Restricted Stock Agreement under the NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.10 filed with Registrant's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)). Form of Restricted Stock Unit Agreement under the NextCure, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.11 filed with Registrant's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)). NextCure, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.12 filed with Registrant's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)). Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.13 filed with Registrant's Registration Statement on Form S-1/A filed with the Commission on April 29, 2019 (File No. 333-230837)). 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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 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 Registrant's Quarterly Report on Form 10-Q filed on November 12, 2019 (File No. 001-38905)).  $10.16^{+*}$ 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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)). 10.17+\* 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 Registrant's Registration Statement on Form S-1 filed with the Commission on April 12, 2019 (File No. 333-230837)).  $10.18^{+*}$ 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 Registrant'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. 23.2 Consent of Hogan Lovells US LLP (included in Exhibit 5.1). II-6

Exhibit Number	Exhibit Description
24.1	Power of Attorney (included on signature page of Registration Statement).
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

<sup>\*</sup> Previously filed.

<sup>+</sup> Indicates a management contract or compensatory plan.

<sup>†</sup> Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Beltsville, Maryland, on this 12th day of November 2019.

#### NEXTCURE, INC.

By:	/s/ MICHAEL RICHMAN
	Michael Richman
	President and Chief Executive Officer

#### POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Michael Richman and Steven P. Cobourn and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this registration statement, including any and all post-effective amendments and amendments thereto, and any subsequent registration statement relating to the same offering as this registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ MICHAEL RICHMAN  Michael Richman	President, Chief Executive Officer and Director (Principal Executive Officer)	November 12, 2019
/s/ STEVEN P. COBOURN  Steven P. Cobourn	Chief Financial Officer (Principal Financial and Accounting Officer)	November 12, 2019
/s/ DAVID KABAKOFF, PH.D.	<ul><li>Chair of the Board</li></ul>	November 12, 2019
David Kabakoff, Ph.D.  /s/ ELAINE V. JONES, PH.D.	Di .	November 12, 2019
Elaine V. Jones, Ph.D.	– Director II-8	
	-	

Signature

<del></del>	<u>—</u>	<del>_</del>	
/s/ CHAU Q. KHUONG	Divector	November 12, 2010	
Chau Q. Khuong	Director	November 12, 2019	
/s/ JUDITH J. LI	Director	November 12, 2019	
Judith J. Li	Director		
/s/ BRIGGS MORRISON, M.D.	Director	November 12, 2019	
Briggs Morrison, M.D.	Director	101cmscr 12, 2015	
/s/ TIM SHANNON, M.D.	Director	November 12, 2019	
Tim Shannon, M.D.			
/s/ STEPHEN WEBSTER	Director	November 12, 2019	
Stephen Webster			
/s/ STELLA XU	Director	November 12, 2019	
Stella Xu			
	II-9		

<u>Title</u>

Date

### [•] Shares

### NEXTCURE, INC.

### COMMON STOCK, PAR VALUE \$0.001 PER SHARE

### UNDERWRITING AGREEMENT

, 2019

Morgan Stanley & Co. LLC BofA Securities, Inc. Piper Jaffray & Co.

c/o Morgan Stanley & Co. LLC 1585 Broadway New York, New York 10036

c/o BofA Securities, Inc. One Bryant Park New York, New York 10036

c/o Piper Jaffray & Co. 800 Nicollet Mall Minneapolis, Minnesota 55402

Ladies and Gentlemen:

NextCure, Inc., a Delaware corporation (the "Company"), proposes to issue and sell to the several Underwriters named in Schedule I hereto (the "Underwriters") [•] shares of its common stock, par value \$0.001 per share (the "Firm Shares"). The Company also proposes to issue and sell to the several Underwriters not more than an additional [•] shares of its common stock, par value \$0.001 per share (the "Additional Shares") if and to the extent that you, as representatives of the several Underwriters (the "Representatives") of the offering, shall have determined to exercise, on behalf of the Underwriters, the right to purchase such shares of common stock granted to the Underwriters in Section 2 hereof. The Firm Shares and the Additional Shares are hereinafter collectively referred to as the "Shares." The shares of common stock, par value \$0.001 per share, of the Company to be outstanding after giving effect to the sales contemplated hereby are hereinafter referred to as the "Common Stock."

The Company has filed with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-1 (File No. 333-[•]) including a prospectus, relating to the Shares. The registration statement as amended at the time it becomes effective, including the information (if any) deemed to be part of the registration statement at the time of effectiveness pursuant to Rule 430A under the Securities Act of 1933, as amended (the "Securities Act"), is hereinafter referred to as the "Registration Statement"; the prospectus in the form first used to confirm sales of Shares (or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act) is hereinafter referred to as the "Prospectus." If the Company has filed an abbreviated registration statement to register

additional shares of Common Stock pursuant to Rule 462(b) under the Securities Act (a "Rule 462 Registration Statement"), then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement.

For purposes of this Agreement, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act, "Time of Sale Prospectus" means the preliminary prospectus contained in the Registration Statement at the time of its effectiveness together with the documents and pricing information set forth in Schedule II hereto, and "broadly available road show" means a "bona fide electronic road show" as defined in Rule 433(h) (5) under the Securities Act that has been made available without restriction to any person. As used herein, the terms "Registration Statement," "preliminary prospectus," "Time of Sale Prospectus" and "Prospectus" shall include the documents, if any, incorporated by reference therein as of the date hereof.

- 1. Representations and Warranties. The Company represents and warrants to and agrees with each of the Underwriters that:
- (a) The Registration Statement has become effective; no stop order suspending the effectiveness of the Registration Statement is in effect, and no proceedings for such purpose are pending before or, to the Company's knowledge, threatened by the Commission.
- (b) (i) The Registration Statement, when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or supplement, any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the Registration Statement and the Prospectus comply and, as amended or supplemented, if applicable, will comply, as of the date of such amendment or supplement, in all material respects with the applicable requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder, (iii) the Time of Sale Prospectus does not, and at the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section 4), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (v) the Prospectus, as of its date, does not contain and, as amended or supplemented, if applicable, will not contain, as of the date of such amendment or supplement, any untrue statement of a material fact or omit to state a material fact necessary to make the statements of a material fact or omit to state a material fact necessary to make the statement of a material fact or omit to state a material fact necessary to make the statement of a material fact or omit to state a material fact necessary to make the statement of a material fact or omit to state a material fact necessary to make the statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, except that the

representations and warranties set forth in this paragraph do not apply to statements or omissions in the Registration Statement, the Time of Sale Prospectus or the Prospectus based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through you expressly for use therein.

- (c) The Company is not an "ineligible issuer" in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the applicable requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or, if filed after the date of this Agreement, will comply, when filed, in all material respects with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Except for the free writing prospectuses, if any, identified in Schedule II hereto, and electronic road shows, if any, each furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, prepare, use or refer to, any free writing prospectus.
- (d) The Company has been duly incorporated, is validly existing as a corporation and in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own or lease its property and to conduct its business as described in the Time of Sale Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not reasonably be expected to have a material adverse effect on the Company.
  - (e) The Company does not have any subsidiaries.
  - (f) This Agreement has been duly authorized, executed and delivered by the Company.
- (g) The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in the sections entitled "Capitalization" and "Description of Capital Stock" in each of the Time of Sale Prospectus and the Prospectus.
- (h) The shares of Common Stock outstanding prior to the issuance of the Shares have been duly authorized and are validly issued, fully paid and non-assessable.

- (i) The Shares have been duly authorized and, when issued, delivered and paid for in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of such Shares will not be subject to any preemptive or similar rights that have not been validly waived.
- (j) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene (i) any provision of applicable law, (ii) the certificate of incorporation or by-laws of the Company, (iii) any agreement or other instrument binding upon the Company that is material to the Company, or (iv) any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company, except in the case of clauses (i), (iii) and (iv) as would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company, and no consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the performance by the Company of its obligations under this Agreement, except such as have been obtained or waived or as may be required by the securities or blue sky laws of the various states in connection with the offer and sale of the Shares.
- (k) There has not occurred any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, management or operations of the Company from that set forth in the Time of Sale Prospectus.
- (1) There are no legal or governmental proceedings pending or, to the Company's knowledge, threatened to which the Company is a party or to which any of the properties of the Company is subject (i) other than (A) proceedings accurately described in all material respects in the Time of Sale Prospectus and (B) proceedings that would not reasonably, individually or in the aggregate, be expected to have a material adverse effect on the Company or on the power or ability of the Company to perform its obligations under this Agreement or to consummate the transactions contemplated by the Time of Sale Prospectus or (ii) that are required to be described in the Registration Statement or the Prospectus and are not so described in all material respects; and there are no statutes, regulations, contracts or other documents to which the Company or its property are subject or bound that are required to be described in the Registration Statement or the Prospectus or to be filed or incorporated by reference as exhibits to the Registration Statement that are not described in all material respects or filed or incorporated by reference as required.
- (m) Each preliminary prospectus filed as part of the Registration Statement as originally filed or as part of any amendment thereto, or filed pursuant to Rule 424 under the Securities Act, complied when so filed in all material respects with the applicable requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder.

- (n) The Company is not, and after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.
- (o) The Company (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("Environmental Laws"), (ii) has received all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business and (iii) is in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company.
- (p) There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) that would, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company.
- (q) There are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Shares registered pursuant to the Registration Statement, except those contracts, agreements and understandings described in the Time of Sale Prospectus and the Prospectus (i) as have been validly waived in connection with the issuance and sale of the Shares or (ii) pursuant to which such right has lapsed in accordance with its terms.
- (r) (i) None of the Company or its controlled affiliates, any director or officer, thereof, or, to the Company's knowledge, any employee, agent or representative of the Company or of any of its controlled affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment, giving or receipt of money, property, gifts or anything else of value, directly or indirectly, to any government official (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) in order to improperly influence official action, or to any person in violation of any applicable anti-corruption laws; (ii) the Company and its controlled affiliates have conducted their

businesses in compliance with applicable anti-corruption laws and have instituted and maintained and will continue to maintain policies and procedures reasonably designed to promote and achieve compliance with such laws and with the representations and warranties contained herein; and (iii) the Company will not use, directly or indirectly, the proceeds of the offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any person in violation of any applicable anti-corruption laws.

- (s) The operations of the Company are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable antimoney laundering statutes of jurisdictions where the Company conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Anti-Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- (t) (i) None of the Company or any director or officer thereof, or, to the Company's knowledge, any employee, agent, affiliate or representative of the Company, is an individual or entity ("**Person**") that is, or is owned or controlled by one or more Persons that are:
  - (A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), or
  - (B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea and Syria).
  - (ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:
    - (A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

- (B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).
- (iii) For the past five years, the Company has not knowingly engaged in, is not now knowingly engaged in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.
- (u) Subsequent to the respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, (i) the Company has not incurred any material liability or obligation, direct or contingent, nor entered into any material transaction; (ii) the Company has not purchased any of its outstanding capital stock, other than in connection with the termination of service of employees, directors or other service providers pursuant to equity compensation plans described in the Time of Sale Prospectus or existing agreements or in connection with the exercise of the Company's right of first refusal upon a proposed transfer, nor declared, paid or otherwise made any dividend or distribution of any kind on its capital stock other than ordinary and customary dividends; and (iii) there has not been any material change in the capital stock (other than the exercise of equity awards or grants of equity awards or repurchase or forfeiture of equity awards or restricted stock outstanding as of such respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus, in each case granted pursuant to the equity compensation plans described in the Time of Sale Prospectus or subject to an existing agreement), short-term debt or long-term debt of the Company, except in each case as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, respectively.
- (v) The Company does not own any real property. The Company has good and marketable title to all personal property owned by it that is material to the business of the Company, in each case free and clear of all liens, encumbrances and defects except such as are described in the Time of Sale Prospectus or such as do not materially diminish the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company; and any real property and buildings held under lease by the Company is held by the Company under valid, subsisting and enforceable leases with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such property and buildings by the Company, in each case except as described in the Time of Sale Prospectus.
- (w) The Company owns, has obtained licenses or can acquire on reasonable terms all material patent rights, inventions, trademarks, trade names, service marks, logos, trade dress, designs, data, database rights, Internet domain names, copyrights, works of authorship, trade secrets, know-how and proprietary

information (including unpatented and unpatentable proprietary or confidential information, systems or procedures) and other intellectual property rights (collectively, "Intellectual Property Rights") necessary to the current conduct of the business as described in the Registration Statement, the Time of Sale Prospectus, and the Prospectus, except where any failure to own, possess or acquire such Intellectual Property Rights would not reasonably be expected to have a material adverse effect on the Company. Such Intellectual Property Rights owned by or licensed to the Company have not been adjudged by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part. To the Company's knowledge: (i) there are no third parties that have rights to any Intellectual Property Rights of the Company except for (a) customary retained and reversionary rights of third-party licensors with respect to Intellectual Property Rights licensed to the Company, (b) non-exclusively licensed Intellectual Property Rights, where the licensor may provide licenses to a third party and (c) third parties that have been explicitly granted licenses by the Company; and (ii) there is no infringement by third parties of any Intellectual Property Rights of the Company. Except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by any third party: (A) challenging the Company's rights in or to any of their Intellectual Property Rights; (B) challenging the validity, enforceability or scope of any Intellectual Property Rights of the Company; or (C) asserting that the Company infringes, misappropriates, or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as under development, infringe, misappropriate, or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others. The Company has complied in all material respects with the terms of each agreement pursuant to which Intellectual Property Rights have been licensed to the Company, and all such agreements are in full force and effect. The Company has taken all reasonable steps necessary to secure its interests in the Company-owned Intellectual Property Rights from its employees and contractors and to protect the confidentiality of all of its confidential information and trade secrets, including the execution of appropriate nondisclosure, confidentiality agreements, invention assignment agreements and invention assignments with its employees, and to the Company's knowledge, no employee of the Company is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement. or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company. The product candidates described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as under development by the Company fall within the scope of one or more claim of one or more patents or patent applications owned by, or exclusively licensed to, the Company: To the Company's knowledge, the duties of candor and good faith required by the United States Patent and Trademark Office, including citation of material prior art that the

Company is aware of, during the prosecution of Company-owned United States patents and patent applications included in the Intellectual Property Rights have been complied with.

- (x) To the Company's knowledge, none of the Company-owned Intellectual Property Rights or technology (including information technology and outsourced arrangements) employed by the Company in the conduct of the business in the manner described in the Registration Statement, the Time of Sale Prospectus or the Prospectus has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or any of its officers, directors or employees or otherwise in violation of the rights of any persons.
- (y) Except as would not reasonably be expected to result in a material adverse effect on the Company, (A) each Plan (as defined below) has been maintained in compliance with its terms and in all material respects with the requirements of any applicable statutes, orders, rules and regulations, including but not limited to the Employee Retirement Income Security Act of 1974, as amended ("ERISA") and the Internal Revenue Code of 1986, as amended (the "Code"); (B) no non-exempt prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan; (C) for each Plan, no failure to satisfy the minimum funding standards (within the meaning of Section 412 of the Code or Section 302 of ERISA), whether or not waived, has occurred or is reasonably expected to occur; (D) no "reportable event" (within the meaning of Section 4043(c) of ERISA, other than those events as to which notice is waived) has occurred or is reasonably expected to occur; and (E) neither the Company nor any member of its "Controlled Group" (defined as any organization that is a member of a controlled group of corporations within the meaning of Section 414 of the Code) has incurred, nor is reasonably expected to incur, any liability under Title IV of ERISA (other than contributions to any Plan or any Multiemployer Plan or premiums to the PBGC, in the ordinary course and without default) in respect of a Plan or a Multiemployer Plan. For purposes of this paragraph, (x) the term "Plan" means an employee benefit plan, within the meaning of Section 3(3) of ERISA, subject to Title IV of ERISA, but excluding any Multiemployer Plan, for which the Company or any member of its "Controlled Group" has any liability and (y) the term "Multiemployer Plan" means a multiemployer plan within the meaning of Section 4001(a)(3) of ERISA.
- (z) No material labor dispute with the employees of the Company exists, except as described in the Time of Sale Prospectus, or, to the knowledge of the Company, is imminent; and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that would reasonably be expected to have a material adverse effect on the Company.

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- (aa) The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are, in the reasonable judgment of the Company, prudent and customary in the businesses in which it is engaged; the Company has not been refused any insurance coverage sought or applied for; and the Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.
- (bb) The Company possesses all certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct its business, except where failure to obtain such certificates, authorizations and permits would not, singly or in the aggregate, reasonably by expected to have a material adverse effect on the Company, and the Company has not received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit that, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.
- (cc) The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as described in the Time of Sale Prospectus, since the end of the Company's most recent audited fiscal year, there has been (i) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (ii) no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting.
- (dd) The financial statements (including the related notes thereto) of the Company included in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus comply in all material respects with the applicable requirements of the Securities Act and present fairly in all material respects the consolidated financial position of the Company as of the dates indicated and the results of its operations and cash flows for the periods specified. Such financial

statements have been prepared in conformity with U.S. GAAP applied on a consistent basis throughout the periods involved. The other financial information of the Company included in the Registration Statement, the Time of Sale Prospectus and the Prospectus has been derived from the accounting or other records of the Company and presents fairly in all material respects the information shown thereby.

- (ee) Ernst & Young LLP, independent public accountants, who have expressed their opinion with respect to certain financial statements (which term as used in this Agreement includes the related notes thereto) of the Company included in the Registration Statement, are independent with respect to the Company within the applicable rules and regulations of the Commission and as required by the Securities Act.
- (ff) The Company maintains disclosure controls and procedures that comply with the requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); such disclosure controls and procedures have been designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and principal financial officer by others within the Company; such disclosure controls and procedures are effective at the reasonable assurance level; and the Company has carried out evaluations of the effectiveness of its disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act through September 30, 2019.
- (gg) Except as described in the Time of Sale Prospectus, the Company has not sold, issued or distributed any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.
- (hh) The Company is in compliance, to the extent required, with all provisions of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), and all rules and regulations promulgated thereunder applicable to the Company as of the date hereof.
- (ii) The Company has filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement or has requested extensions thereof, except where the failure to file would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company, and has paid all taxes required to be paid thereon, except for cases in which the failure to file or pay would not reasonably be expected to have a material adverse effect on the Company, or, except as currently being contested in good faith and for which reserves required by U.S. GAAP have been created in the financial statements of the Company, and no tax deficiency has been determined adversely to the Company that has had (nor does the Company have

any notice or knowledge of any tax deficiency that would reasonably be expected to be determined adversely to the Company and that would reasonably be expected to have) a material adverse effect on the Company.

- (jj) From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.
- (kk) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.
- (ll) As of the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers, none of (A) the Time of Sale Prospectus, (B) any free writing prospectus, when considered together with the Time of Sale Prospectus, and (C) any individual Written Testing-the-Waters Communication, when considered together with the Time of Sale Prospectus, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (mm) The Company has complied, and is presently in compliance, in all material respects with its privacy and security policies, and with all obligations, laws and regulations regarding the collection, use, transfer, storage, protection, disposal or disclosure of personally identifiable information or any other information collected from or provided by third parties. The Company has taken commercially reasonable steps to protect the information technology systems and data used in connection with the operation of the Company. The Company has used reasonable efforts to establish, and has established, commercially reasonable disaster recovery and security plans, procedures and facilities for the business, including, without limitation, for the information technology systems and data

held or used by or for the Company. To its knowledge, there has been no material security breach or attack or other compromise of or relating to any such information technology system or data.

- (nn) The statistical, industry and market-related data included in the Registration Statement, the Time of Sale Prospectus and the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate. To the Company's knowledge, it does not require the consent of any third party for the use of any such data except as already obtained.
- (oo) The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in any stabilization or manipulation of the price of the Shares to facilitate the sale or resale thereof.
- (pp) The preclinical tests and clinical trials, and other studies (collectively, "studies") that are described in, or the results of which are referred to in, the Registration Statement, the Time of Sale Prospectus or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company has no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus; the Company has made all such filings and obtained all such approvals or authorizations as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or from any other U.S. or foreign government or drug regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies"), except where the failure to make such filing or obtain such approval would not reasonably be expected to result in a material adverse effect on the Company; except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, the Company has not received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the Time of Sale Prospectus; and the Company has operated and currently is in compliance in all material respects with all applicable rules and regulations of the Regulatory Agencies.
- (qq) The Company is, and at all times has been, in compliance with all applicable Health Care Laws except where failure to be in compliance would not be reasonably expected to have a material adverse effect on the Company. For purposes of this Agreement, "**Health Care Laws**" means: (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), the Public Health Service Act (42 U.S.C. §§ 201 et seq.) and the regulations promulgated thereunder; (ii) all

applicable federal, state, local and foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the U.S. False Statements Law (42 U.S.C. § 1320a-7b(a)), the Civil Monetary Penalties Law (42 U.S.C. §1320a-7a), the U.S. Civil False Claims Act (31 U.S.C. § 3729 et seq.), all applicable federal, state, local and foreign criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. §§ 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. §§ 1320d et seq.), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the exclusion law (42 U.S.C. §1320a-7), the statutes, regulations and directives of applicable federal healthcare programs (as defined in 42 U.S.C. § 1320a-7b(f)), and the regulations promulgated pursuant to such statutes, including but not limited to Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Social Security Act); (iii) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), and the regulations promulgated thereunder, including without limitation, the Standards for Privacy of Individually Identifiable Health Information, the Security Standards, and the Standards for Electronic Transactions and Code Sets, and any state or non-U.S. counterpart thereof or other law or regulation the purpose of which is to protect the privacy of individuals or prescribers; (iv) the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, the regulations promulgated thereunder; and (v) any and all other applicable health care laws and regulation applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company. The Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that it is in violation of any Health Care Laws, and, to the Company's knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened. Neither the Company nor its officers, directors, or, to the Company's knowledge, its employees, contractors or agents, is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company nor any of its officers, directors, or to the Company's knowledge, its employees, contractors or agents has been excluded, suspended or debarred from participation in any federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in such debarment, suspension, or exclusion. The Company has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by the Health Care Laws, and all such reports,

documents, forms, notices, applications, records, claims, submissions and supplements or amendments were timely, complete, accurate and not misleading on the date filed (or were corrected or supplemented by a subsequent submission), except as would not reasonably be expected to have a material adverse effect on the Company.

- (rr) The interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- 2. *Agreements to Sell and Purchase.* The Company hereby agrees to sell to the several Underwriters, and each Underwriter, upon the basis of the representations and warranties herein contained, but subject to the conditions hereinafter stated, agrees, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth in Schedule I hereto opposite its name at \$[•] a share (the "**Purchase Price**").

On the basis of the representations and warranties contained in this Agreement, and subject to its terms and conditions, the Company agrees to sell to the Underwriters the Additional Shares, and the Underwriters shall have the right to purchase, severally and not jointly, up to [\*] Additional Shares at the Purchase Price, provided, however, that the amount paid by the Underwriters for any Additional Shares shall be reduced by an amount per share equal to any dividends declared by the Company and payable on the Firm Shares but not payable on such Additional Shares. You may exercise this right on behalf of the Underwriters in whole or from time to time in part by giving written notice to the Company not later than 30 days after the date of this Agreement. Any exercise notice shall specify the number of Additional Shares to be purchased by the Underwriters and the date on which such shares are to be purchased. Each purchase date must be at least one business day after the written notice is given and may not be earlier than the Closing Date nor later than ten business days after the date of such notice. Additional Shares may be purchased as provided in Section 4 hereof solely for the purpose of covering over-allotments made in connection with the offering of the Firm Shares. On each day, if any, that Additional Shares are to be purchased (an "Option Closing Date"), each Underwriter agrees, severally and not jointly, to purchase the number of Additional Shares (subject to such adjustments to eliminate fractional shares as you may determine) that bears the same proportion to the total number of Additional Shares to be purchased on such Option Closing Date as the number of Firm Shares set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of Firm Shares.

3. *Terms of Public Offering*. The Company is advised by you that the Underwriters propose to make a public offering of their respective portions of the Shares as soon after the Registration Statement and this Agreement have become effective as in your judgment is advisable. The Company is further advised by you that the Shares are to be offered to the public initially at \$[•] a share (the "Public Offering Price") and to certain dealers selected by you at a price that represents a concession not in excess of \$[•] a share under the Public Offering Price, and that any Underwriter may allow, and such

dealers may reallow, a concession, not in excess of \$[•] a share, to any Underwriter or to certain other dealers.

4. *Payment and Delivery*. Payment for the Firm Shares shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Firm Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on [ ], 2019, or at such other time on the same or such other date, not later than [ ], 2019, as shall be designated in writing by you. The time and date of such payment are hereinafter referred to as the "Closing Date".

Payment for any Additional Shares shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Additional Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on the date specified in the corresponding notice described in Section 2 or at such other time on the same or on such other date, in any event not later than [ ], 2019, as shall be designated in writing by you.

The Firm Shares and Additional Shares shall be registered in such names and in such denominations as you shall request in writing not later than one full business day prior to the Closing Date or the applicable Option Closing Date, as the case may be. The Firm Shares and Additional Shares shall be delivered to you on the Closing Date or an Option Closing Date, as the case may be, for the respective accounts of the several Underwriters designated by you through the facilities of the Depository Trust Company, with any transfer taxes payable in connection with the transfer of the Shares to the Underwriters duly paid, against payment of the Purchase Price therefor.

5. *Conditions to the Underwriters' Obligations.* The obligations of the Company to sell the Shares to the Underwriters and the several obligations of the Underwriters to purchase and pay for the Shares on the Closing Date are subject to the condition that the Registration Statement shall have become effective not later than 4:00pm (New York City time) on the date hereof.

The several obligations of the Underwriters are subject to the following further conditions:

- (a) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date:
- (i) no order suspending the effectiveness of the Registration Statement shall be in effect, and no proceeding for such purpose or pursuant to Section 8A under the Securities Act shall be pending before or threatened by the Commission;
- (ii) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any of the securities of the

Company by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act: and

- (iii) there shall not have occurred any change, or any development involving a prospective change, in the condition, financial or otherwise, or in the earnings, business, management or operations of the Company from that set forth in the Time of Sale Prospectus that, in your judgment, is material and adverse and that makes it, in your judgment, impracticable to market the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus.
- (b) The Underwriters shall have received on the Closing Date a certificate, dated the Closing Date and signed on behalf of the Company by an executive officer of the Company, to the effect set forth in Section 5(a)(i) above and to the effect that the representations and warranties of the Company contained in this Agreement are true and correct as of the Closing Date and that the Company has complied with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date.

The officer signing and delivering such certificate may rely upon the best of his or her knowledge as to proceedings threatened.

- (c) The Underwriters shall have received on the Closing Date an opinion and negative assurance letter of Hogan Lovells US LLP, outside counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.
- (d) The Underwriters shall have received on the Closing Date an opinion and negative assurance letter of Smith, Gambrell & Russell, LLP, intellectual property counsel for the Company, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.
- (e) The Underwriters shall have received on the Closing Date an opinion and negative assurance letter of Cooley LLP, counsel for the Underwriters, dated the Closing Date, in form and substance reasonably satisfactory to the Underwriters.

With respect to the opinion and negative assurance letters to be delivered pursuant to Sections 5(c) and 5(e) above, Hogan Lovells US LLP and Cooley LLP, respectively, may state that their opinions and beliefs are based upon their participation in the preparation of the Registration Statement, the Time of Sale Prospectus and the Prospectus and any amendments or supplements thereto and review and discussion of the contents thereof, but are without independent check or verification, except as specified.

The opinion of Hogan Lovells US LLP described in Section 5(c) above shall be rendered to the Underwriters at the request of the Company and shall so state therein.

- (f) The Underwriters shall have received, on each of the date hereof and the Closing Date, a letter dated the date hereof or the Closing Date, as the case may be, in form and substance reasonably satisfactory to the Underwriters, from Ernst & Young LLP, independent registered public accounting firm, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus; provided that the letter delivered on the Closing Date shall use a "cut-off date" not earlier than the date hereof.
- (g) The "lock-up" agreements, each substantially in the form of Exhibit A hereto, between you and the officers, directors and certain stockholders of the Company relating to sales and certain other dispositions of shares of Common Stock or certain other securities, delivered to you on or before the date hereof, shall be in full force and effect on the Closing Date.
- (h) [The Underwriters shall have received, on each of the date hereof and the Closing Date, a certificate of the accuracy of certain financial information included in the Time of Sale Prospectus and the Prospectus, in form and substance reasonably satisfactory to the Underwriters, signed by the Chief Financial Officer of the Company.]
- (i) The several obligations of the Underwriters to purchase Additional Shares hereunder are subject to the delivery to you on the applicable Option Closing Date of the following:
  - (i) a certificate, dated the Option Closing Date and signed on behalf of the Company by an executive officer of the Company, confirming that the certificate delivered on the Closing Date pursuant to Section 5(b) hereof remains true and correct as of such Option Closing Date;
  - (ii) an opinion of Hogan Lovells US LLP, outside counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(c) hereof;
  - (iii) an opinion of Smith, Gambrell & Russell, LLP, intellectual property counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(d) hereof;
  - (iv) an opinion of Cooley LLP, counsel for the Underwriters, dated the Option Closing Date, relating to the Additional Shares to be

purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(e) hereof;

- (v) a letter dated the Option Closing Date, in form and substance reasonably satisfactory to the Underwriters, from Ernst & Young LLP, independent registered public accounting firm, substantially in the same form and substance as the letter furnished to the Underwriters pursuant to Section 5(e) hereof; *provided* that the letter delivered on the Option Closing Date shall use a "cut-off date" not earlier than three business days prior to such Option Closing Date; and
- (vi) such other documents as you may reasonably request with respect to the good standing of the Company, the due authorization and issuance of the Additional Shares to be sold on such Option Closing Date and other matters related to the issuance of such Additional Shares.
- 6. *Covenants of the Company*. The Company covenants with each Underwriter as follows:
- (a) To furnish to you, without charge and upon request, four conformed copies of the Registration Statement (including exhibits thereto) and for delivery to each other Underwriter a conformed copy of the Registration Statement (without exhibits thereto) and to furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period mentioned in Section 6(e) or 6(f) below, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.
- (b) Before amending or supplementing the Registration Statement, the Time of Sale Prospectus or the Prospectus, to furnish to you a copy of each such proposed amendment or supplement and not to file any such proposed amendment or supplement to which you reasonably object in writing, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.
- (c) To furnish to you a copy of each proposed free writing prospectus to be prepared by or on behalf of, used by, or referred to by the Company and not to use or refer to any proposed free writing prospectus to which you reasonably object.
- (d) Not to take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.

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- (e) If the Time of Sale Prospectus is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement then on file, or if, in the reasonable opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not, in the light of the circumstances when the Time of Sale Prospectus is delivered to a prospective purchaser, be misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.
- (f) If, during such period after the first date of the public offering of the Shares as in the reasonable opinion of counsel for the Underwriters the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is required by law to be delivered in connection with sales by an Underwriter or dealer, any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, not misleading, or if, in the reasonable opinion of counsel for the Underwriters, it is necessary to amend or supplement the Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to the dealers (whose names and addresses you will furnish to the Company) to which Shares may have been sold by you on behalf of the Underwriters and to any other dealers upon request, either amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law.
- (g) To endeavor to qualify the Shares for offer and sale under the securities or blue sky laws of such jurisdictions as you shall reasonably request, provided, however, that nothing contained herein shall require the Company to qualify to do business in any jurisdiction, to execute a general consent to service of process in any jurisdiction, or to subject itself to taxation in any jurisdiction in which it is not otherwise subject.

- (h) To make generally available (which may be satisfied by filing with the Commission on its Electronic Data Gathering, Analysis, and Retrieval system) to the Company's security holders and to you as soon as practicable an earnings statement covering a period of at least 12 months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement that shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.
- Whether or not the transactions contemplated in this Agreement are consummated or this Agreement is terminated, to pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including: (i) the fees, disbursements and expenses of the Company's counsel and the Company's accountants in connection with the registration and delivery of the Shares under the Securities Act and all other fees or expenses in connection with the preparation and filing of the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company and amendments and supplements to any of the foregoing, including all printing costs associated therewith, and the mailing and delivering of copies thereof to the Underwriters and dealers, in the quantities hereinabove specified, (ii) all costs and expenses related to the transfer and delivery of the Shares to the Underwriters, including any transfer or other taxes payable thereon, (iii) the reasonable cost of printing or producing any blue sky or legal investment memorandum in connection with the offer and sale of the Shares under state securities laws and all expenses incurred in connection with the qualification of the Shares for offer and sale under state securities laws as provided in Section 6(g) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the blue sky or legal investment memorandum, (iv) all filing fees and the reasonable fees and disbursements of counsel to the Underwriters incurred in connection with the review and qualification of the offering of the Shares by the Financial Industry Regulatory Authority, Inc. provided that the amount payable by the Company with respect to fees and disbursements of the Underwriters and counsel for the Underwriters pursuant to subsections (iii) and (iv) shall not exceed \$35,000 in the aggregate, (v) all costs and expenses incident to listing the Shares on the Nasdaq Global Select Market, (vi) the cost of printing certificates representing the Shares, (vii) the costs and charges of any transfer agent, registrar or depositary, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and 50% of the cost of any aircraft chartered in connection with the road show (the remaining 50% of the cost of such aircraft to be paid by the Underwriters), (ix) the document production

charges and expenses associated with printing this Agreement and (x) all other costs and expenses incident to the performance of the obligations of the Company hereunder for which provision is not otherwise made in this Section. It is understood, however, that except as provided in this Section, Section 8(a) entitled "Indemnity and Contribution" and the last paragraph of Section 10 below, the Underwriters will pay all of their costs and expenses, including fees and disbursements of their counsel, stock transfer taxes payable on resale of any of the Shares by them and any advertising expenses connected with any offers they may make and all travel and other expenses of the Underwriters, their representatives, their counsel or any of their employees incurred by them in connection with their participation in investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares.

- (j) To promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Shares within the meaning of the Securities Act and (b) completion of the Restricted Period (as defined in this Section 6).
- (k) If at any time during the period in which delivery of a prospectus is required by the Securities Act following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication, as then amended or supplemented, included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, to promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

The Company also covenants with each Underwriter that, without the prior written consent of the Representatives, on behalf of the Underwriters, it will not, during the period ending 90 days after the date of the Prospectus (the "Restricted Period"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise or (3) file any registration statement with the Commission relating to the offering of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock.

The restrictions contained in the preceding paragraph shall not apply to (a) the Shares to be sold hereunder, (b) the issuance by the Company of shares of Common Stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof, as described in the Time of Sale Prospectus and the

Prospectus or of which the Underwriters have been advised in writing, (c) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, *provided* that (i) such plan does not provide for the transfer of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period, (d) the grant or issuance by the Company of options, restricted stock awards, restricted stock units or any other type of equity award to employees, officers, directors, advisors or consultants of the Company pursuant to employee benefit plans described in the Time of Sale Prospectus, (e) the filing by the Company of one or more registration statements with the Commission on Form S-8 with respect to employee benefit plans in described in the Time of Sale Prospectus and the Prospectus, or (f) the sale or issuance of or entry into an agreement to sell or issue shares of Common Stock or securities convertible into or exercisable for Common Stock in connection with any (i) merger, (ii) acquisition of securities, businesses, technology, property or any other assets, (iii) joint venture, (iv) strategic alliance or (v) equipment leasing arrangement, provided that the aggregate number of shares of Common Stock or securities convertible into or exercisable for Common Stock (on an as-converted or as exercised basis, as the case may be) that the Company may sell or issue or agree to sell or issue pursuant to this clause (f) shall not exceed 5% of the total number of shares of the Company's Common Stock issued and outstanding immediately following the completion of the transactions contemplated by this Agreement, and provided further, that each recipient of shares of Common Stock or secu

- 7. *Covenants of the Underwriters*. Each Underwriter severally covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.
- 8. Indemnity and Contribution. (a) The Company agrees to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other reasonable expenses incurred in connection with defending or investigating any such action or claim) arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing prospectus as defined in Rule 433(h) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act, any Written

Testing-the-Waters Communication arising out of or based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages or liabilities arising out of or based upon such untrue statement or omission or alleged untrue statement or omission based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through you expressly for use therein.

- (b) Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the foregoing indemnity from the Company to such Underwriter, but only with reference to information relating to such Underwriter furnished to the Company in writing by such Underwriter through you expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, road show or the Prospectus or any amendment or supplement thereto.
- In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to Section 8(a) or 8(b), such person (the "indemnified party") shall promptly notify the person against whom such indemnity may be sought (the "indemnifying party") in writing and the indemnifying party, upon request of the indemnified party, shall retain counsel reasonably satisfactory to the indemnified party to represent the indemnified party and any others the indemnifying party may designate in such proceeding and shall pay the reasonably incurred fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed in writing to the retention of such counsel, (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them (iii) the indemnified party shall have reasonably concluded that there may be legal defenses available to it that are different from or in addition to those available to the indemnifying party, or (iv) the indemnifying party has failed within a reasonable time to retain counsel reasonably satisfactory to the indemnified party. It is understood that the indemnifying party shall not, in respect of the legal expenses of any indemnified party in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all such indemnified parties and that all such fees and expenses shall be reimbursed as they are incurred. Such firm shall be designated in writing by the Representatives, in the case of parties indemnified pursuant to Section 8(a), and by the Company, in the case of parties indemnified

pursuant to Section 8(b). The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

To the extent the indemnification provided for in Section 8(a) or 8(b) is unavailable to an indemnified party or insufficient in respect of (d) any losses, claims, damages or liabilities referred to therein, then each indemnifying party under such paragraph, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand from the offering of the Shares or (ii) if the allocation provided by clause 8(d)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause 8(d)(i) above but also the relative fault of the indemnifying party or parties on the one hand and of the indemnified party or parties on the other hand in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other hand in connection with the offering of the Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Shares (before deducting expenses) received by the Company and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate Public Offering Price of the Shares. The relative fault of the Company on the one hand and the Underwriters on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or

omission. The Underwriters' respective obligations to contribute pursuant to this Section 8(a) are several in proportion to the respective number of Shares they have purchased hereunder, and not joint.

- (e) The Company and the Underwriters agree that it would not be just or equitable if contribution pursuant to this Section 8(a) were determined by *pro rata* allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 8(d)(i). The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred to in Section 8(d)(i) shall be deemed to include, subject to the limitations set forth above, any legal or other reasonable expenses incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8(a), no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The remedies provided for in this Section 8(a) are not exclusive and shall not limit any rights or remedies that may otherwise be available to any indemnified party at law or in equity.
- (f) The indemnity and contribution provisions contained in this Section 8(a) and the representations, warranties and other statements of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Underwriter, any person controlling any Underwriter or any affiliate of any Underwriter or by or on behalf of the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Shares.
- 9. Termination. The Underwriters may terminate this Agreement by notice given by you to the Company, if after the execution and delivery of this Agreement and prior to the Closing Date (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange, NYSE American, the Nasdaq Global Market, the Chicago Board of Options Exchange, the Chicago Mercantile Exchange or the Chicago Board of Trade or other relevant exchanges, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any overthe-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States or other relevant jurisdiction shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal or New York State authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in your judgment, is material and adverse and which, singly or

together with any other event specified in this clause (v), makes it, in your judgment, impracticable or inadvisable to proceed with the offer, sale or delivery of the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus or the Prospectus.

10. Effectiveness; Defaulting Underwriters. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

If, on the Closing Date or an Option Closing Date, as the case may be, any one or more of the Underwriters shall fail or refuse to purchase Shares that it has or they have agreed to purchase hereunder on such date, and the aggregate number of Shares that such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of the Shares to be purchased on such date, the other Underwriters shall be obligated severally in the proportions that the number of Firm Shares set forth opposite their respective names in Schedule I bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as you may specify, to purchase the Shares that such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date; provided that in no event shall the number of Shares that any Underwriter has agreed to purchase pursuant to this Agreement be increased pursuant to this Section 10 by an amount in excess of one-ninth of such number of Shares without the written consent of such Underwriter. If, on the Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Firm Shares and the aggregate number of Firm Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Firm Shares to be purchased on such date, and arrangements satisfactory to you and the Company for the purchase of such Firm Shares are not made within 36 hours after such default, this Agreement shall terminate without liability on the part of any non-defaulting Underwriter or the Company. In any such case either you or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement, in the Time of Sale Prospectus, in the Prospectus or in any other documents or arrangements may be effected. If, on an Option Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Additional Shares and the aggregate number of Additional Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Additional Shares to be purchased on such Option Closing Date, the non-defaulting Underwriters shall have the option to (i) terminate their obligation hereunder to purchase the Additional Shares to be sold on such Option Closing Date or (ii) purchase not less than the number of Additional Shares that such non-defaulting Underwriters would have been obligated to purchase in the absence of such default. Any action taken under this paragraph shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

If this Agreement shall be terminated by the Underwriters, or any of them, because of any failure or refusal on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement required to be complied with or fulfilled by the Company, or if for any reason the Company shall be unable to perform its obligations under this Agreement (other than by reason of a default by the Underwriters

or the occurrence of any of the events described in clauses (i), (iii), (iv) or (v) of Section 10), the Company will reimburse the Underwriters or such Underwriters as have so terminated this Agreement with respect to themselves, severally, for all reasonable and documented out-of-pocket expenses (including the reasonable and documented fees and disbursements of their counsel) incurred by such Underwriters in connection with this Agreement or the offering contemplated hereunder.

- 11. *Entire Agreement*. (a) This Agreement together with any contemporaneous written agreements and any prior written agreements (to the extent not superseded by this Agreement) that relate to the offering of the Shares represents the entire agreement between the Company and the Underwriters with respect to the preparation of any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, the conduct of the offering, and the purchase and sale of the Shares.
  - (b) The Company acknowledges that in connection with the offering of the Shares: (i) the Underwriters have acted at arm's length, are not agents of, and owe no fiduciary duties to, the Company or any other person; (ii) the Underwriters owe the Company only those duties and obligations set forth in this Agreement and prior written agreements (to the extent not superseded by this Agreement), if any; and (iii) the Underwriters may have interests that differ from those of the Company. The Company waives to the full extent permitted by applicable law any claims it may have against the Underwriters arising from an alleged breach of fiduciary duty in connection with the offering of the Shares.
- 12. Recognition of the U.S. Special Resolution Regimes. (a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.
  - (b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section: (i) a "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); (ii) "Covered Entity" means any of the following: (A) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (B) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); (iii) "Default Right" has the meaning assigned to that term

in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and (iv) "U.S. Special Resolution Regime" means each of (A) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (B) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

- 13. *Counterparts.* This Agreement may be signed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.
- 14. *Applicable Law.* This Agreement and any claim, controversy or dispute arising out of this Agreement shall be governed by and construed in accordance with the internal laws of the State of New York.
- 15. *Headings*. The headings of the sections of this Agreement have been inserted for convenience of reference only and shall not be deemed a part of this Agreement.
- 16. *Notices*. All communications hereunder shall be in writing and effective only upon receipt and if to the Underwriters shall be delivered, mailed or sent to you in care of Morgan Stanley & Co. LLC, 1585 Broadway, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department; BofA Securities, Inc., One Bryant Park, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department; Piper Jaffray & Co., 800 Nicollet Mall, Minneapolis, Minnesota 55402, Attention: Equity Syndicate Desk, with a copy to the Legal Department, and in each case with a copy (which shall not constitute notice) to Cooley LLP, 55 Hudson Yards, New York, New York 10001, Attention: Div Gupta, Brent Siler and Josh Kaufman; and if to the Company shall be delivered, mailed or sent to 9000 Virginia Manor Road, Suite 200, Beltsville, Maryland 20705, with a copy (which shall not constitute notice) to Hogan Lovells US LLP, 100 International Drive, Suite 2000, Baltimore, Maryland 21202, Attention: William I. Intner.

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Very truly yours,  NextCure, Inc. By:
Name: Title:

BofA Piper : Acting	In Stanley & Co. LLC Securities, Inc. Jaffray & Co. g severally on behalf of themselves and the several Underwriters named chedule I hereto.	
By:	Morgan Stanley & Co. LLC	
By:		_
	Name: Title:	
By:	BofA Securities, Inc.	
By:		_
	Name: Title:	
By:	Piper Jaffray & Co.	
By:		_
	Name: Title:	
	Titic.	

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Accepted as of the date hereof

SCHEDULE I

Underwriter		Number of Firm Shares To Be Purchased
Morgan Stanley & Co. LLC		
BofA Securities, Inc.		
Piper Jaffray & Co.		
Total:		
	I-1	

# **Time of Sale Prospectus**

- 1. Preliminary Prospectus issued [date]
- 2. Price per share to the public:  $[\cdot]$

Number of shares offered:  $[\cdot]$ 

Underwriters' option to purchase additional shares:  $[\cdot]$ 

II-1

# **Written Testing-the-Waters Communication**

None

# FORM OF LOCK-UP LETTER

A-1

Morgan Stanley & Co. LLC BofA Securities, Inc. Piper Jaffray & Co.

c/o Morgan Stanley & Co. LLC 1585 Broadway New York, New York 10036

c/o BofA Securities, Inc. One Bryant Park New York, New York 10036

c/o Piper Jaffray & Co. 800 Nicollet Mall Minneapolis, Minnesota 55402

### Ladies and Gentlemen:

The undersigned understands that Morgan Stanley & Co. LLC ("Morgan Stanley"), Bof A Securities, Inc. ("BofAS") and Piper Jaffray and Co. (together with Morgan Stanley and BofAS, the "Representatives"), propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with NextCure, Inc., a Delaware corporation (the "Company"), providing for the public offering (the "Public Offering") by the several Underwriters, including the Representatives (the "Underwriters"), of a number of shares (the "Shares") of the common stock, par value \$0.001 per share, of the Company (the "Common Stock") in an amount to be determined.

To induce the Underwriters that may participate in the Public Offering to continue their efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Representatives, on behalf of the Underwriters, it will not, during the period commencing on the date hereof and ending 90 days after the date of the final prospectus (the "Restricted Period") relating to the Public Offering (the "Prospectus"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock beneficially owned (as such term is used in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for Common Stock (together, with Common Stock, "Securities") or make any public announcement of its intention to enter into any of the foregoing or (2) enter into any swap or other

arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Securities, in cash or otherwise. The foregoing sentence shall not apply to:

- (a) transactions relating to Securities acquired in the Public Offering or in open market transactions after the completion of the Public Offering; *provided* that no filing under Section 16(a) of the Exchange Act shall be required, or shall be voluntarily made during the Restricted Period, in connection with subsequent sales of Securities acquired in such open market transactions;
- (b) transfers of Securities
  - (i) as a bona fide gift or charitable contribution;
  - (ii) upon death or by will, testamentary document or intestate succession to the legal representative, heir, beneficiary or an immediate family member (as defined below) of the undersigned;
  - (iii) to an immediate family member of the undersigned or to any trust, partnership or limited liability company for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this agreement, "immediate family" shall mean any relationship by blood, current or former marriage or adoption, not more remote than first cousin);
  - (iv) not involving a change in beneficial ownership;
  - (v) if the undersigned is a trust, to any beneficiary of the undersigned or the estate of any such beneficiary;
  - (vi) as forfeitures to satisfy tax withholding obligations of or pursuant to a net or cashless exercise by the undersigned in connection with the vesting or exercise of equity awards by the undersigned to the extent such equity awards are outstanding as of the date of the Prospectus and granted pursuant to any equity incentive plan of the Company existing as of the date of the Prospectus and described in the Prospectus and so long as such net or cashless exercise is effected solely by the surrender of outstanding equity awards and the Company's cancellation of all or a portion thereof to pay the exercise price (including the payment of taxes due as a result of such vesting event or exercise) and/or withholding tax obligations, but for the avoidance of doubt, excluding all methods of exercise that would involve a sale of any Securities related to such equity awards, whether to cover the applicable exercise price, withholding tax obligations or otherwise; provided that no filing under Section 16(a) of the Exchange Act or any other public filing or disclosure of such receipt or transfer by or on

behalf of the undersigned shall be required or shall be voluntarily made within 30 days after the date of the Prospectus, and after such 30th day, any filing under Section 16(a) of the Exchange Act shall clearly indicate in the footnotes thereto that no shares were sold by the undersigned and the purpose of such transfer was to cover tax obligations of the undersigned or to pay the exercise price in connection with such exercise;

- pursuant to a bona fide third-party tender offer for all outstanding shares of the Company, merger, consolidation or other similar transaction made to all holders of the Company's Securities involving a Change of Control (as defined below) of the Company (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of Securities in connection with such transaction, or vote any Securities in favor of any transaction), *provided* that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such Securities held by the undersigned shall remain subject to the provisions of this letter agreement, *provided further* that if the undersigned is required to make a filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock during the Restricted Period, the undersigned shall include a statement that such transfer is being made pursuant to the circumstances described in this clause (b)(vii) (as used herein, "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than any Underwriters pursuant to the Public Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity));
- (viii) by operation of law pursuant to an order of a court or regulatory agency, *provided* that if the undersigned is required to make a filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock during the Restricted Period, the undersigned shall include a statement that such transfer is being made pursuant to the circumstances described in this clause (b)(viii);
- (ix) if the undersigned is a corporation, partnership, limited liability company or other entity, (A) distributions of Securities to stockholders, direct or indirect affiliates (within the meaning set forth in Rule 405 under the Securities Act of 1933, as amended), current or former partners (general or limited), members, directors, officers or managers of the undersigned, as applicable, or to the estates of any such stockholders, affiliates, partners, members, directors, officers or managers or (B) sales or transfers of any Securities to another such entity that is a direct or indirect affiliate of the

undersigned, or to any investment fund or other entity that is, directly or indirectly, controlling or managing, controlled or managed by, or under common control or management with, the undersigned or affiliates of the undersigned; or

- (x) to the Company pursuant to any contractual arrangement that provides for the repurchase by the Company or forfeiture to the Company of the undersigned's Securities upon termination of the undersigned's employment or service with the Company, *provided* that if the undersigned is required to make a filing under the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock during the Restricted Period, the undersigned shall include a statement that such transfer is being made pursuant to the circumstances described in this clause (b)(x);
- (c) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, *provided* that (i) such plan does not provide for the transfer of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period; or
- (d) dispositions or transfers to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (a) and (b) above;

provided that in the case of any transfer or distribution pursuant to clause (b), (i) each transferee, recipient, donee, distributee, trustee or beneficiary shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of Common Stock, shall be required or shall be voluntarily made during the Restricted Period except as otherwise provided in clauses (b) (vi), (b)(vii), and (b)(x).

In addition, the undersigned agrees that, without the prior written consent of the Representatives, on behalf of the Underwriters, it will not, during the Restricted Period, make any demand for or exercise any right with respect to, the registration of any Securities. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's shares of Common Stock except in compliance with the foregoing restrictions.

The undersigned understands that, if (a) the Underwriting Agreement does not become effective by December 31, 2019, (b) the Company informs the undersigned that the Board of Directors has determined not to proceed with the Public Offering prior to the execution of the Underwriting Agreement or the registration statement filed with the U.S.

Securities and Exchange Commission in connection with the Public Offering is withdrawn, (c) a Representative informs the Company that the Representatives have determined not to proceed with the Public Offering prior to the execution of the Underwriting Agreement, or if (d) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities, this agreement shall terminate and the undersigned shall be released from all obligations hereunder.

The undersigned understands that the Company and the Underwriters are relying upon this agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns. This letter agreement and any claim, controversy or dispute arising under or related to this letter agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof.

[Signature Page Follows]

made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.		
•	Very truly yours,	
Ō	(Name)	
ō	(Address)	
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Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be



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November 12, 2019

Board of Directors NextCure, Inc. 9000 Virginia Manor Road Suite 200 Beltsville, Maryland 20705

## Ladies and Gentlemen:

We are acting as counsel to NextCure, Inc., a Delaware corporation (the "Company"), in connection with its registration statement on Form S-1, as amended, and any Rule 462(b) registration statement (collectively, the "Registration Statement"), filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act") relating to the proposed public offering of up to 3,680,000 shares of the common stock, par value \$0.001 per share (the "Common Stock") of the Company (such shares together with any additional shares of Common Stock that may be sold pursuant to Rule 462(b) under the Act, the "Shares"), all of which shares are to be sold by the Company. This opinion letter is furnished to you at your request to enable you to fulfill the requirements of Item 601(b)(5) of Regulation S-K, 17 C.F.R. § 229.601(b)(5), in connection with the Registration Statement.

For purposes of this opinion letter, we have examined copies of such agreements, instruments and documents as we have deemed an appropriate basis on which to render the opinions hereinafter expressed. In our examination of the aforesaid documents, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the accuracy and completeness of all documents submitted to us, the authenticity of all original documents, and the conformity to authentic original documents of all documents submitted to us as copies (including pdfs). As to all matters of fact, we have relied on the representations and statements of fact made in the documents so reviewed, and we have not independently established the facts so relied on. This opinion letter is given, and all statements herein are made, in the context of the foregoing.

This opinion letter is based as to matters of law solely on the Delaware General Corporation Law, as amended. We express no opinion herein as to any other statutes, rules or regulations.

Based upon, subject to and limited by the foregoing, we are of the opinion that following (i) execution and delivery by the Company of the Underwriting Agreement, (ii) effectiveness of the Registration Statement, (iii) issuance of the Shares pursuant to the terms of the Underwriting Agreement, and (iv) receipt by the Company of the consideration for the Shares specified in the resolutions of the Board of Directors and the Pricing Committee of the Board of Directors, the Shares will be validly issued, fully paid, and nonassessable.

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This opinion letter has been prepared for use in connection with the Registration Statement. We assume no obligation to advise of any changes in the foregoing subsequent to the effective date of the Registration Statement.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the Registration Statement and to the reference to this firm under the caption "Legal Matters" in the prospectus constituting a part of the Registration Statement. In giving this consent, we do not thereby admit that we are an "expert" within the meaning of the Act.

Very truly yours,

/s/ HOGAN LOVELLS US LLP

HOGAN LOVELLS US LLP

# Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 5, 2019 (except for the fourth paragraph of Note 16, as to which the date is May 3, 2019) in the Registration Statement (Form S-1) and related Prospectus of NextCure, Inc. for the registration of 3,680,000 shares of its common stock.

/s/ Ernst & Young LLP

Tysons, VA November 12, 2019