

**UNITED STATES
 SECURITIES AND EXCHANGE COMMISSION**
 Washington, D.C. 20549

**FORM S-1
 REGISTRATION STATEMENT
 UNDER
 THE SECURITIES ACT OF 1933**

Annexon, Inc.

(Exact name of registrant as specified in its charter)

Delaware
 (State or other jurisdiction of
 incorporation or organization)

2834
 (Primary Standard Industrial
 Classification Code Number)

27-5414423
 (I.R.S. Employer
 Identification Number)

**180 Kimball Way, Suite 200
 South San Francisco, California 94080
 (650) 822-5500**

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

**Douglas Love, Esq.
 President and Chief Executive Officer
 Annexon, Inc.
 180 Kimball Way, Suite 200
 South San Francisco, California 94080
 (650) 822-5500**

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

Copies to:

**Kathleen M. Wells
 Brian J. Cuneo
 Latham & Watkins LLP
 140 Scott Drive
 Menlo Park, California 94025
 (650) 328-4600**

**Charles S. Kim
 Kristin VanderPas
 Michael Tenta
 David Peinsipp
 Cooley LLP
 4401 Eastgate Mall
 San Diego, California 92121
 (858) 550-6000**

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.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)	Amount of registration fee(2)
Common Stock, \$0.001 par value per share	\$	\$

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares of common stock that the underwriters have the option to purchase.
 (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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 U.S. Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED _____, 2020

PRELIMINARY PROSPECTUS

Shares



Common Stock

This is an initial public offering of shares of common stock of Annexon, Inc. We are offering _____ shares of our common stock. We currently expect the initial public offering price to be between \$ _____ and \$ _____ per share of common stock.

Prior to this offering, there has been no public market for our common stock. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "ANNX."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per Share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions(1)	\$ _____	\$ _____
Proceeds to Annexon, Inc., before expenses	\$ _____	\$ _____

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page 12 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities nor passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

We have granted the underwriters the option for a period of 30 days to purchase up to an additional _____ shares from us at the initial price to the public less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on _____, 2020.

J.P. Morgan

BofA Securities

Cowen

Prospectus dated _____, 2020.

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“Annexon,” “Annexon Biosciences,” the Annexon logo and other trademarks, trade names or service marks of Annexon, Inc. appearing in this prospectus are the property of Annexon, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus. You should carefully consider, among other things, the sections titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms “Annexon,” the “company,” “we,” “us,” “our” and similar references in this prospectus refer to Annexon, Inc. and its consolidated subsidiary.

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, eye and brain. Our pipeline is based on our platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Evidence suggests that potent and selective inhibition of C1q can prevent tissue damage triggered in antibody-mediated autoimmune disease and preserve loss of functioning synapses associated with cognitive and functional decline in complement-mediated neurodegeneration. Our upstream complement approach targeting C1q acts as an “on/off switch” designed to block all downstream components of the classical complement pathway that lead to excess inflammation, tissue damage and patient disability in a host of complement-mediated disorders, while preserving the normal immune function of the lectin and alternative complement pathways involved in the clearance of pathogens and damaged cells.

Our pipeline of product candidates is designed to block the activity of C1q and the entire classical complement pathway in a broad set of complement-mediated diseases. Our first product candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune and neurodegenerative disorders. Our second product candidate, ANX007, is an antigen-binding fragment, or Fab, formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. We are also developing ANX009, an investigational, subcutaneous formulation designed for the treatment of systemic autoimmune diseases. We have completed Phase 1b safety and dose-ranging clinical trials for ANX005 and ANX007 in patients with Guillain-Barré Syndrome, or GBS, and glaucoma, respectively. While the trials were not statistically powered for significance on the efficacy measures, both molecules were well-tolerated and showed full inhibition of C1q and the classical complement pathway.

Based on learnings from our initial trials, we are advancing our current programs while evaluating additional orphan and large market indications. We are also developing novel product candidates designed to inhibit C1q and other components of the early classical complement cascade with the goal of further broadening our portfolio. Finally, we are leveraging our disciplined development strategy in early clinical trials utilizing established biomarkers in an effort to enhance patient selection, measure target engagement and assess our product candidates’ potential to meaningfully impact the disease process and improve the probability of technical success over shorter development timelines.

We hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates, which allows us to strategically maximize value from our product portfolio over time. Our patent portfolio includes patent protection for our upstream complement platform and each of our product candidates.

The complement system is an integral component of the immune system that consists of many circulating and locally-produced molecules. This system evolved to enhance, or complement, other components of the adaptive and innate immune systems. The complement system rapidly responds to pathogens, damaged cells and unwanted tissue components to facilitate their removal by the immune system.

There are three main complement pathways—the classical, lectin and alternative pathways. Each pathway is initiated by different molecules that respond to distinct triggers. The classical pathway is initiated by C1q, which recognizes antibody complexes, specific pathogens, damaged cells or unwanted cellular components. While the lectin and alternative pathways are initiated by distinct molecules, all three pathways converge downstream on common pathway components known as C3 and C5. Specific activated components of the complement cascade, triggered by any of the pathways, have important immune functions that contribute to three key outcomes involving immune cell recruitment and inflammation, directed immune cell attack and membrane damage.

The classical complement cascade has a well-established role in augmenting antibody function within the immune system. C1q recognizes antibodies bound to pathogens or cells and activates the classical pathway to trigger their removal and clearance by the immune system. C1q can also directly recognize pathogens, damaged cells or unwanted cellular components leading to similar downstream clearance. A more recent finding made by the laboratory of the late Dr. Ben Barres, our scientific founder, is that C1q also directly interacts with neuronal connections, or synapses, during early development. Recognition of weaker synapses by C1q triggers the classical complement cascade and directs immune cells to “prune” the synapses away from neurons, thereby reinforcing stronger synapses to establish appropriate neuronal connections.

Because of its central role in immune function, aberrant activation of C1q and the classical complement cascade can lead to damage of healthy tissue and destruction of functioning synapses. We are focused on two distinct disease processes involving C1q as a key mediator of tissue damage: antibody-mediated autoimmune disease and complement-mediated neurodegeneration. To our knowledge, our two clinical-stage product candidates, ANX005 and ANX007, are the first clinical-stage product candidates designed to inhibit C1q and the entire classical complement pathway. By inducing full inhibition of C1q and the classical cascade, we seek to block upstream tissue-damaging components of the classical pathway as well as the downstream membrane attack complex, while leaving the lectin and alternative pathways intact to perform their normal immune functions.

We believe our approach has broad utility for the treatment of antibody-mediated autoimmune disease and complement-mediated neurodegeneration, in which full inhibition of the entire classical complement cascade may be beneficial. Our initial indications represent our beachhead within both disease areas, and we will selectively pursue both orphan and larger patient population diseases with clear biological evidence of classical complement activation. We are also developing novel product candidates targeting C1q and additional components of the classical complement cascade, and will utilize different drug modalities to target these components.

We are deploying a disciplined, biomarker-driven development strategy designed to establish confidence that each of our product candidates is engaging the specific target at a well-tolerated therapeutic dose in the intended patient tissue. We design small, early-stage clinical trials to rigorously evaluate the product candidate using target engagement and pharmacodynamic biomarkers. We are utilizing sensitive, specific assays for C1q and downstream classical complement components to evaluate target engagement in patient tissues and employ biomarkers, such as neurofilament light chain, or NfL, to provide proof-of-concept in small patient trials. We believe that this development strategy allows us to make rational decisions regarding our therapeutic pipeline, increasing the probability of technical success over shorter development timelines for product candidates we advance into later stage trials.

Annexon was co-founded by Dr. Ben Barres, former member of the National Academy of Sciences, Chair of Neurobiology at Stanford University and a pioneer in complement-mediated neurodegeneration, and Dr. Arnon Rosenthal, a world-renowned scientist and industry executive. We have assembled a seasoned and accomplished management team that has been involved in the development, approval and commercialization of numerous marketed drugs, and has been studying the complement pathway and autoimmune and neurodegenerative disorders for decades. Our team is further supported by an experienced scientific advisory board and leading

healthcare investors that share our commitment to advancing transformative medicines for patients suffering from debilitating autoimmune and neurodegenerative diseases. Our key investors include Adage, Bain Capital Life Sciences, Blackstone (Clarus), New Enterprise Associates, Novartis Venture Fund, Satter Investment Management and Surveyor (Citadel).

Our Pipeline

Our pipeline is focused on antibody-mediated autoimmune and complement-mediated neurodegenerative disorders for which there is significant unmet medical need. Our product candidates are summarized below:

Therapy	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Status
AUTOIMMUNE DISEASES						
ANX005 (IV)	Guillain-Barré Syndrome (GBS) [†]					<ul style="list-style-type: none"> ✓ Ph 1b complete ✓ Initiated DDI • Initiate Ph 2 in H1 2020
ANX005 (IV)	Warm Autoimmune Hemolytic Anemia (wAIHA) [*]					<ul style="list-style-type: none"> • Initiate Ph 2 in 2020
ANX009 (SubQ)	Autoantibody-mediated Diseases					<ul style="list-style-type: none"> • Initiate FIH trial in 2020
NEURODEGENERATIVE DISEASES						
ANX005 (IV)	Huntington's Disease (HD) [*]					<ul style="list-style-type: none"> • Initiate Ph 2a in H1 2020
ANX005 (IV)	Amyotrophic Lateral Sclerosis (ALS) [*]					<ul style="list-style-type: none"> • Initiate Ph 2a in 2020
ANX007 (IVT)	Glaucoma [†] / Geographic Atrophy (GA) [*]					<ul style="list-style-type: none"> ✓ Ph 1b complete • Planning Ph 2 in 2020

* Following the filing and clearance of the applicable investigational new drug applications, we intend to initiate Phase 2 clinical trials in the follow-on disease indications.
 † We have filed investigational new drug applications for these indications.

Our first clinical-stage product candidate is ANX005, an investigational monoclonal antibody designed to block C1q and activation of the classical complement cascade. For GBS, ANX005 is designed to act early in the disease course to prevent nerve damage and irreversible neurological disability in GBS patients. In the Phase 1b dose-ranging trial in GBS patients, ANX005 was well-tolerated and resulted in full and prolonged C1q engagement and classical cascade inhibition in the blood and cerebrospinal fluid, or CSF. While our Phase 1b trial was not powered to show statistical significance, we did observe statistically significant results in certain, but not all, of the key GBS outcome measures evaluated. Patients treated with ANX005 also showed positive numerical trends across key GBS outcome measures, and a significant reduction in NFL, a well-accepted marker of nerve damage in neurodegenerative disease that has been shown to correlate with disease severity and clinical outcomes. GBS is a rare, acute, antibody-mediated autoimmune disease impacting the peripheral nervous system. There are currently no approved therapies for GBS in the United States, but intravenous immunoglobulin, or IVIg, and plasma exchange are the current standard of care in the Western world and parts of Asia.

We have initiated a Phase 1b drug-drug interaction, or DDI, trial, to assess any potential pharmacokinetic, or PK, interaction between ANX005 and co-administered IVIg, to evaluate the safety of this combination in GBS patients and to enable dose selection for a Phase 3 trial of this combination. This trial is being conducted in the United States, Europe and Bangladesh. Any objective responses observed in this trial will be in patients receiving ANX005 together with IVIg. The trial is not powered to show a statistically significant efficacious outcome with the combined administration of ANX005 and IVIg and will provide no evidence of the efficacy of ANX005 as a monotherapy. We anticipate that the results from the DDI trial will enable a global Phase 3 pivotal trial of ANX005 in combination with IVIg in GBS patients.

In addition, we intend to advance ANX005 into a Phase 2 monotherapy trial in GBS patients in the first half of 2020. The placebo-controlled Phase 2 monotherapy trial will be conducted in Bangladesh and will evaluate the efficacy of ANX005 in improving disability in GBS patients. ANX005 has received both Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration, or FDA, for the treatment of GBS.

Beyond GBS, we also intend to study ANX005 in patients with warm autoimmune hemolytic anemia, or wAIHA, an antibody-mediated autoimmune disease characterized by the premature destruction of red blood cells. The classical complement pathway plays an important role in wAIHA through the removal of red blood cells labeled by activated complement components in the spleen or liver (extra-vascular hemolysis) and less common destruction of red blood cells in the blood vessels by the classical complement generated membrane attack complex (intravascular hemolysis). We plan to initiate a Phase 2 trial in patients with the primary diagnosis of wAIHA in 2020. With regard to complement-mediated neurodegeneration, we intend to study ANX005 in patients with Huntington's disease, or HD, as well as patients with amyotrophic lateral sclerosis, or ALS—two neurodegenerative disorders where aberrant classical complement activation has been shown to be associated with synapse loss, elevated levels of NfL and disease progression. We plan to initiate Phase 2a trials in patients with HD in the first half of 2020 and in patients with ALS in 2020 to assess ANX005's safety, tolerability, target engagement and impact on disease-related biomarkers such as NfL.

Our second clinical-stage product candidate is ANX007, an investigational C1q Fab designed for intravitreal administration in patients with complement-mediated neurodegenerative ophthalmic disorders. Consistent with the results we observed in preclinical studies, in the Phase 1b trial with intravitreal administration in glaucoma patients, ANX007 was well-tolerated and showed full target engagement and inhibition of C1q in the eye for at least four weeks. We believe inhibition of C1q may provide neuroprotective benefit by preventing the aberrant loss of functioning synapses in the retina in a variety of ophthalmic disorders, including glaucoma and geographic atrophy, or GA. Based on a range of considerations, including preclinical data, clinical results observed to date, proximate clinical validation and an established, objective clinical and regulatory path, we are planning a Phase 2 trial of ANX007 in patients with glaucoma or GA in 2020 with the goal of protecting against the loss of photoreceptor neurons in a well-defined patient population.

Our preclinical pipeline includes ANX009, an investigational C1q Fab designed for subcutaneous delivery. We are developing ANX009 to enable chronic dosing for patients with antibody-mediated autoimmune disorders where anti-C1q may have a disease-modifying effect and where we can utilize our targeted biomarker-driven approach. These disorders may include autoimmune hemolytic anemias and a subset of lupus nephritis patients who are selected for pathogenic anti-C1q antibodies, or PACA, and who have a high risk of renal flare. We intend to advance ANX009 through investigational new drug, or IND, enabling studies, select our initial lead autoimmune disease indication and commence a first-in-human, or FIH, clinical trial in healthy volunteers in 2020.

Our Strategy

Our goal is to develop disease-modifying medicines for patients suffering from classical complement-mediated diseases. Key elements of our strategy include:

- ***Leveraging our distinct approach of inhibiting C1q and aberrant upstream classical complement activity to address a broad range of well characterized classical complement-mediated diseases.*** By inhibiting C1q and the early classical cascade, we believe our product candidates are uniquely designed to address a wide range of antibody-mediated autoimmune diseases as well as complement-mediated neurodegenerative disorders. We believe full classical complement inhibition may result in clinical benefit by blocking aberrant upstream immune cell activation in our targeted indications and potentially provide safety advantages by leaving the lectin and alternative pathways intact to perform their normal immune functions.

- **Advancing ANX005 through clinical development in multiple autoimmune and neurodegenerative indications of high unmet need.** Our Phase 1b trial in patients with GBS demonstrated full target engagement of C1q in serum and the CSF, as well as a significant reduction in NfL, a well-accepted biomarker shown to be elevated in patients with GBS, HD and ALS and correlated with disease severity and clinical course and outcomes. We intend to advance ANX005 into a Phase 2 monotherapy trial in patients with GBS in the first half of 2020, and into Phase 2a trials in patients with HD in the first half of 2020 and in patients with ALS in 2020. We also intend to advance ANX005 into a Phase 2 trial in patients with wAIHA in 2020.
- **Evaluating ANX007 as an agent for neuroprotective benefit in ophthalmic indications.** We are developing ANX007 in neurodegenerative ophthalmic indications, such as glaucoma and GA. ANX007 reduced retinal damage in animal models of glaucoma and GA. In our Phase 1b trial in glaucoma patients, intravitreal administration of ANX007 resulted in full target engagement of C1q at both low and high doses. Based on this clinical dosing data, our preclinical data in glaucoma and GA, and proximate clinical validation from a downstream complement approach, we believe that ANX007 may provide neuroprotective benefit in patients with these and other complement-mediated ophthalmic disorders. We are planning a Phase 2 trial of ANX007 in patients with glaucoma or GA in 2020.
- **Expanding our autoimmune and neurodegenerative portfolios informed by data from our beachhead indications.** Our initial indications represent our beachhead within antibody-mediated autoimmune and complement-mediated neurodegenerative diseases. We intend to leverage learnings from our initial indications to inform selection of additional orphan and larger patient populations involving related biological mechanisms. In our autoimmune portfolio, potential indications include antibody-mediated autoimmune disorders such as wAIHA, Cold Agglutinin Disease, or CAD, and lupus nephritis, (specifically in lupus nephritis patients with endogenous PACA). In our neurodegenerative portfolio, potential indications include complement-mediated neurodegeneration disorders in the eye and brain such as glaucoma, GA, HD, ALS and Alzheimer's disease.
- **Developing additional product candidates that are designed to inhibit activation of the classical complement cascade.** We have secured broad intellectual property protection for our upstream complement platform and intend to leverage our intellectual property and know-how to protect and enhance our leading position in developing novel therapeutics that target the classical complement cascade. We are developing product candidates, such as ANX009, to modulate the classical pathway with the potential to become tailored therapeutics for a large range of indications using different molecular modalities, dosing regimens and tissue localization strategies.
- **Maximizing the value of our product candidates.** We currently hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates. We intend to pursue independent development and commercialization in select indications and markets that we can address with a focused sales and marketing organization. We may opportunistically explore licensing agreements, collaborations or partnerships to develop our product candidates in larger market indications where we could accelerate development utilizing the resources of larger biopharmaceutical companies.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we

anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.
- Our business is heavily dependent on the successful development, regulatory approval and commercialization of our two clinical-stage product candidates, ANX005 and ANX007, each of which is in early stages of clinical development.
- Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- Our product candidates may cause undesirable and unforeseen side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- We rely on third-party suppliers to manufacture our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.
- Our current and any future product candidates or products could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our products.
- We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

Our Corporate Information

We were incorporated under the laws of the State of Delaware on March 3, 2011. Our principal executive offices are located at 180 Kimball Way, Suite 200, South San Francisco, California 94080, and our telephone number is (650) 822-5500. Our corporate website address is www.annexonbio.com. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this prospectus or the registration statement of which it forms a part. We have included our website in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by

non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- We will present in this prospectus only two years of audited consolidated financial statements, plus unaudited condensed consolidated financial statements for any interim period, and related management's discussion and analysis of financial condition and results of operations;
- We will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- We will provide less extensive disclosure about our executive compensation arrangements; and
- We will not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

Accordingly, the information contained herein may be different than the information you receive from our competitors that are public companies or other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. 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 avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

The Offering

Common stock offered by us	shares.
Option to purchase additional shares	The underwriters have been granted an option to purchase up to additional shares of common stock from us at any time within 30 days from the date of this prospectus.
Common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund: the Phase 2 and Phase 1b drug-drug interaction clinical trials of ANX005 in GBS and Good Manufacturing Practices, or GMP, manufacturing activities for ANX005; the Phase 2a clinical trials of ANX005 in HD and ALS and the Phase 2 clinical trial of ANX005 in wAIHA; the preparation for Phase 2 clinical development of ANX007 in glaucoma or GA and GMP manufacturing activities for ANX007; and advancement of our earlier-stage programs, including ANX009, and certain other research and development activities; and the remainder for working capital and other general corporate purposes. See the section titled “Use of Proceeds” for additional information.</p>
Risk factors	You should read the section titled “Risk Factors” for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	“ANNX”

The number of shares of our common stock to be outstanding after this offering is based on 115,569,451 shares of common stock as of September 30, 2019, and excludes:

- 18,336,476 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2019, with a weighted-average exercise price of \$0.54 per share;
- shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to September 30, 2019, with a weighted-average exercise price of \$ per share;
- shares of our common stock reserved for future issuance under our 2020 Incentive Award Plan, or the 2020 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2020 Plan; and
- shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan, or the ESPP, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering and the adoption of our amended and restated bylaws immediately prior to the completion of this offering;
- the conversion of all of our outstanding shares of redeemable convertible preferred stock into 111,748,065 shares of our common stock immediately prior to the completion of this offering;
- a -for- reverse stock split of our common stock and redeemable convertible preferred stock effected on , 2020;
- no exercise of the outstanding options; and
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock.

Summary Consolidated Financial Data

The following tables set forth our summary consolidated statements of operations and consolidated balance sheet data. The summary consolidated statements of operations data for the years ended December 31, 2017 and 2018 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The summary consolidated statements of operations data for the nine months ended September 30, 2018 and 2019 and the summary consolidated balance sheet data as of September 30, 2019 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2019. You should read the following summary consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018	2019
	(unaudited)			
	(in thousands, except share and per share data)			
Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 17,853	\$ 15,528	\$ 11,591	\$ 17,729
General and administrative	2,624	3,619	2,576	5,660
Total operating expenses	<u>20,477</u>	<u>19,147</u>	<u>14,167</u>	<u>23,389</u>
Loss from operations	(20,477)	(19,147)	(14,167)	(23,389)
Gain (loss) on remeasurement of redeemable convertible preferred stock liability	—	260	—	(5,670)
Other income, net	1,770	584	525	821
Net loss before taxes	(18,707)	(18,303)	(13,642)	(28,238)
Provision for income taxes	1	1	1	3
Net loss	(18,708)	(18,304)	(13,643)	(28,241)
Accretion on redeemable convertible preferred stock	87	176	75	815
Net loss attributable to common stockholders	<u>\$ (18,795)</u>	<u>\$ (18,480)</u>	<u>\$ (13,718)</u>	<u>\$ (29,056)</u>
Net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>\$ (6.16)</u>	<u>\$ (5.21)</u>	<u>\$ (3.96)</u>	<u>\$ (7.61)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>3,051,792</u>	<u>3,548,177</u>	<u>3,460,382</u>	<u>3,818,365</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u>\$</u>		<u>\$</u>
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾				

(1) See Notes 2 and 11 to our audited consolidated financial statements and Notes 2 and 10 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for explanations of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

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	As of September 30, 2019		
	Actual	Pro Forma(1) (unaudited) (in thousands)	Pro Forma As Adjusted(2) (3)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 53,662	\$	\$
Working capital(4)	49,578		
Total assets	58,600		
Redeemable convertible preferred stock	143,704		
Accumulated deficit	(93,638)		
Total stockholders' (deficit) equity	(91,759)		
(1)	The pro forma column reflects: (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock into 111,748,065 shares of our common stock, which will occur immediately prior to the completion of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation in Delaware, which will be in effect immediately prior to the completion of this offering.		
(2)	The pro forma as adjusted column reflects: (i) the pro forma adjustments set forth in footnote (1) above and (ii) the sale of _____ shares of our common stock in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.		
(3)	The pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming the assumed initial public offering price of \$ _____ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.		
(4)	We define working capital as current assets less current liabilities. See our unaudited interim condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.		

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may 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 Limited Operating History, Financial Condition and Capital Requirements

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have no products approved for commercial sale and have not generated any revenue from sales of our product candidates and have incurred losses in each year since our inception in March 2011. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical, biopharmaceutical and biotechnology industry.

We have had significant operating losses since our inception. Our net loss for the years ended December 31, 2017 and 2018 was approximately \$18.7 million and \$18.3 million, respectively, and \$13.6 million and \$28.2 million for the nine months ended September 30, 2018 and 2019, respectively. As of September 30, 2019, we had an accumulated deficit of approximately \$93.6 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. Our product candidates will require additional clinical development, and we intend to conduct additional research and development activities to discover and develop new product candidates, including conducting preclinical studies and clinical trials, all of which will require substantial additional funds. We will continue to expend significant resources for the foreseeable future in connection with these activities. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or any future product candidates.

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As of September 30, 2019, we had capital resources consisting of cash and cash equivalents of approximately \$53.7 million. We expect our existing capital resources, together with the proceeds from this offering, will fund our planned operating expenses for at least the next months following the date of this offering. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned through public or private equity offerings or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to our stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates or any other future products candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our planned Phase 2 clinical trials of ANX005 and ANX007;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to our current or any future license or collaboration agreements;
- the cost of manufacturing our product candidates or any future product candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities of our product candidates, if approved for sale, including marketing, sales and distribution costs;
- our ability to establish strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or any future product candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or any future product candidate, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

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We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on developing product candidates to address classical complement-mediated autoimmune and neurodegenerative diseases. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between aggressively advancing our two clinical-stage product candidates, ANX005 and ANX007, in identified indications and exploring additional indications or mechanisms as well as developing future product candidates. However, due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and the amount of resources to allocate to each such product candidate.

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, any decision to delay, terminate or collaborate with third parties in respect of 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 programs or product candidates or misread trends in the autoimmune or neurodegenerative or pharmaceutical, biopharmaceutical or biotechnology 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.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Risks Related to Our Business

Our business is heavily dependent on the successful development, regulatory approval and commercialization of our two clinical-stage product candidates, ANX005 and ANX007, each of which is in early stages of clinical development.

We have no products approved for sale, and our two clinical-stage product candidates are in early stages of clinical development. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, the advancement of our current clinical-stage product candidates, ANX005 and ANX007. However, given our stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

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While inhibition of the complement pathway has been validated as a therapeutic approach, C1q inhibition is a novel therapeutic approach, which exposes us to certain risks. For example, we may discover unforeseen safety events or that our product candidates do not possess certain properties required for therapeutic effectiveness, or that even if found to be effective in one type of disease, a product candidate, or the therapeutic approach, is not effective in other diseases. In addition, given the novel nature of this therapeutic approach, designing preclinical studies and clinical trials to demonstrate the effect of the product candidates is complex and exposes us to risks, including that our biomarker-driven approach may not translate into therapeutic effectiveness.

In the future, we may also become dependent on other product candidates that we may develop or acquire. The clinical and commercial success of our product candidates and future product candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete an investigational new drug application, or IND, enabling studies and successfully submit INDs or comparable applications;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the U.S. Food and Drug Administration, or FDA, or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;

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- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement 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 product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

We are at an early stage of clinical development of our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our current and future product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates will require significant additional clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization and significant marketing efforts before we generate any revenue from

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product sales, if at all. Any clinical studies that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

The FDA or other regulatory agencies may not agree with our clinical development plan and require that we conduct additional clinical trials to support our regulatory submissions. We have not yet conducted an end of Phase 2 meeting with the FDA to discuss the registration pathway for ANX005, and our current clinical development plans for ANX005 in Guillain-Barre Syndrome, or GBS, may change as a result of future interactions with the FDA. For example, the FDA may require that we conduct more than one pivotal trial in order to gain approval in GBS. Furthermore, any approval of ANX005 for GBS may be limited to ANX005 in combination with the existing standard of care. While not approved for use in GBS in the United States due to differing levels of efficacy in GBS patients, IVIg has developed as the standard of care in the Western world and parts of Asia for patients with GBS and has been shown to be a reasonably effective treatment in some GBS patients. The trials we intend to conduct, including a planned Phase 3 in the United States and major markets, are designed to generate proof-of-concept data in GBS patients utilizing a combination of ANX005 and IVIg.

If any of our product candidates successfully completes clinical trials, we plan to seek regulatory approval to market our product candidates in the United States, the European Union and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. We may also rely on collaborators or partners to conduct the required activities to support an application for regulatory approval and to seek approval for one or more of our product candidates. We cannot be sure that any such collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we or any future collaborators or partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Any approval we may obtain could be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND or a clinical trial application, or CTA, will result in the FDA or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if

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these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- identifying, recruiting and training suitable clinical investigators;
- obtaining institutional review board, or IRB, approval at each trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, or equivalent foreign application or amendment;
- new safety findings that present unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical trial operations or study sites;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidates for use in preclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;

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- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates or such requirements may not be as we anticipate; and
- any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs and managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks.

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 preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to

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generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations 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. If one or more of our product candidates proves to be ineffective, unsafe or commercially unviable, our business, financial condition, results of operations and prospects may be materially and adversely affected.

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

We may not be able to initiate or continue clinical trials on a timely basis or at all for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. The 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 study until its conclusion. 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 severity and difficulty of diagnosing the disease under investigation;
- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the existing body of safety and efficacy data with respect to the study drug and safety concerns;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out before completion of the trial;
- ability to monitor patients adequately during and after treatment;
- availability and efficacy of approved medications or therapies, or other clinical trials, for the disease or condition under investigation;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and 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 being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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Our product candidates may cause undesirable and unforeseen side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. 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 materially and adversely affect our business, financial condition, results of operations and prospects.

In addition, early clinical trials may only include a limited number of subjects and limited duration of exposure to our product candidates. In particular, we are pursuing a novel approach to inhibiting upstream molecules of the classical complement pathway, primarily C1q, and as a result, our product candidates may cause unforeseen safety events when evaluated in larger patient populations. Further, clinical trials 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 and unforeseen side effects caused by such product, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;
- 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, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and

adversely affect our results of operations and business. In addition, if one or more of our product candidates prove to be unsafe, our business, financial condition, results of operations and prospects may be materially and adversely affected.

Interim “top-line” and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim “top-line” or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publish such data. As a result, the “top-line” results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete 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. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

Clinical trials of ANX005 in combination with IVIg in patients with GBS will provide no evidence of the efficacy of ANX005.

While not approved for use in GBS in the United States due to differing levels of efficacy in GBS patients, IVIg has developed as the standard of care in the Western world and parts of Asia for patients with GBS and has been shown to be a reasonably effective treatment in some but not all GBS patients. We have initiated a Phase 1b drug-drug, or DDI, interaction trial evaluating ANX005 with IVIg. This trial and the other trials we currently intend to conduct for ANX005 are designed to generate proof-of-concept data in GBS patients utilizing a combination of ANX005 and IVIg. The purpose of our DDI clinical trial is to assess safety and if there are any pharmacokinetic or pharmacodynamic effects on ANX005’s dosing profile by administering the two drug products in combination. Any objective responses observed in this trial will be in patients receiving ANX005 together with IVIg, and attribution of objective responses to the effects of ANX005 as a monotherapy will not be possible. Moreover, the trial is not powered to show a statistically significant efficacious outcome with the combined administration of ANX005 and IVIg. As a result, this clinical trial evaluating ANX005 with IVIg will provide no evidence of the efficacy of ANX005, which may not be fully understood by investors or market participants, potentially leading to negative effects on our stock price.

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Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

Even if one or more of our product candidates receive FDA or other regulatory approvals, the commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our product candidates may not be commercially successful. For a variety of reasons, including, among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans, insurers and other healthcare payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, if approved for commercial sale;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our products;
- the willingness of physicians, operators of clinics and patients to utilize or adopt our products as a solution;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

We have received Orphan Drug designation for ANX005 for the treatment of GBS, and we may seek Orphan Drug designation for certain future product candidates. We may be unable to obtain such designations or to maintain the benefits associated with Orphan Drug designation, including market exclusivity, which may cause any revenue from product sales to be reduced.

We have received Orphan Drug designation in the United States for ANX005 for the treatment of GBS. Although we may seek Orphan product designation for some or all of our other product candidates, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an Orphan Drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan Drug designation must be requested before submitting a biologics license application, or BLA. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants Orphan Drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants Orphan Drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with Orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. In the European Union, Orphan Drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the Orphan Drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable to not justify maintenance of market exclusivity.

Even if we obtain Orphan Drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain Orphan Drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective or makes a major contribution to patient care. Orphan Drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a Breakthrough Therapy designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

A Fast Track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA has granted Fast Track designation for ANX005 in GBS, and, in the future, we may seek Fast Track designation for other of our product candidates. If a drug or biologic, in our case, is intended for the treatment of a serious or life-threatening condition and the biologic demonstrates the potential to address unmet medical needs for this condition, the biologic sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Fast Track designation may not result in a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many biologics that have received Fast Track designation have failed to obtain approval.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. We and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. We may not promote our products "off-label" for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

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.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive 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 unable to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example,

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over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough certain FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We have conducted, and in the future plan to conduct, clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted clinical trials of our product candidates outside the United States, and plan to continue to do so in the future. For example, we conducted our Phase 1b clinical trial of ANX005 in Bangladesh. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, any comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) if necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

If the product candidates that we develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for our product candidates and adversely affect our business.

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or any future collaborators' ability to develop, manufacture, promote and sell product candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the European Union, or EU, and many other jurisdictions, we and any future collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or any future collaborators fail to comply with the regulatory requirements in international markets or to obtain all required marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and adversely affect our business.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application, or BLA, for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We rely on third-party suppliers to manufacture our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. The facilities used by our contract manufacturers 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 processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs. If our contract manufacturers 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 our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities 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.

We currently intend to supply our product candidates in all territories for our clinical development programs. We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our two clinical-stage product candidates involve several manufacturers that specialize in specific operations of

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the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product manufacturing. As a result, the supply chain for the manufacturing of our product candidates is complicated, and we expect the logistical challenges associated with our supply chain to grow more complex as our product candidates are further developed.

We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. We generally do not begin preclinical or clinical trials unless we believe we have access to a sufficient supply of a product candidate to complete such study. In addition, any significant delay in, or quality control problems with respect to, the supply of a product candidate, or the raw material components thereof, for an ongoing study could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates.

We have not yet engaged any manufacturers for the commercial supply of our product candidates. Although we intend to enter into such agreements prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our product candidates, we will have no other means of producing our product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

In addition, to manufacture our product candidates in the quantities which we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and we may need to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels or in adequate quantities, if at all, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved.

We rely on third parties in the conduct of all of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.

We currently do not have the ability to independently conduct preclinical studies or clinical trials that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements or good clinical practice, or GCP, requirements, respectively. The FDA and regulatory authorities in other jurisdictions require us to comply with GCP 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 GCP-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

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have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical trials play a significant role in the conduct of these studies 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 programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-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. 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 GLPs or GCPs, 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 business, 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.

If we are not successful in identifying, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued development and potential approval of our current product candidates, a key element of our strategy is to identify, develop and commercialize a portfolio of products that address classical complement-mediated autoimmune and neurodegenerative diseases. A component of our strategy is to evaluate our product candidates in multiple indications based, in part, on our evaluation of certain biomarkers in a disease area. For example, we intend to evaluate ANX005 in neurodegenerative diseases, including amyotrophic lateral sclerosis, or ALS, and Huntington's disease, or HD; however, we have not yet evaluated ANX005 in these patient populations and we may find that while we have seen promising results in one neurodegenerative disease, that effect is not replicated across other neurodegenerative or autoimmune diseases. Even if we successfully identify product candidates, we may still fail to yield product candidates for development and commercialization for many reasons, including the following:

- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians and patients.

We therefore cannot provide any assurance that we will be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunities may be limited.

We face significant competition in an environment of rapid technological and scientific change, and our product candidates, if approved, will face significant competition, which may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.

The pharmaceutical, biopharmaceutical and biotechnology industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical, biopharmaceutical and biotechnology companies, generic drug companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Mergers and acquisitions in the pharmaceutical, biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles. Furthermore, currently approved products could be discovered to have application for the intended indication of our product candidates, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, European Medicines Agency, or EMA, or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see the section of this prospectus captioned “Business—Competition.”

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. 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 and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations 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. Even if we obtain coverage for 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 product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical, biopharmaceutical and biotechnology products and services, and many third-party payors may refuse to provide coverage and

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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 cost of 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 amounts we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. 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 investment in the development of product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private 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 exists 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 will 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.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other foreign jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amounts that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and 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.

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We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

Prior to this offering, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the year ended December 31, 2018, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting. The material weakness that was identified related to an inadequate number of qualified personnel within our accounting function, which impacted our ability to perform effective reviews over non-routine transactions. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We are implementing measures designed to improve our internal control over financial reporting to address the underlying causes of this material weakness, including the hiring of accounting personnel and establishing new accounting and financial reporting procedures, policies and processes to have in place an appropriate level of internal control over financial reporting. While we intend to implement these measures to remediate this material weakness, we cannot predict the success of such measures or the outcome of our assessment of these measures at this time. If our steps are insufficient to successfully remediate the material weakness and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be materially and adversely affected. We can give no assurance that this implementation will remediate this deficiency in internal control or that additional material weaknesses in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations.

Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. For as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical, biopharmaceutical and biotechnology

products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

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

As of September 30, 2019, we had 20 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our two clinical-stage product candidates or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, particularly our President and Chief Executive Officer, Douglas Love, Esq., Executive Vice President and Chief Medical Officer, Sanjay Keswani, MBBS, BSc, FRCP, and Executive Vice President and Chief Scientific Officer, Ted Yednock, Ph.D., as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates or any future product candidates.

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

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we

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develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

If we are unable to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims, the commercialization of our current or any future product candidates we develop could be inhibited or prevented. We currently carry product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

While we have not entered into any collaboration agreements to date, we may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. For example, certain of the disease areas that we believe our product candidates address, including, among others, ophthalmic indications, require large, costly and later-stage clinical trials, which a collaboration partner may be better positioned to finance and/or conduct. In addition, a component of our strategy is to maximize the commercial value of our current and future product candidates, which may also strategically align with partnering commercial rights with partners that have larger and established sales organizations. To the extent that we decide to enter into collaboration agreements, we may face significant competition for appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to enter into collaboration agreements. The terms of collaborations or other arrangements that we may establish may not be favorable to us.

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The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and collaborators that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the

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foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which has experienced both severe earthquakes and the effects of wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and could materially and adversely affect our business, financial condition, results of operations and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Significant disruptions of information technology systems, breaches of data security and other incidents could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure 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. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of any future collaborators and our contractors, consultants, vendors and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, 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 lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to investigate, mitigate and remediate security incidents, breaches, disruptions, 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, negative publicity 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. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. Moreover, if a computer security breach affects our systems or results in the unauthorized access to or unauthorized use, disclosure, release or other processing of personally identifiable information or clinical trial data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws, and our reputation could be materially damaged. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions and civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

We and any future collaborators are subject to or affected by federal, state and foreign data protection laws and regulations which address privacy and data security. In the United States, numerous federal and state laws and regulations, including the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, which govern the collection, use, disclosure and protection of health-related and other personal information, may apply to our operations and the operations of any future collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and other privacy and data security laws. Depending on the facts and circumstances, we could be subject to significant administrative, civil and criminal penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Foreign data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information data subjects in the EU or the United Kingdom, or UK. The GDPR went into effect on May 25, 2018. Companies that must comply with the GDPR face increased compliance obligations and risk, including robust regulatory enforcement of data protection requirements as well as potential fines for noncompliance of up to €20 million or 4% of annual global revenue of the noncompliance company, whichever is greater. The GDPR imposes numerous requirements for the collection, use, storage and disclosure of personal information of EU or UK data subjects, including requirements relating to providing notice to and obtaining consent from data subjects, personal data breach notification, cross-border transfers of personal information, and honoring and providing for the rights of EU or UK individuals in relation to their personal information, including the right to access, correct and delete their data. In the United States, California recently enacted the California Consumer Privacy Act of 2018, or CCPA. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. A number of amendments are currently pending, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities

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and as a result may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

Moreover, clinical trial subjects about whom we or any of our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could materially and adversely affect our business, financial condition, results of operations and prospects.

Our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and any third-party manufacturers and suppliers are

subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

We cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, nor can we eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from hazardous materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Intellectual Property

Our current and any future product candidates or products could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our products.

Our commercial success depends on our ability to develop, manufacture and market our current and any future product candidates that may be approved for sale, and to use our proprietary technology without infringing the patents and other proprietary rights of third parties. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to suffer. We operate in an industry with extensive intellectual property litigation. As the pharmaceutical, biopharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated.

Whether merited or not, we may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including patents held by our competitors or by non-practicing entities. We may also face allegations that our employees have misappropriated the intellectual

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property rights of their former employers or other third parties. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether claims that we are infringing patents or other intellectual property rights have merit, the claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our products and features while we develop non-infringing substitutes, or may result in significant settlement costs. For example, litigation can involve substantial damages for infringement, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees. We may also be prohibited from selling or licensing our products unless the third party licenses rights to us, which it is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use or sale.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our product candidates, we have not conducted a freedom-to-operate search or analysis for any of our product candidates, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

In addition, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents), and publications in the scientific literature often lag behind actual discoveries. Therefore, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on whether the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention in the United States. The costs of patent litigation and other proceedings could be substantial, and it is possible that such efforts would be unsuccessful if it is determined that the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such invention.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. We may receive claims from third parties asserting infringement of their intellectual property rights. Future litigation may be necessary to establish our intellectual property rights or to defend ourselves by determining the scope, enforceability and validity of third-party intellectual property rights. There can be no assurance with respect to the outcome of any current or future litigation brought by or against us, and the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable, and outcomes are uncertain. Further, as the costs and outcome of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can. 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

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or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.

We have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will issue in a form that will provide adequate protection. The U.S. Patent and Trademark Office, or USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications, and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide us with protection for our products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of any legal actions we may take against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide protection and/or may not prove to be enforceable in actions against specific alleged infringers.

The market for pharmaceuticals and biopharmaceuticals is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and any future products for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with any future products. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use or sell products that are substantially the same as any future products we may sell without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market.

We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our currently pending or any future patent applications, and our issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us.

If we or any future collaborators we may have were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including obviousness or lack of novelty, enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a

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misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our product candidates or any future products that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have patents that dominate, block or are otherwise relevant to our technology. There may be prior public disclosures or other art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many international jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect the patents and patent applications of our licensors, our existing or future patents and patent applications and our ability to obtain additional patents in the future.

Patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business and financial condition. Any future changes in the patent laws of the United States, or even the possibility of such changes, may further increase these uncertainties and costs.

In addition, we have a number of international patents and patent applications, and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. The laws of some international jurisdictions may not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in obtaining, protecting and defending such rights in international jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in international jurisdictions, our business, financial condition, results of operations and prospects could be materially and adversely affected. Earlier patent filings in

certain international countries may also permit third parties to allege priority to certain technology in those countries.

Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing (including any patent term extension or adjustment filing), whether intentional or unintentional, may also result in the loss of patent rights important to our business. Certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect confidential information and 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. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products, and may in the future seek to enforce our patents or other rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products competitive to our products. In addition, we may need to defend our patents from third-party challenges, such as interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions or other patent proceedings. We may need to initiate infringement claims or litigation.

Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn materially and adversely affect our business, financial condition, results of operations and prospects, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court or other judicial body may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question or that stopping the other party would harm the public interest. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against

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us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings and litigation costs.

We license patent rights from third-party owners. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.

We are a party to licenses that give us rights to third-party intellectual property that are necessary or useful for our business, and we may enter into additional licenses in the future. Under these license agreements we are obligated to pay the licensor fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business.

If the licensor retains control of prosecution of the patents and patent applications licensed to us, we may have limited or no control over the manner in which the licensor chooses to prosecute or maintain its patents and patent applications and have limited or no right to continue to prosecute any patents or patent applications that the licensor elects to abandon.

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, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

We jointly own certain patent rights with third parties. Our ability to out-license these patent rights, or to prevent the third party from out-licensing these patent rights, may be limited in certain countries.

We jointly own certain patents and patent applications with third parties, and may jointly own patents and patent applications with third parties in the future. Unless we enter into an agreement with the joint owner, we will be subject to certain default rules pertaining to joint ownership. Certain countries require the consent of all joint owners to license jointly owned patents, and if we are unable to obtain such consent from the joint owner,

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we may not be able to license our rights under these patents and patent applications. In certain other countries, including the United States, the joint owner could license its rights under these patents and patent applications to another party without our consent and without any duty of accounting to us.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, any future collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and could even face litigation for infringing patents that we had regarded as ours. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and 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 not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions 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 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 any future products we may sell, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition with potential partners, physicians or patients in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeeded in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our future products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our commercial success abilities may be impacted.

Risks Related to Government Regulation

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We will have to comply with requirements concerning advertising and promotion for any future products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. We may not promote products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

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 any future 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.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from

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future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration 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.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

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

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as Orphan Drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

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- establishment of a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance and delaying the implementation of certain fees mandated by the Affordable Care Act. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the Affordable Care Act are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of prescription drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it 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 amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment

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amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations 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 or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or judicial action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If we choose to develop a small molecule product candidate and it obtains regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit a new drug application, or NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if we choose to develop a small molecule product candidate, and the product is approved, competitors could file ANDAs for generic versions of our small molecule drug products or 505(b)(2) NDAs that

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reference our small molecule drug products. If there are patents listed for our small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, without limitation:

- the U.S. federal civil and criminal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, 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 U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the HITECH and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;

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- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, 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 U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy, security and disposal of personal information and 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;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, 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; and
- similar data protection and healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal data, including the GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union and European Economic Area (including with regard to health data).

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, such as the provision of stock options to physicians who may influence the ordering, prescribing or use of our product candidates, if approved, as compensation for consulting services, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Changes in tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes

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could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Common Stock and this Offering

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock following this offering could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section of this prospectus and others such as:

- results from, and any delays in, our clinical trials for our two clinical-stage product candidates or any other future clinical development programs;
- announcements of regulatory approval or disapproval of our current or any future product candidates;
- failure or discontinuation of any of our research and development programs;
- the termination of any of our existing license agreements;
- announcements relating to any future licensing, collaboration or development agreements;

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- delays in the commercialization of our current or any future product candidates;
- public misperception regarding the use of our product candidates;
- acquisitions and sales of new products or product candidates, technologies or businesses;
- manufacturing and supply issues related to our product candidates for clinical trials or future product candidates for commercialization;
- quarterly variations in our results of operations or those of our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products or product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance;
- any major changes in our board of directors or management;
- new legislation or regulation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock.

An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.

Prior to this offering, there has been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained after this offering. We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other product candidates, businesses or technologies using our shares as consideration.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry

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analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an “emerging growth company,” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an “emerging growth company,” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We will incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that could materially and adversely affect our business, financial condition, results of operations and prospects.

We will incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Stock Market LLC and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on

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our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

After this offering, we will be subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we are unable to remediate our existing material weakness in our internal control over financial reporting, or we identify additional material weaknesses, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could materially and adversely affect our business, financial condition, results of operations and prospects, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend in part on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Market or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations and prospects.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate substantial dilution of approximately \$ per share, based on an assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover of this prospectus, and our pro forma as adjusted net tangible book value as of September 30, 2019. In addition, following this offering, purchasers in this offering will have contributed approximately % of the total gross consideration paid by stockholders to us to purchase shares of our common stock through September 30, 2019, but will own only approximately % of the shares of common stock outstanding immediately after this offering. Furthermore, if the underwriters exercise their option to purchase additional shares or outstanding options are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled "Dilution."

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred

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stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of November 30, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 87.9% of our voting stock and, upon the closing of this offering, that same group will hold approximately % of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options). Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based upon the number of shares outstanding as of September 30, 2019 (including the conversion of all of our shares of redeemable convertible preferred stock into 111,748,065 shares of our common stock), upon the closing of this offering, we will have outstanding a total of _____ shares of common stock, assuming no exercise of the underwriters' option to purchase additional shares. Of these shares, substantially all of the shares of our common stock sold in this offering (excluding any shares sold to our director or officers in the directed share program), plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. Based upon the number of shares outstanding as of September 30, 2019, after the lock-up agreements expire, up to approximately _____ additional shares of common stock will be eligible for sale in the public market, approximately _____ of which shares are held by directors, executive officers and other affiliates and will be subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, as of September 30, 2019, approximately 21,684,277 shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of approximately 111,748,065 shares of our common stock, or approximately % of our total outstanding shares of common stock, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the

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Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds of this offering, together with our existing cash and cash equivalents, to fund: the Phase 2 and Phase 1b drug-drug interaction clinical trials of ANX005 in GBS and GMP manufacturing activities for ANX005; the Phase 2a clinical trials of ANX005 in HD and ALS and the Phase 2 clinical trial of ANX005 in wAIHA; the preparation for Phase 2 clinical development of ANX007 in glaucoma or geographic atrophy and GMP manufacturing activities for ANX007; the advancement of our earlier-stage programs, including ANX009, and certain other research and development activities; and the remainder for working capital and other general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of this offering and/or subsequent shifts in our stock ownership (some of which are outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective immediately prior to the completion of this offering, will contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy, however occurring, including by an expansion of the board of directors, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including voting or other rights or preferences, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

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- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. For a description of our capital stock, see the section titled "Description of Capital Stock."

As a California-domiciled public company, we will be required to have at least one woman on our board of directors by the end of 2019 and two or three women on our board of directors by the end of 2021, depending on the size of our board at the time.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified individuals to our board of directors. As a public company headquartered in California, we will be required to have at least one woman on our board of directors by the end of 2019. By the end of 2021, we are required to have two or three women on our board of directors, depending on the size of our board of directors at the time. While we currently meet the requirement to have at least one woman on the board of directors, recruiting and retaining board members carries uncertainty, and failure to comply with this California requirement will result in financial penalties.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws to be effective immediately prior to the completion of this offering and our indemnification agreements that we have entered into with our directors and officers will provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

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- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain a directors' and officers' insurance policy, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may adversely impact our cash position.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and 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 certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive

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any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

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

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “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 other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates, if approved for commercial use;
- our clinical and regulatory development plans;
- our expectations with regard to the results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies;
- the timing of commencement of future nonclinical studies and clinical trials and research and development programs;
- our ability to acquire, discover, develop and advance product candidates into, and successfully complete, clinical trials;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and expectations;
- our intentions with respect to the commercialization of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business and product candidates, including additional indications for which we may pursue;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our anticipated use of proceeds from this offering;
- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing products.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to

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the section titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward- looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

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 the forward-looking statements in this prospectus by these cautionary statements.

MARKET AND INDUSTRY DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by approximately \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease, as applicable, the net proceeds to us by approximately \$ million, assuming the assumed initial public offering price of \$ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public markets. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$ million to \$ million to fund the Phase 2 and Phase 1b drug-drug interaction, or DDI, clinical trials of ANX005 in Guillain-Barré Syndrome, or GBS, and Good Manufacturing Practices, or GMP, manufacturing activities for ANX005;
- approximately \$ million to \$ million to fund the Phase 2a clinical trials of ANX005 in Huntington's disease, or HD, and amyotrophic lateral sclerosis, or ALS, and the Phase 2 clinical trial of ANX005 in warm autoimmune hemolytic anemia, or wAIHA;
- approximately \$ million to \$ million to fund the preparation for Phase 2 clinical development of ANX007 in glaucoma or geographic atrophy, or GA, and GMP manufacturing activities for ANX007;
- approximately \$ million to \$ million to advance our earlier-stage programs, including ANX009, and fund certain other research and development activities; and
- the remainder for working capital and other general corporate purposes.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months from the date of this offering. In particular, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will allow us to complete our planned DDI clinical trials and Phase 2 trial of ANX005 in GBS, complete our planned Phase 2a trials of ANX005 in both HD and ALS, and prepare for a Phase 2 trial of ANX007 in glaucoma or GA.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in the drug development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this

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offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of our preclinical studies and ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, the amount of cash obtained through any future collaborations and other factors described in the section titled “Risk Factors.”

The expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates. We expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaborations, and license and development agreements. We have based these estimates on assumptions that may prove to be incorrect, and we could expend our available capital resources at a rate greater than we currently expect.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

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

- an actual basis;
- a pro forma basis, to reflect: (i) the conversion of all of our outstanding shares of redeemable convertible preferred stock into 111,748,065 shares of our common stock, which will occur immediately prior to the completion of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation in Delaware, which will be in effect immediately prior to the completion of this offering; and
- a pro forma as adjusted basis, to reflect (i) the pro forma adjustments set forth above and (ii) the sale of _____ shares of our common stock in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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You should read this table together with the sections titled “Selected Consolidated Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. The pro forma information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

	As of September 30, 2019		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted(1)
	(in thousands, except share and per share amounts)		
Cash and cash equivalents	\$ 53,662	\$	\$
Redeemable convertible preferred stock, \$0.001 par value, per share; 119,155,472 shares authorized, 111,748,065 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 143,704		
Stockholders’ (deficit) equity:			
Preferred stock, \$0.001 par value, no shares authorized, issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—		
Common stock, \$0.001 par value per share; 150,000,000 shares authorized, 3,821,386 shares issued and outstanding, actual; shares authorized and 115,569,451 shares issued and outstanding, pro forma; shares authorized and shares issued and outstanding, pro forma as adjusted	4		
Additional paid-in capital	1,958		
Accumulated other comprehensive loss	(83)		
Accumulated deficit	(93,638)		
Total stockholders’ (deficit) equity	(91,759)		
Total capitalization	\$ 51,945	\$	\$

- (1) Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity and total capitalization by approximately \$ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity and total capitalization by approximately \$ million, assuming that the assumed initial public offering price of \$ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted, in the table above is based on 115,569,451 shares of common stock outstanding as of September 30, 2019 (including conversion of all of our outstanding shares of redeemable convertible preferred stock into 111,748,065 shares of our common stock), and excludes:

- 18,336,476 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2019, with a weighted-average exercise price of \$0.54 per share;
- shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to September 30, 2019, with a weighted-average exercise price of \$ per share;

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- shares of our common stock reserved for future issuance under the 2020 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2020 Plan; and
- shares of our common stock reserved for future issuance under the ESPP, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

DILUTION

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

Our historical net tangible book value (deficit) as of September 30, 2019 was \$(91.8) million, or \$(24.01) per share of our common stock. Our historical net tangible book value (deficit) represents our total tangible assets less total liabilities and redeemable convertible preferred stock. Historical net tangible book value (deficit) per share is our historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding as of September 30, 2019.

Our pro forma net tangible book value as of September 30, 2019 was \$ million, or \$ per share of our common stock, based on the total number of shares of our common stock outstanding as of September 30, 2019. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of outstanding shares of common stock, after giving effect to the conversion of all of the outstanding shares of redeemable convertible preferred stock into an aggregate of 111,748,065 shares of common stock.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2019 would have been \$ million, or \$ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of September 30, 2019	\$(24.01)
Pro forma increase in net tangible book value per share as of September 30, 2019 attributable to the pro forma transactions described above	_____
Pro forma net tangible book value per share as of September 30, 2019	_____
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	_____
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors participating in this offering	\$ _____

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by \$ per share and the dilution per share to new investors participating in this offering by \$ per share, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase of 1.0 million in the number of shares of common stock offered by us would increase the pro forma as adjusted net tangible book value after this offering by \$ per share and decrease the dilution per share to new investors participating in this offering by \$ per share, and a decrease of 1.0 million shares of common stock offered by us would decrease the pro forma as adjusted net tangible book value by \$ per

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share, and increase the dilution per share to new investors in this offering by \$ per share, assuming that the assumed initial public offering price of \$ per share remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase additional shares of common stock from us, the pro forma as adjusted net tangible book value per share after giving effect to this offering would be \$ per share, representing an immediate increase to existing stockholders of \$ per share, and dilution to new investors participating in this offering of \$ per share.

The following table summarizes on the pro forma as adjusted basis described above, the differences between the number of shares purchased from us, the total consideration paid and the average price per share paid to us by existing stockholders and by investors purchasing shares in this offering at the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page on this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	\$	%	\$
New investors					\$
Total		100%	\$	100%	

A \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, an increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors to % and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors to %, assuming that the assumed initial public offering price of \$ per share remains the same.

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted, in the table above is based on 115,569,451 shares of common stock outstanding as of September 30, 2019 (including the conversion of all of our outstanding shares of redeemable convertible preferred stock into 111,748,065 shares of our common stock), and excludes:

- 18,336,476 shares of our common stock issuable upon the exercise of outstanding stock options as of September 30, 2019, with a weighted-average exercise price of \$0.54 per share;
- shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to September 30, 2019, with a weighted-average exercise price of \$ per share;
- shares of our common stock reserved for future issuance under the 2020 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under our 2020 Plan; and

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- shares of our common stock reserved for future issuance under the ESPP, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

To the extent that any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated statements of operations and consolidated balance sheet data. The selected consolidated statements of operations data for the years ended December 31, 2017 and 2018 and the selected consolidated balance sheet data as of December 31, 2017 and 2018 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The selected consolidated statements of operations data for the nine months ended September 30, 2018 and 2019 and the selected consolidated balance sheet data as of September 30, 2019 are derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2019. You should read the following selected consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by the consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018 (unaudited)	2019 (unaudited)
Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 17,853	\$ 15,528	\$ 11,591	\$ 17,729
General and administrative	2,624	3,619	2,576	5,660
Total operating expenses	<u>20,477</u>	<u>19,147</u>	<u>14,167</u>	<u>23,389</u>
Loss from operations	(20,477)	(19,147)	(14,167)	(23,389)
Gain (loss) on remeasurement of redeemable convertible preferred stock liability	—	260	—	(5,670)
Other income, net	1,770	584	525	821
Net loss before taxes	(18,707)	(18,303)	(13,642)	(28,238)
Provision for income taxes	1	1	1	3
Net loss	<u>(18,708)</u>	<u>(18,304)</u>	<u>(13,643)</u>	<u>(28,241)</u>
Accretion on redeemable convertible preferred stock	87	176	75	815
Net loss attributable to common stockholders	<u>\$ (18,795)</u>	<u>\$ (18,480)</u>	<u>\$ (13,718)</u>	<u>\$ (29,056)</u>
Net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>\$ (6.16)</u>	<u>\$ (5.21)</u>	<u>\$ (3.96)</u>	<u>\$ (7.61)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	<u>3,051,792</u>	<u>3,548,177</u>	<u>3,460,382</u>	<u>3,818,365</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u>\$</u>		<u>\$</u>
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽¹⁾		<u></u>		<u></u>

(1) See Notes 2 and 11 to our audited consolidated financial statements and Notes 2 and 10 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for explanations of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

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	As of December 31,		As of September 30,
	2017	2018	2019
		(in thousands)	(unaudited)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 2,966	\$ 44,175	\$ 53,662
Working capital(1)	1,977	42,380	49,578
Total assets	7,821	48,149	58,600
Redeemable convertible preferred stock liability	—	5,140	—
Redeemable convertible preferred stock	48,971	102,082	143,704
Accumulated deficit	(47,093)	(65,397)	(93,638)
Total stockholders' deficit	(46,211)	(64,202)	(91,759)

(1) We define working capital as current assets less current liabilities. See our audited consolidated financial statements and our unaudited interim condensed consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and 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 our consolidated financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, eye and brain. Our pipeline is based on our platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Evidence suggests that potent and selective inhibition of C1q can prevent tissue damage triggered in antibody-mediated autoimmune disease and preserve loss of functioning synapses associated with cognitive and functional decline in complement-mediated neurodegeneration. Our upstream complement approach targeting C1q acts as an "on/off switch" designed to block all downstream components of the classical complement pathway that lead to excess inflammation, tissue damage and patient disability in a host of complement-mediated disorders, while preserving the normal immune function of the lectin and alternative complement pathways involved in the clearance of pathogens and damaged cells.

Our pipeline of product candidates is designed to block the activity of C1q and the entire classical complement pathway in a broad set of complement-mediated diseases. Our first product candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune disorders. Our second product candidate, ANX007, is an antigen-binding fragment, or Fab, formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. We are also developing ANX009, an investigational, subcutaneous formulation designed for the treatment of systemic autoimmune diseases. We have completed Phase 1b safety and dose-ranging clinical trials for ANX005 and ANX007 in patients with Guillain-Barré Syndrome, or GBS, and glaucoma, respectively. While the trials were not statistically powered for significance on the efficacy measures, both molecules were well-tolerated and showed full inhibition of C1q and the classical complement pathway.

Based on learnings from our initial trials, we are advancing our current programs while expanding into additional orphan and large market indications. In particular, we intend to advance ANX005 into multiple Phase 2 trials in 2020 including in patients with GBS, Huntington's disease, amyotrophic lateral sclerosis and warm autoimmune hemolytic anemia. We are also planning a Phase 2 trial of ANX007 in patients with glaucoma or geographic atrophy in 2020. Additionally, we are developing novel product candidates designed to inhibit C1q and other components of the early classical complement cascade with the goal of further broadening our portfolio. Finally, we are leveraging our disciplined development strategy in early clinical trials utilizing established biomarkers in an effort to enhance patient selection, measure target engagement and assess our product candidates' potential to meaningfully impact the disease process and improve the probability of technical success over shorter development timelines.

We hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates, which allow us to strategically maximize value from our patent portfolio over time. Our patent portfolio includes patent protection for our upstream complement platform and each of our product candidates.

We were incorporated in March 2011 and commenced operations later that year. To date, we have focused primarily on performing research and development activities, hiring personnel and raising capital to support and

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expand these activities. We do not have any products approved for sale, and we have not generated any revenue from product sales. We have incurred net losses each year since our inception. Our net losses were \$18.7 million and \$18.3 million for the years ended December 31, 2017 and 2018, respectively, and \$13.6 million and \$28.2 million for the nine months ended September 30, 2018 and 2019, respectively. As of September 30, 2019, we had an accumulated deficit of \$93.6 million and cash and cash equivalents of \$53.7 million. We expect to incur significant and increasing losses in the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, particularly as they advance into later stages of development and as we conduct larger clinical trials, engage in other research and development activities, seek regulatory approvals for any product candidates that successfully complete clinical trials, prepare for commercialization, hire additional personnel, protect our intellectual property and incur additional expenses as a result of operating as a public company. We also expect to increase the size of our administrative function to support the growth of our business. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors, including: the timing and cost of, and level of investment in, research and development; the number and timing of the clinical trials we commence; the cost of manufacturing our product candidates; the timing and cost of commercialization activities relating to our product candidates, if approved; and expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies.

We have funded our operations to date primarily from the issuance and sale of equity securities. From our inception through September 30, 2019, we have raised aggregate net cash proceeds of \$137.3 million from the sale of our equity securities. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. As a result, we will need to raise additional capital. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months from the date of this offering.

Components of Operating Results

Revenue

Our product candidates are not approved for commercial sale. We have not generated any revenue from sales of our product candidates and do not expect to do so in the foreseeable future and until we complete clinical development, submit regulatory filings and receive approvals from applicable regulatory bodies for such product candidates, if ever.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses. Research and development expenses consist primarily of direct and indirect costs incurred for the development of our product candidates.

Direct expenses include:

- preclinical and clinical outside service costs associated with discovery, preclinical and clinical testing of our product candidates;

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- professional services agreements with third party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities on our behalf;
- contract manufacturing costs to produce clinical trial materials; and
- laboratory supplies and materials.

Indirect expenses include:

- compensation and personnel-related expenses (including stock-based compensation);
- allocated expenses for facilities and depreciation; and
- other indirect costs.

We record research and development expenses as incurred. Payments made to other entities are under agreements that are generally cancelable by us. Advance payments for goods or services to be received in future periods for use in research and development activities are deferred as prepaid expenses. The prepaid amounts are then expensed as the related services are performed. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, particularly as they advance into later stages of development and as we conduct larger clinical trials, engage in other research and development activities and seek regulatory approvals for any product candidates that successfully complete clinical trials and as we incur expenses associated with hiring additional personnel to support our research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

General and Administrative

General and administrative expenses consist primarily of compensation and personnel-related expenses (including stock-based compensation) for our personnel in executive, finance and other administrative functions. General and administrative expenses also include professional fees paid for accounting, legal and tax services, allocated expenses for facilities and depreciation and other general and administrative costs.

We expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to support our research and development activities, grow our business and, if any of our product candidates receive marketing approval, commercialization activities. We will also incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Sarbanes-Oxley Act and the Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

Gain (Loss) on Remeasurement of Redeemable Convertible Preferred Stock Liability

Gain (loss) on remeasurement of redeemable convertible preferred stock liability consists of gains and losses from the remeasurement to fair value of the redeemable convertible preferred stock liability related to our Series C redeemable convertible preferred stock. We remeasured the liability each reporting period until the second closing of our Series C redeemable convertible preferred stock which occurred in August 2019.

Other Income, Net

Other income, net, primarily consists of non-recurring income from research grants and interest income earned on our cash equivalents.

[Table of Contents](#)**Results of Operations****Comparison of the Nine Months Ended September 30, 2018 and 2019**

The following tables summarize our results of operations for the periods presented.

	Nine Months Ended September 30,		Dollar Change	% Change
	2018	2019 (unaudited) (in thousands)		
Operating expenses:				
Research and development	\$ 11,591	\$ 17,729	\$ 6,138	53
General and administrative	2,576	5,660	3,084	120
Total operating expenses	<u>14,167</u>	<u>23,389</u>	<u>9,222</u>	65
Loss from operations	(14,167)	(23,389)	(9,222)	65
Loss on remeasurement of redeemable convertible preferred stock liability	—	(5,670)	(5,670)	*
Other income, net	525	821	296	56
Net loss before taxes	(13,642)	(28,238)	(14,596)	107
Provision for income taxes	1	3	2	*
Net loss	<u>\$ (13,643)</u>	<u>\$ (28,241)</u>	<u>\$ (14,598)</u>	107

* Not meaningful

Research and Development Expenses

	Nine Months Ended September 30,		Dollar Change	% Change
	2018	2019 (unaudited) (in thousands)		
Direct costs:				
Preclinical and clinical outside services	\$ 5,518	\$ 7,375	\$ 1,857	34
Professional services	1,869	1,340	(529)	(28)
Contract manufacturing	848	4,388	3,540	*
Laboratory supplies and materials	203	365	162	80
Indirect costs:				
Compensation and personnel-related (including stock-based compensation)	2,514	3,542	1,028	41
Facilities and depreciation	618	646	28	5
Other	21	73	52	248
Total research and development expenses	<u>\$ 11,591</u>	<u>\$ 17,729</u>	<u>\$ 6,138</u>	53

* Not meaningful

Research and development expenses increased by \$6.1 million, or 53%, from \$11.6 million for the nine months ended September 30, 2018 to \$17.7 million for the nine months ended September 30, 2019. The increase was primarily due to an increase of \$1.9 million in direct preclinical and clinical outside services related to increased activities of our ongoing clinical trials. Contract manufacturing expenses increased by \$3.5 million primarily due to the scale up of manufacturing to support continued advancement of our product candidates through clinical trials. Direct professional services costs decreased by \$0.5 million due to an increase in internal research and development capabilities during the nine months ended September 30, 2019.

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Compensation and personnel-related expenses increased by \$1.0 million due to an increase in headcount and related employee costs.

General and Administrative Expenses

	Nine Months Ended September 30,		Dollar Change	% Change
	2018	2019		
	(unaudited) (in thousands)			
Compensation and personnel-related (including stock-based compensation)	\$ 1,267	\$ 2,575	\$1,308	103
Professional services	962	2,642	1,680	*
Facilities and depreciation	288	318	30	10
Other	59	125	66	112
Total general and administrative expenses	<u>\$ 2,576</u>	<u>\$ 5,660</u>	<u>\$3,084</u>	120

* Not meaningful

General and administrative expenses increased by \$3.1 million, or 120%, from \$2.6 million for the nine months ended September 30, 2018 to \$5.7 million for the nine months ended September 30, 2019. The increase was primarily due to an increase of \$1.7 million in professional services for accounting, legal and tax service fees, and an increase of \$1.3 million in compensation and personnel-related expenses primarily related to an increase of \$0.9 million in stock-based compensation expense resulting from new option grants and an increase in headcount.

Loss on Remeasurement of Redeemable Convertible Preferred Stock Liability

For the nine months ended September 30, 2019, we recorded a loss on remeasurement of redeemable convertible preferred stock liability of \$5.7 million related to the change in fair value of the liability. The liability was recognized in connection with the initial closing of our Series C redeemable convertible preferred stock financing in December 2018 and was settled in August 2019 upon the completion of the second closing.

Other Income, Net

Other income, net, increased by \$0.3 million from \$0.5 million for the nine months ended September 30, 2018 to \$0.8 million for the nine months ended September 30, 2019. The increase was primarily due to an increase of \$0.5 million in interest income from increased investments in money market funds resulting from the Series C redeemable convertible preferred stock financing in December 2018 and August 2019.

[Table of Contents](#)**Comparison of the Years Ended December 31, 2017 and 2018**

The following tables summarize our results of operations for the periods presented.

	Year Ended December 31,		Dollar Change	% Change
	2017	2018		
	(in thousands)			
Operating expenses:				
Research and development	\$ 17,853	\$ 15,528	\$(2,325)	(13)
General and administrative	2,624	3,619	995	38
Total operating expenses	20,477	19,147	(1,330)	(6)
Loss from operations	(20,477)	(19,147)	1,330	(6)
Gain on remeasurement of redeemable convertible preferred stock liability	—	260	260	*
Other income, net	1,770	584	(1,186)	(67)
Net loss before taxes	(18,707)	(18,303)	404	(2)
Provision for income taxes	1	1	—	—
Net loss	<u>\$(18,708)</u>	<u>\$(18,304)</u>	<u>\$ 404</u>	(2)

* Not meaningful

Research and Development Expenses

	Year Ended December 31,		Dollar Change	% Change
	2017	2018		
	(in thousands)			
Direct costs:				
Preclinical and clinical outside services	\$ 6,480	\$ 7,235	\$ 755	12
Professional services	2,377	2,294	(83)	(3)
Contract manufacturing	4,513	1,433	(3,080)	(68)
Laboratory supplies and materials	690	259	(431)	(62)
Indirect costs:				
Compensation and personnel-related (including stock-based compensation)	3,012	3,455	443	15
Facilities and depreciation	769	823	54	7
Other	12	29	17	*
Total research and development expenses	<u>\$17,853</u>	<u>\$15,528</u>	<u>\$(2,325)</u>	(13)

* Not meaningful

Research and development expenses decreased by \$2.3 million, or 13%, from \$17.9 million for the year ended December 31, 2017 to \$15.5 million for the year ended December 31, 2018. The decrease was primarily due to the decrease of \$3.1 million in contract manufacturing costs as the manufacturing validation process for our clinical candidates was substantially completed during 2017 and a decrease of \$0.4 million in laboratory supplies and materials. Preclinical and clinical outside services increased by \$0.8 million primarily due to increased activities associated with our ongoing clinical trials in 2018. Compensation and personnel-related expenses increased by \$0.4 million due to an increase in headcount.

General and Administrative Expenses

	Year Ended December 31,		Dollar Change	% Change
	2017	2018		
	(in thousands)			
Compensation and personnel-related (including stock-based compensation)	\$ 964	\$1,682	\$ 718	74
Professional services	1,334	1,470	136	10
Facilities and depreciation	232	391	159	69
Other	94	76	(18)	(19)
Total general and administrative expenses	<u>\$2,624</u>	<u>\$3,619</u>	<u>\$ 995</u>	<u>38</u>

General and administrative expenses increased by \$1.0 million, or 38%, from \$2.6 million for the year ended December 31, 2017 to \$3.6 million for the year ended December 31, 2018. The increase was primarily due to an increase of \$0.7 million in compensation and personnel-related expenses due to an increase in headcount, an increase of \$0.2 million in depreciation expense related to new leasehold improvements in December 2017 and an increase of \$0.1 million in consulting expenses.

Gain on Remeasurement of Redeemable Convertible Preferred Stock Liability

For the year ended December 31, 2018, we recorded a gain on remeasurement of redeemable convertible preferred stock liability of \$0.3 million related to the change in fair value of the liability. The liability was recognized in connection with the initial closing of our Series C redeemable convertible preferred stock financing in December 2018.

Other Income, Net

Other income, net, decreased by \$1.2 million, or 67%, from \$1.8 million for the year ended December 31, 2017 to \$0.6 million for the year ended December 31, 2018. The decrease was primarily attributable to the decrease of \$1.4 million in non-recurring income from research and development grants in 2018.

Liquidity and Capital Resources

Sources of Liquidity

Due to our significant research and development expenditures, we have generated operating losses since our inception. We have funded our operations primarily through the sale of equity securities. From our inception through September 30, 2019, we have raised aggregate net cash proceeds of \$137.3 million from the sale of our equity securities. As of September 30, 2019, we had available cash and cash equivalents of \$53.7 million and an accumulated deficit of \$93.6 million.

Historical Cash Flows

	Year Ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018	2019
	(in thousands)			
Cash used in operating activities	\$(19,260)	\$(17,190)	\$(12,326)	\$(19,569)
Cash used in investing activities	(567)	(17)	(18)	(168)
Cash provided by financing activities	42	58,456	13,673	29,241
Net (decrease) increase in cash and cash equivalents	<u>\$(19,785)</u>	<u>\$ 41,249</u>	<u>\$ 1,329</u>	<u>\$ 9,504</u>

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2019 was \$19.6 million, which consisted of a net loss of \$28.2 million, partially offset by \$7.5 million in non-cash charges and a net change of \$1.1 million in our net operating assets and liabilities. The non-cash charges consisted of the loss on remeasurement of the redeemable convertible preferred stock liability of \$5.7 million, stock-based compensation of \$1.5 million and depreciation and amortization of \$0.3 million. The net change in our operating assets and liabilities was primarily due to an increase of \$0.9 million in accounts payable as a result of the increase in our clinical and manufacturing activities and a decrease of \$0.5 million in prepaid expenses and other current assets primarily related to prepayments for our clinical activities, partially offset by a decrease of \$0.3 million in deferred rent due to the amortization of deferred rent balance.

Cash used in operating activities for the nine months ended September 30, 2018 was \$12.3 million, which consisted of a net loss of \$13.6 million, partially offset by \$0.7 million in non-cash charges and a net change of \$0.6 million in our net operating assets and liabilities. The non-cash charges consisted of depreciation and amortization of \$0.4 million and stock-based compensation of \$0.3 million. The net change in our operating assets and liabilities was primarily due to a decrease of \$1.0 million in prepaid expenses and other current assets primarily related to prepayments for our clinical activities and the decrease in government grants received related to research and development activities, partially offset by a decrease of \$0.2 million in accrued liabilities primarily due to the decrease in contract manufacturing activities and a decrease of \$0.2 million in deferred rent due to the amortization of deferred rent balance.

Cash used in operating activities for the year ended December 31, 2018 was \$17.2 million, which consisted of a net loss of \$18.3 million, partially offset by \$0.6 million in non-cash charges and a net change of \$0.5 million in our net operating assets and liabilities. The non-cash charges consisted of depreciation and amortization of \$0.5 million and stock-based compensation of \$0.4 million, partially offset by the gain on remeasurement of redeemable convertible preferred stock liability of \$0.3 million. The net change in our operating assets and liabilities was primarily due to an increase of \$0.6 million in accrued liabilities due to timing of invoices and a decrease of \$0.4 million in prepaid expenses and other current assets due to the decrease in payments for clinical activities and the decrease in government grants received related to research and development activities. This was partially offset by a decrease of \$0.3 million in deferred rent related to the amortization of deferred rent balance and a decrease of \$0.3 million in accounts payable due to the decrease in research and development activities from our Australian subsidiary.

Cash used in operating activities for the year ended December 31, 2017 was \$19.3 million, which consisted of a net loss of \$18.7 million and a net change of \$1.3 million in our net operating assets and liabilities, partially offset by \$0.7 million in non-cash charges. The non-cash charges consisted of stock-based compensation of \$0.4 million and depreciation and amortization of \$0.3 million. The net change in our operating assets and liabilities was primarily due to an increase of \$1.6 million in prepaid expenses and other current assets related to payments for clinical activities, partially offset by a decrease of \$0.3 million in accounts payable and accrued liabilities due to timing of payments.

Cash Flows from Investing Activities

Cash used in investing activities for the nine months ended September 30, 2018 and 2019 was \$18,000 and \$168,000, respectively, related to purchases of property and equipment.

Cash used in investing activities for the years ended December 31, 2017 and 2018 was \$0.6 million and \$17,000, respectively, related to purchases of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2019 was \$29.2 million which consisted of net proceeds received from the second closing of our Series C redeemable convertible preferred stock of \$30.0 million in August 2019, partially offset by payments for deferred offering costs of \$0.8 million.

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Cash provided by financing activities for the nine months ended September 30, 2018 was \$13.7 million, which consisted of net proceeds received from the issuance of our redeemable convertible preferred stock of \$13.6 million and proceeds from the exercise of stock options of \$0.1 million.

Cash provided by financing activities for the year ended December 31, 2018 was \$58.5 million which consisted of net proceeds received from the issuance of our redeemable convertible preferred stock of \$58.3 million and proceeds from the exercise of stock options of \$0.1 million.

Cash provided by financing activities for the year ended December 31, 2017 was \$42,000 which primarily consisted of proceeds from the exercise of stock options.

Funding Requirements

We use our cash to fund operations, primarily to fund our clinical trials, research and development expenditures and related personnel costs. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to our product candidates, particularly as they advance into later stages of development and as we conduct larger clinical trials, engage in other research and development activities, seek regulatory approvals for any product candidates that successfully complete clinical trials and as we incur expenses associated with hiring additional personnel to support our research and development efforts. In addition, we expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to support our research and development activities and to grow our business and as we expect to engage in commercialization activities, if any of our product candidates receive marketing approval. We will also incur additional expenses as a result of operating as a public company and also expect to increase the size of our administrative function to support the growth of our business. The timing and amount of our operating expenditures will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates or any other future products candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our planned Phase 2 clinical trials of ANX005 and ANX007;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to our current or any future license or collaboration agreements;
- the cost of manufacturing our lead product candidates or any future product candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities of our product candidates, if approved for sale, including marketing, sales and distribution costs;
- our ability to establish strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with operating as a public company;

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- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products.

Without giving effect to the anticipated net proceeds from this offering, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months from the date of this offering. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect to continue to expend significant resources for the foreseeable future. Until such time, if ever, as we can generate substantial product revenue, we will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations and other commitments as of December 31, 2018:

	Payments Due by Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
Operating lease obligations	\$ 696	\$1,463	\$1,565	\$ 361	\$4,085
Total contractual obligations	\$ 696	\$1,463	\$1,565	\$ 361	\$4,085

The obligations noted above represent operating lease obligations related to our currently occupied premises in South San Francisco, California. We also enter into contracts in the normal course of business with various third parties for preclinical studies, clinical trials and other services. These contracts generally provide for termination upon notice, and therefore we believe that our noncancelable obligations under these agreements are not material. These payments are not included in the table above. This table also does not include any milestone or royalty payments to third parties as the amounts, timing and likelihood of such payments are not known at this time.

Internal Control Over Financial Reporting

During the audit of our financial statements for the year ended December 31, 2018, a material weakness was identified in our internal control over financial reporting. Under standards established by the Public Company

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Accounting Oversight Board, a material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weakness that was identified related to an inadequate number of qualified personnel within our accounting function, which impacted our ability to perform effective reviews over non-routine transactions.

We are implementing measures designed to improve our internal control over financial reporting to address the underlying causes of this material weakness, including the hiring of accounting personnel and establishing new accounting and financial reporting procedures, policies and processes to have in place an appropriate level of internal control over financial reporting.

We, and our independent registered public accounting firm, were not required to perform an evaluation of our internal control over financial reporting as of December 31, 2018 in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley Act after the completion of this offering.

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 SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and consolidated results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated 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 consolidated financial statements, as well as the reported expenses incurred during the reporting periods. 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. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our consolidated financial statements included elsewhere in this prospectus, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Accrued and Prepaid Research and Development Costs

We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on our behalf. In recording service fees as either prepaid or accrued costs, we estimate the period over which services will be performed and the level of effort to be expended in each period. These estimates of the expense are based on communications with and information provided by the third-party service providers at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the amounts recorded accordingly. The estimates are trueed up to reflect the best information available at the time of the financial statement issuance. We have not experienced any material differences between accrued or prepaid costs and actual costs incurred since inception.

We defer and capitalize non-refundable advance payments for goods or services that will be used or rendered for future research and development activities as prepaid expenses until the related goods are delivered

or services are performed. We evaluate such payments for current or long-term classification based on when such services are expected to be received.

Prepaid research and development costs were \$1.1 million, \$1.1 million and \$0.5 million as of December 31, 2017 and 2018, and September 30, 2019, respectively. Accrued research and development expenses were \$0.6 million, \$0.8 million and \$0.7 million as of December 31, 2017 and 2018, and September 30, 2019, respectively.

Stock-Based Compensation

We maintain a stock-based compensation plan as a long-term incentive for employees, non-employee directors and consultants. The plan allows for the issuance of incentive stock options, non-qualified stock options, restricted stock units and other forms of equity awards.

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period and account for forfeitures as they occur. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model. This model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

Fair Value of Common Stock—See the subsection titled “—Common Stock Valuations” below.

Expected Term—The expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility—Because we have been privately held and do not have any trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life sciences companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend Yield—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 9 to our audited consolidated financial statements and Note 8 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

We recorded stock-based compensation expense of \$0.4 million for each of the years ended December 31, 2017 and 2018. For the nine months ended September 30, 2018 and 2019, we recorded stock-based compensation expense of \$0.3 million and \$1.5 million, respectively. As of September 30, 2019, we had \$7.1 million of total unrecognized stock-based compensation cost which we expect to recognize over an estimated weighted-average period of 2.5 years. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

The intrinsic value of all outstanding options as of September 30, 2019 was \$ million based on an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, of which approximately \$ million is related to vested options and approximately \$ million is related to unvested options.

Common Stock Valuations

Historically, for all periods prior to this offering, fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. Our board of directors considered, among other things, valuations of our common stock which were prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

For our valuations performed prior to December 31, 2018, we used the option pricing method, or OPM, backsolve method. In an OPM framework, the backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility and risk-free interest rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. This method was selected as we concluded that the contemporaneous financing transaction was an arms-length transaction. Furthermore, as of the valuation dates prior to December 31, 2018, we were at an early stage of development and future liquidity events were difficult to forecast.

For our valuations performed subsequent to December 31, 2018, we used a Probability Weighted Expected Return Method, or PWERM, whereby our total equity value was estimated under various exit scenarios and allocated to our different classes of equity. The PWERM included two scenarios, initial public offering, or IPO, or staying private, that considered our estimate of the timing of each scenario and were weighted based on our estimate of the probability of each event occurring. The equity value under the IPO scenario was based on our estimate and recent IPO values of comparable companies. The OPM was utilized to estimate our equity value under the staying private scenario. The equity value under all scenarios was reduced by a discount for lack of marketability.

Given the absence of a public trading market, our board of directors with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to:

- contemporaneous valuations performed by an independent third-party valuation firm;
- important developments in our business;
- sales of our redeemable convertible preferred stock;
- the rights, preferences and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- lack of marketability of our common stock as a private company;
- actual operating results;
- financial performance;
- the progress of clinical development;
- the likelihood of achieving a liquidity event for our securityholders, such as an IPO or a sale of our company, given prevailing market conditions;
- the trends, developments and conditions in the life sciences and biotechnology industry sectors;
- the economy in general; and
- the stock price performance and volatility of comparable public companies.

For valuations after the completion of this offering, the fair value of each share of underlying common stock will be based on the closing price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Redeemable Convertible Preferred Stock Liability

The obligation to issue additional shares of Series C redeemable convertible preferred stock at a future date was determined to be a freestanding financial instrument that should be accounted for as a liability. At issuance, we recorded the redeemable convertible preferred stock liability on the balance sheet at its estimated fair value, using the Black-Scholes option pricing model, with an expected term based on the expected contractual closing date. The other inputs to the Black-Scholes option pricing model, including volatility and risk-free interest rate, were estimated using a similar methodology as described above for our stock option grants. This methodology was also used to remeasure the liability at December 31, 2018. During 2019, in light of our progress towards an IPO, the liability was remeasured using a PWERM. The PWERM included two scenarios, IPO or staying private, that were weighted based on our estimate of the probability of each event occurring.

The liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized as in gain (loss) on remeasurement of redeemable convertible preferred stock liability in the statements of the operations. Upon settlement of the redeemable convertible preferred stock liability, which occurred in August 2019, we remeasured the liability and reclassified the fair value to the carrying value of the Series C redeemable convertible preferred stock.

Income Taxes

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. In evaluating our valuation allowance, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial performance. 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 and tax credit carryforwards.

At December 31, 2018, we had \$60.8 million of federal and \$36.6 million of state net operating loss, or NOL, carryforwards available to offset future taxable income. If not utilized, these carryforward losses will expire in various amounts for federal and state tax purposes beginning in 2031. NOLs generated after December 31, 2017 will be carried forward indefinitely with the yearly NOL utilization limited to eighty percent of taxable income generated in a given tax year.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, substantial changes in our ownership may limit the amount of NOL and research and development credit carryforwards that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of federal and state NOL carryforwards, credit carryforwards, and other deferred tax assets may be limited or lost if cumulative changes in ownership exceeds fifty percent within any three-year period. We have not completed a Section 382/383 analysis under the Code regarding the limitation of NOL and credit carryforwards. If a change in ownership were to have occurred, the annual limitation may result in the expiration of NOL carryforwards and credits before utilization. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

We record unrecognized tax benefits as liabilities and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available.

Recent Accounting Pronouncements

See Note 2 to our audited consolidated financial statements and Note 2 to our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus for more information.

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

Interest Rate Risk

We held cash and cash equivalents of \$44.2 million and \$53.7 million as of December 31, 2018 and September 30, 2019, respectively. We generally hold our cash in interest-bearing money market accounts. We believe that historical fluctuations in interest rates have not had a material effect on our results of operations during the periods presented. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash.

Foreign Currency

Our reporting currency is the U.S. dollar. The functional currency of the subsidiary located in Australia is the Australian Dollar. Balance sheets prepared in the functional currencies are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders' equity accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using a weighted-average rate during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the consolidated balance sheets. Foreign exchange translation losses for the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019 were not material. Gains and losses resulting from exchange-rate changes on transactions denominated in a currency other than the local currency are included in earnings as incurred.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our results of operations during the periods presented.

Emerging Growth Company Status

We expect to be an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that 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 consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, eye and brain. Our pipeline is based on our platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Evidence suggests that potent and selective inhibition of C1q can prevent tissue damage triggered in antibody-mediated autoimmune disease and preserve loss of functioning synapses associated with cognitive and functional decline in complement-mediated neurodegeneration. Our upstream complement approach targeting C1q acts as an “on/off switch” designed to block all downstream components of the classical complement pathway that lead to excess inflammation, tissue damage and patient disability in a host of complement-mediated disorders, while preserving the normal immune function of the lectin and alternative complement pathways involved in the clearance of pathogens and damaged cells.

Our pipeline of product candidates is designed to block the activity of C1q and the entire classical complement pathway in a broad set of complement-mediated diseases. Our first product candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune and neurodegenerative disorders. Our second product candidate, ANX007, is an antigen-binding fragment, or Fab, formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. We are also developing ANX009, an investigational, subcutaneous formulation designed for the treatment of systemic autoimmune diseases. We have completed Phase 1b safety and dose-ranging clinical trials for ANX005 and ANX007 in patients with Guillain-Barré Syndrome, or GBS, and glaucoma, respectively. While the trials were not statistically powered for significance on the efficacy measures, both molecules were well-tolerated and showed full inhibition of C1q and the classical complement pathway.

Based on learnings from our initial trials, we are advancing our current programs while evaluating additional orphan and large market indications. We are also developing novel product candidates designed to inhibit C1q and other components of the early classical complement cascade with the goal of further broadening our portfolio. Finally, we are leveraging our disciplined development strategy in early clinical trials utilizing established biomarkers in an effort to enhance patient selection, measure target engagement and assess our product candidates’ potential to meaningfully impact the disease process and improve the probability of technical success over shorter development timelines.

Annexon was co-founded by the late Dr. Ben Barres, former member of the National Academy of Sciences, Chair of Neurobiology at Stanford University and a pioneer in complement-mediated neurodegeneration, and Dr. Arnon Rosenthal, a world-renowned scientist and industry executive. We have assembled a seasoned and accomplished management team that has been involved in the development, approval and commercialization of numerous marketed drugs, and has been studying the complement pathway and autoimmune and neurodegenerative disorders for decades. Our team is further supported by an experienced scientific advisory board and leading healthcare investors that share our commitment to advancing transformative medicines for patients suffering from debilitating autoimmune and neurodegenerative diseases. Our key investors include Adage, Bain Capital Life Sciences, Blackstone (Clarus), New Enterprise Associates, Novartis Venture Fund, Satter Investment Management and Surveyor (Citadel).

We hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates, which allows us to strategically maximize value from our product portfolio over time. Our intellectual property portfolio includes patent protection for our upstream complement platform and each of our product candidates.

Our Pipeline

Our pipeline is focused on antibody-mediated autoimmune and complement-mediated neurodegenerative disorders for which there is significant unmet medical need. Our product candidates are summarized below:

Therapy	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Status
AUTOIMMUNE DISEASES						
ANX005 (IV)	Guillain-Barré Syndrome (GBS) [†]					<ul style="list-style-type: none"> ✓ Ph 1b complete ✓ Initiated DDI • Initiate Ph 2 in H1 2020
ANX005 (IV)	Warm Autoimmune Hemolytic Anemia (wAIHA) [*]					<ul style="list-style-type: none"> • Initiate Ph 2 in 2020
ANX009 (SubQ)	Autoantibody-mediated Diseases					<ul style="list-style-type: none"> • Initiate FIH trial in 2020
NEURODEGENERATIVE DISEASES						
ANX005 (IV)	Huntington's Disease (HD) [*]					<ul style="list-style-type: none"> • Initiate Ph 2a in H1 2020
ANX005 (IV)	Amyotrophic Lateral Sclerosis (ALS) [*]					<ul style="list-style-type: none"> • Initiate Ph 2a in 2020
ANX007 (IVT)	Glaucoma [‡] / Geographic Atrophy (GA) [*]					<ul style="list-style-type: none"> ✓ Ph 1b complete • Planning Ph 2 in 2020

* Following the filing and clearance of the applicable investigational new drug applications, we intend to initiate Phase 2 clinical trials in the follow-on disease indications.

† We have filed investigational new drug applications for these indications.

Our first clinical-stage product candidate is ANX005, an investigational monoclonal antibody designed to block C1q and activation of the classical complement cascade. For GBS, ANX005 is designed to act early in the disease course to prevent nerve damage and irreversible neurological disability in GBS patients. In the Phase 1b dose-ranging trial in GBS patients, ANX005 was well-tolerated and resulted in full and prolonged C1q engagement and classical cascade inhibition in the blood and cerebrospinal fluid, or CSF. While our Phase 1b trial was not powered to show statistical significance, we did observe statistically significant results in certain, but not all, of the key GBS outcome measures evaluated. Patients treated with ANX005 also showed positive numerical trends across key GBS outcome measures, and a significant reduction in neurofilament light chain, or NfL, a well-accepted marker of nerve damage in neurodegenerative disease that has been shown to correlate with disease severity and clinical outcomes. GBS is a rare, acute, antibody-mediated autoimmune disease impacting the peripheral nervous system. There are currently no approved therapies for GBS in the United States, but intravenous immunoglobulin, or IVIg, and plasma exchange are the current standard of care in the Western world and parts of Asia.

We have initiated a Phase 1b drug-drug interaction, or DDI, trial, to assess any potential pharmacokinetic, or PK, interaction between ANX005 and co-administered IVIg, to evaluate the safety of this combination in GBS patients and to enable dose selection for a Phase 3 trial of this combination. This trial is being conducted in the United States, Europe and Bangladesh. Any objective responses observed in this trial will be in patients receiving ANX005 together with IVIg. The trial is not powered to show a statistically significant efficacious outcome with the combined administration of ANX005 and IVIg and will provide no evidence of the efficacy of ANX005 as a monotherapy. We anticipate that the results from the DDI trial will enable a global Phase 3 pivotal trial of ANX005 in combination with IVIg in GBS patients.

In addition, we intend to advance ANX005 into a Phase 2 monotherapy trial in GBS patients in the first half of 2020. The placebo-controlled Phase 2 monotherapy trial will be conducted in Bangladesh and will evaluate the efficacy of ANX005 in improving disability in GBS patients. ANX005 has received both Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration, or FDA, for the treatment of GBS.

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Beyond GBS, we also intend to study ANX005 in patients with warm autoimmune hemolytic anemia, or wAIHA, an antibody-mediated autoimmune disease characterized by the premature destruction of red blood cells. The classical complement pathway plays an important role in wAIHA through the removal of red blood cells labeled by activated complement components in the spleen or liver (extra-vascular hemolysis) and less common destruction of red blood cells in the blood vessels by the classical complement generated membrane attack complex (intravascular hemolysis). We plan to initiate a Phase 2 trial in patients with the primary diagnosis of wAIHA in 2020. With regard to complement-mediated neurodegeneration, we intend to study ANX005 in patients with Huntington's disease, or HD, as well as patients with amyotrophic lateral sclerosis, or ALS—two neurodegenerative disorders where aberrant classical complement activation has been shown to be associated with synapse loss, elevated levels of NfL and disease progression. We plan to initiate a Phase 2a trial in patients with HD in the first half of 2020, and in patients with ALS in 2020 to assess ANX005's safety, tolerability, target engagement and impact on disease-related biomarkers such as NfL.

Our second clinical-stage product candidate is ANX007, an investigational C1q antigen-binding fragment, or Fab, designed for intravitreal administration in patients with complement-mediated neurodegenerative ophthalmic disorders. Consistent with the results we observed in preclinical studies, in the Phase 1b trial with intravitreal administration in glaucoma patients, ANX007 was well-tolerated and showed full target engagement and inhibition of C1q in the eye for at least four weeks. We believe inhibition of C1q may provide neuroprotective benefit by preventing the aberrant loss of functioning synapses in the retina in a variety of ophthalmic disorders, including glaucoma and geographic atrophy, or GA. Based on a range of considerations, including preclinical data, clinical results observed to date, proximate clinical validation and an established, objective clinical and regulatory path, we are planning a Phase 2 trial of ANX007 in patients with glaucoma or GA in 2020 with the goal of protecting against the loss of photoreceptor neurons in a well-defined patient population.

Our preclinical pipeline includes ANX009, an investigational C1q Fab designed for subcutaneous delivery. We are developing ANX009 to enable chronic dosing for patients with antibody-mediated autoimmune disorders where anti-C1q may have a disease-modifying effect and where we can utilize our targeted biomarker-driven approach. These disorders may include autoimmune hemolytic anemias and a subset of lupus nephritis patients who are selected for pathogenic anti-C1q antibodies, or PACA, and who have a high risk of renal flare. We intend to advance ANX009 through investigational new drug, or IND, enabling studies, select our initial lead autoimmune disease indication and commence a first-in-human, or FIH, clinical trial in healthy volunteers in 2020.

Our Strategy

Our goal is to develop disease-modifying medicines for patients suffering from classical complement-mediated diseases. Key elements of our strategy include:

- ***Leveraging our distinct approach of inhibiting C1q and aberrant upstream classical complement activity to address a broad range of well-characterized classical complement-mediated diseases.*** By inhibiting C1q and the early classical cascade, we believe our product candidates are uniquely designed to address a wide range of antibody-mediated autoimmune diseases and complement-mediated neurodegenerative disorders. We believe full classical complement inhibition may result in clinical benefits by blocking aberrant upstream immune cell activation in our targeted indications, as well as potentially provide safety advantages by leaving the lectin and alternative pathways intact to perform their normal immune functions. We believe our two clinical-stage product candidates, ANX005 and ANX007, are the first and leading clinical-stage product candidates designed to inhibit C1q and the entire classical complement pathway.
- ***Advancing ANX005 through clinical development in multiple autoimmune and neurodegenerative indications of high unmet need.*** Our Phase 1b trial in patients with GBS demonstrated full target engagement of C1q in serum and the CSF, as well as a significant reduction in NfL, a well-accepted biomarker shown to be elevated in patients with GBS, HD and ALS and correlated with disease

severity and clinical course and outcomes. We intend to advance ANX005 into a Phase 2 monotherapy trial in patients with GBS in the first half of 2020, and into Phase 2a trials in patients with HD in the first half of 2020 and in patients with ALS in 2020. We also intend to advance ANX005 into a Phase 2 trial in patients with wAIHA in 2020.

- **Evaluating ANX007 as an agent for neuroprotective benefit in ophthalmic indications.** We are developing ANX007 in neurodegenerative ophthalmic indications, such as glaucoma and GA. ANX007 reduced retinal damage in animal models of glaucoma and GA. In our Phase 1b trial in glaucoma patients, intravitreal administration of ANX007 resulted in full target engagement of C1q at both low and high doses. Based on this clinical dosing data, our preclinical data in glaucoma and GA, and proximate clinical validation from a downstream complement approach, we believe that ANX007 may provide neuroprotective benefit in patients with these and other complement-mediated ophthalmic disorders. We are planning a Phase 2 trial of ANX007 in patients with glaucoma or GA in 2020.
- **Expanding our autoimmune and neurodegenerative portfolios informed by data from our beachhead indications.** Our initial indications represent our beachhead within antibody-mediated autoimmune and complement-mediated neurodegenerative diseases. We intend to leverage learnings from our initial indications to inform selection of additional orphan and larger patient populations involving related biological mechanisms. In our autoimmune portfolio, potential indications include antibody-mediated autoimmune disorders such as wAIHA, Cold Agglutinin Disease, or CAD, and lupus nephritis, (specifically in lupus nephritis patients with endogenous PACA). In our neurodegenerative portfolio, potential indications include complement-mediated neurodegeneration disorders in the eye and brain such as glaucoma, GA, HD, ALS and Alzheimer's disease. We plan to efficiently prosecute these broad opportunities utilizing our disciplined, biomarker-driven development strategy.
- **Developing additional product candidates that are designed to inhibit activation of the classical complement cascade.** We have secured broad intellectual property protection for our upstream complement platform and intend to leverage our intellectual property and know-how to protect and enhance our leading position in developing novel therapeutics that target the classical complement cascade. We are developing product candidates, such as ANX009, to modulate the classical pathway with the potential to become tailored therapeutics for a large range of indications using different molecular modalities, dosing regimens and tissue localization strategies.
- **Maximizing the value of our product candidates.** We currently hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates. We intend to pursue independent development and commercialization in select indications and markets that we can address with a focused sales and marketing organization. We may opportunistically explore licensing agreements, collaborations or partnerships to develop our product candidates in larger market indications where we could accelerate development utilizing the resources of larger biopharmaceutical companies.

Overview of the Complement System and C1q Biology

The Complement System—three main complement pathways

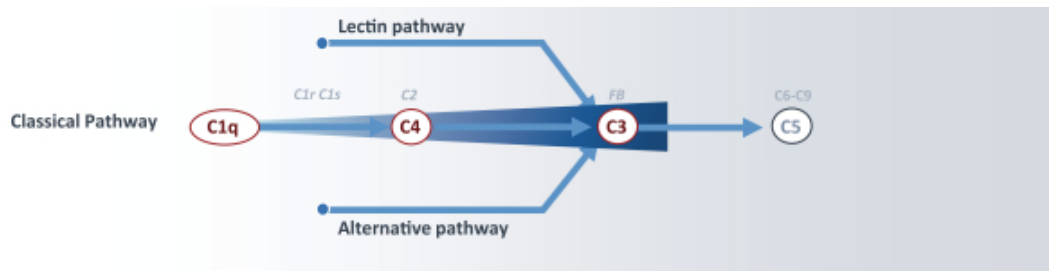
The complement system is an integral component of the immune system that consists of many circulating and locally-produced molecules. This system evolved to enhance, or complement, other components of the adaptive and innate immune systems. The complement system, also known as the complement cascade, rapidly responds to pathogens, damaged cells and unwanted tissue components to facilitate their removal by the immune system.

There are three main complement pathways (also called cascades)—the classical, lectin and alternative pathways. Each pathway is initiated by different molecules that respond to distinct triggers. When activated, the initiating molecules set in motion a cascade of enzymatic reactions that greatly amplify, or complement, an inflammatory response. The classical pathway is initiated by C1q, which recognizes antibody complexes, specific

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pathogens, damaged cells or unwanted cellular components. The lectin pathway is triggered by carbohydrates on the surface of pathogens or cells. The alternative pathway amplifies the action of the other two pathways and also self-activates to eliminate pathogens or cells that are not specifically shielded by the body's built-in self-protective systems. While these three pathways are initiated by distinct molecules, they converge downstream on common pathway components known as C3 and C5.

The three main pathways of the complement cascade are activated by independent molecules but converge at C3

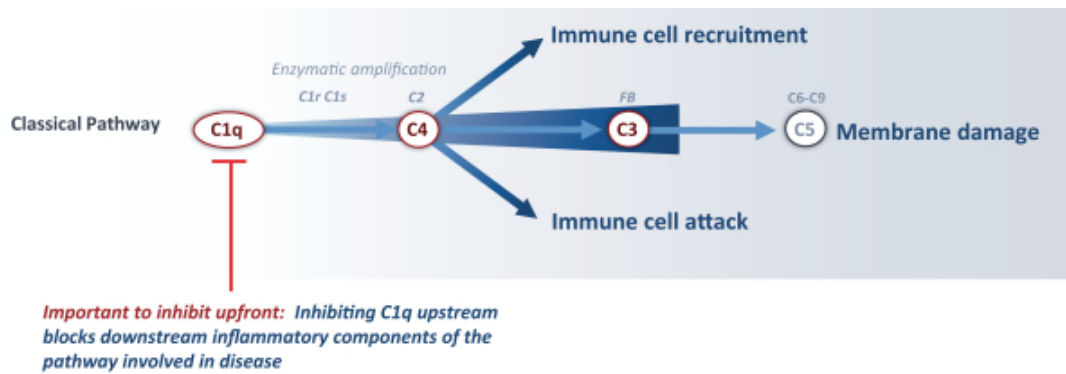


Aberrant activation of the complement system can result in a range of diseases characterized by an attack on healthy tissue, such as red blood cells, nerve cells or kidney components. A broad range of diseases are known to be associated with pathological activation of the complement cascade, including antibody-mediated autoimmune disorders such as GBS, wAIHA, CAD and lupus nephritis, and complement-mediated neurodegeneration disorders in the eye and brain such as glaucoma, GA, HD, ALS and Alzheimer's disease. We believe intervening in the activation of the complement cascade offers a potent and selective mechanism for specifically slowing or reversing these disease processes.

Specific activated components of the complement cascade have important immune functions that contribute to three key outcomes:

- **Immune cell recruitment and inflammation.** Specific activated molecules from the cascade serve as soluble signals to make blood vessels leaky and attract immune cells into tissues.
- **Directed immune cell attack.** Several complement components, including C1q, bind directly to the pathogen and serve as receptors that direct immune cell attack and pathogen engulfment.
- **Membrane damage.** Downstream components of the cascade directly puncture the pathogen or cell surface, causing membrane damage and lysis.

Aberrant activation of the initiating molecule, C1q, can lead to three main outcomes

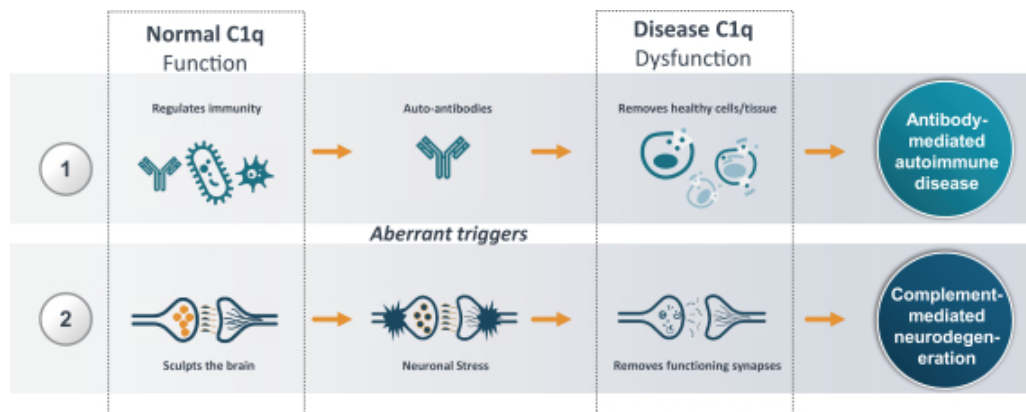


Broad potential for Classical Complement pathway targeted therapeutics in Autoimmune and Neurodegenerative Diseases

The classical complement cascade has a well-established role in augmenting antibody function within the immune system. C1q recognizes antibodies bound to pathogens or cells and activates the classical pathway to trigger their removal and clearance by the immune system. C1q can also directly recognize pathogens, damaged cells or unwanted cellular components leading to similar downstream clearance. A more recent finding made by the laboratory of Dr. Ben Barres, our scientific founder, is that C1q also directly interacts with neuronal connections, or synapses, during early development. Recognition of weaker synapses by C1q triggers the classical complement cascade and directs immune cells to “prune” the synapses away from neurons, thereby reinforcing stronger synapses to establish appropriate neuronal connections.

Because of its central role in immune function, aberrant activation of C1q can lead to damage of healthy tissue and destruction of functioning synapses. We are focused on two distinct disease processes involving C1q as a key mediator of tissue damage: antibody-mediated autoimmune disease and complement-mediated neurodegeneration.

Our platform targets two diseases processes



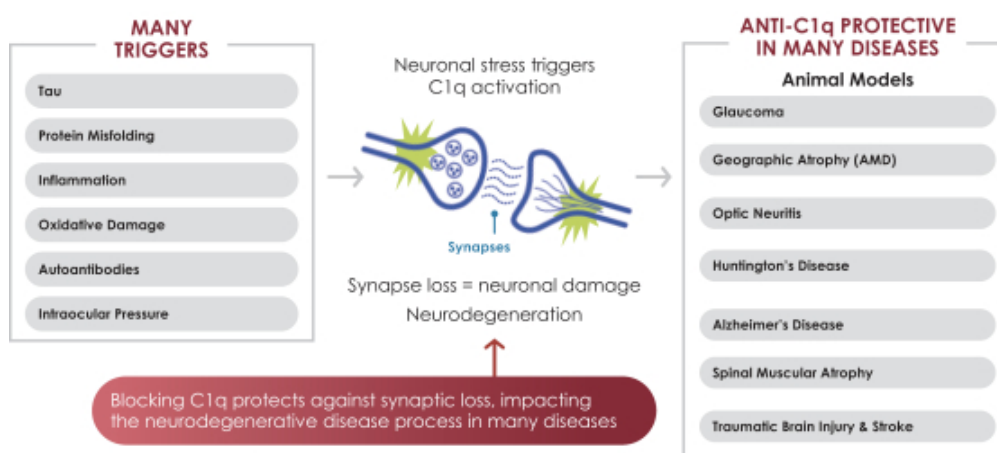
In antibody-mediated autoimmune disease, self-reactive antibodies bind to cells or tissues, activating C1q and leading to damaging inflammatory responses. We have observed that inhibition of C1q was protective in

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several animal models of antibody-mediated autoimmune disease, including neuromyelitis optica, or NMO, and two variants of GBS. In NMO, auto-antibodies recognize cells within the central nervous system, or CNS, and can lead to rapid localized destruction of the optic nerve and regions of the spinal cord, while in GBS pathogenic antibodies react with components of the peripheral nerve system, or PNS, to cause widespread peripheral nerve damage and paralysis. This disease process is also evident in antibody-mediated autoimmune disease involving blood components, such as wAIHA and CAD, characterized by auto-reactive antibodies that trigger destruction of red blood cells, and systemic lupus erythematosus, or SLE, where endogenous pathogenic antibodies against C1q itself drive aberrant C1q activation and are highly associated with kidney damage or lupus nephritis.

In complement-mediated neurodegeneration, aberrant activation of C1q at synapses in aging and disease can lead to excessive synapse loss and neuronal damage, driving disease progression in multiple neurodegenerative disorders regardless of the initiating factor. In animal models, C1q accumulated on synapses with age, building up to 300-fold higher levels than in younger animals. It did not activate with normal aging, but other inflammatory stimuli, including misfolded proteins, metabolic dysfunction or increases in intraocular pressure, appeared to aberrantly reactivate C1q's developmental role in synapse elimination. Complement activation and aberrant synapse pruning in disease may lead to neuroinflammation, loss of synaptic neuronal connections and neurodegeneration. In support of this hypothesis, we and other investigators have observed that C1q inhibition was protective in numerous models of neurodegenerative disease, including diseases of the eye, such as glaucoma and age-related macular degeneration, chronic diseases of the CNS, such as Alzheimer's, HD and Spinal Muscular Atrophy, or SMA, and acute injury, such as traumatic brain injury and stroke.

Synaptic loss is a pathogenic driver of disability in many neurodegenerative diseases, protected with C1q inhibition



Our differentiated approach to treating complement-mediated autoimmune and neurodegenerative disease through inhibition of C1q

We believe that in order to selectively inhibit aberrant activation of the classical complement pathway implicated in driving certain complement-mediated autoimmune and neurodegenerative diseases, it is important to target the early components of the classical cascade, particularly C1q, C4 and C3. Activated fragments of C4 and C3 induce vascular leakiness and immune cell recruitment into the tissue, while other fragments of C4 and C3, as well as C1q, work together to direct immune cell attack to the cell or synapse surface. Furthermore, C1q inhibition blocks downstream activation of C5 and its membrane damaging effects. We believe that inhibition of C1q does not block the activity of these components in the lectin or alternative complement pathways, and both of these pathways will continue to perform their normal immune functions.

Our Platform

Our novel upstream complement platform is designed to completely inhibit classical complement activity for the treatment of antibody-mediated autoimmune disease and complement-mediated neurodegeneration. We believe there are potential advantages to our approach of upstream inhibition of the classical complement cascade, which include:

- **Full inhibition of the classical cascade while preserving healthy immune function of the other complement pathways.** Inhibition of C1q fully inhibits the classical cascade, including components downstream of C1q such as C4, C3, C5 and the downstream membrane attack complex. As a result, we believe our approach is designed to block all classical complement activity that can contribute to disease pathology, including immune cell recruitment, directed immune cell attack and membrane damage. By targeting upstream tissue-damaging components of the classical complement pathway, our approach leaves the lectin and alternative pathways to perform their normal immune function, which may aid both clinical improvement and safety. Our approach is also distinct from inhibiting C3 or C5. Inhibition of C5 will not affect the upstream components of the classical pathway involved in pathology (C1q, C4 and C3), while inhibition of C3 will block downstream components in all three complement pathways.
- **Broad applicability across many indications.** We believe our approach has broad utility for the treatment of diseases in which full inhibition of the entire classical complement cascade may be beneficial. We believe our approach is distinguishable from those that target only downstream complement components. Our initial indications represent our beachhead within antibody-mediated autoimmune and complement-mediated neurodegenerative diseases, and we will selectively pursue both orphan and larger patient population diseases with clear biological evidence of classical complement activation. We are also developing novel product candidates targeting C1q and early components of the classical complement cascade, and will utilize different modalities to target these components of the classical complement pathway.
- **Disciplined, biomarker-driven development strategy for our product candidates.** We are deploying a disciplined, biomarker-driven development strategy designed to establish confidence that our product candidates are engaging the specific target at a well-tolerated therapeutic dose in the intended patient tissue. We design small, early-stage clinical trials to rigorously evaluate our product candidates using target engagement and pharmacodynamic biomarkers. We are utilizing sensitive, specific assays for C1q and downstream classical complement components to evaluate target engagement in patient tissues that are most relevant for the diseases that we are treating, such as CSF for neurological diseases and aqueous humor for ocular diseases. In neurodegenerative diseases, we are measuring our product candidate's impact on NfL, a sensitive marker of neurodegeneration, to provide proof-of-concept in small patient trials. We believe that this development strategy allows us to make rational decisions regarding our therapeutic pipeline, increasing the probability of technical success over shorter development timelines for product candidates we advance into later stage trials.

Our Pipeline

Our pipeline is focused on antibody-mediated autoimmune and complement-mediated neurodegenerative disorders for which there is significant unmet medical need. Our product candidates are summarized in the table below.

Therapy	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Status
AUTOIMMUNE DISEASES						
ANX005 (IV)	Guillain-Barré Syndrome (GBS) [†]					<ul style="list-style-type: none"> ✓ Ph 1b complete ✓ Initiated DDI • Initiate Ph 2 in H1 2020
ANX005 (IV)	Warm Autoimmune Hemolytic Anemia (wAIHA) [*]					<ul style="list-style-type: none"> • Initiate Ph 2 in 2020
ANX009 (SubQ)	Autoantibody-mediated Diseases					<ul style="list-style-type: none"> • Initiate FIH trial in 2020
NEURODEGENERATIVE DISEASES						
ANX005 (IV)	Huntington's Disease (HD) [*]					<ul style="list-style-type: none"> • Initiate Ph 2a in H1 2020
ANX005 (IV)	Amyotrophic Lateral Sclerosis (ALS) [*]					<ul style="list-style-type: none"> • Initiate Ph 2a in 2020
ANX007 (IVT)	Glaucoma [‡] / Geographic Atrophy (GA) [*]					<ul style="list-style-type: none"> ✓ Ph 1b complete • Planning Ph 2 in 2020

* Following the filing and clearance of the applicable investigational new drug applications, we intend to initiate Phase 2 clinical trials in the follow-on disease indications.

† We have filed investigational new drug applications for these indications.

Our First Product Candidate, ANX005

ANX005 is an investigational humanized recombinant monoclonal antibody that is designed to potently bind and inhibit C1q. Our Investigational New Drug, or IND, application for ANX005 in GBS was authorized to proceed in February 2019. We have completed a Phase 1b clinical trial for ANX005 in patients with GBS, and we have initiated a Phase 1b DDI trial assessing the concomitant use of ANX005 and IVIg in GBS patients. We anticipate data from this DDI trial in 2020. Further, we plan to advance ANX005 into a Phase 2 monotherapy trial in GBS patients in the first half of 2020, as well as Phase 2a trials in patients with HD in the first half of 2020 and in patients with ALS in 2020. We anticipate data from these trials in 2021. ANX005 has been granted Orphan Drug and Fast Track designations from the FDA for the treatment of GBS.

ANX005 for the Treatment of GBS

Overview of Guillain-Barré Syndrome

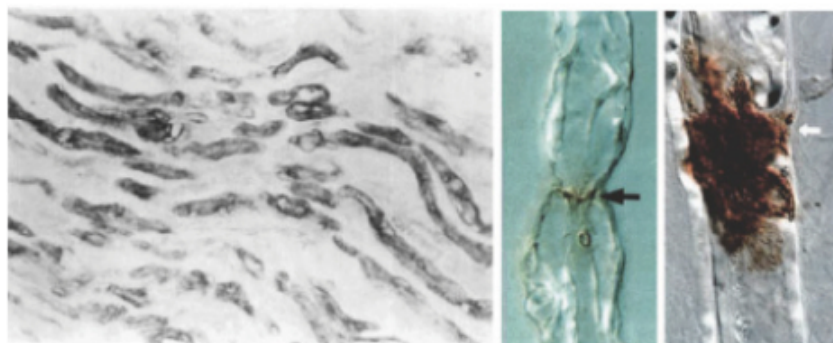
GBS is a severe acute inflammatory disease typically triggered by a preceding infection, in which aberrant auto-antibodies cause neuronal injury and acute paralytic neuropathy. In 2011, the estimated annual incidence of GBS was approximately 12,000 in North America and Europe. The economic cost of GBS is substantial, largely due to the permanent disability and mortality it can cause.

Based on 2011 estimates, the clinical course of GBS usually involves rapidly progressive weakness in the limbs culminating in neuromuscular paralysis within two to four weeks of onset. According to these estimates, 20 to 30 percent of patients require mechanical ventilation, over 20 percent have permanent motor or sensory disability and 2 to 17 percent of cases result in death globally. Many patients with GBS require extensive monitoring and supportive care and will seek treatment in a hospital within a few days of onset of the disease. Because approximately a quarter of patients need artificial ventilation, and many go on to develop autonomic disturbances, many patients need admission in an intensive care unit. Symptoms peak within four weeks, followed by a recovery period that can last months or years, as the autoantibody response decays and the nervous system repairs itself.

There are currently no therapies approved by the FDA for the treatment of GBS. Treatment guidelines published by the American Academy of Neurology recommend early initiation of IVIg or plasma exchange in patients diagnosed with GBS. IVIg and plasma exchange are the established standard of care in the Western world and parts of Asia. Although IVIg and plasma exchange have been shown to provide some benefit, significant unmet need still exists, and many patients, despite receiving the standard of care, are left with residual neurological disability, accompanied by chronic pain and fatigue.

C1q is a key driver of pathogenesis in GBS

GBS is an acute, autoimmune disease driven by antibodies that lead to activation of the classical complement cascade. Pathological nerve-targeting auto-antibodies, which may be triggered by an infection, lead to the activation of C1q and the classical complement cascade. Studies have shown that pathogenic auto-antibodies are present in the serum and that activated components of the complement cascade deposited on peripheral nerve tissue from GBS patients. The figure below illustrates the activation of the classical complement pathway within peripheral nerves in a GBS patient. The left image shows a low magnification view of a peripheral nerve from a GBS patient showing numerous individual nerve fibers coated with membrane-damaging complement activation products (C5b-9; dark staining), the middle image shows a high magnification view of an individual nerve fiber showing deposition of C3d (dark staining), a complement activation product that directs immune cell attack, and the right image shows a high power image of an individual nerve fiber being probed by an infiltrating immune cell (macrophage).



We believe that by blocking the activity of C1q early in the onset of the disease, we can minimize the neural damage caused by these pathogenic auto-antibodies, in turn reducing the patients' symptoms and accelerating their neurological recovery.

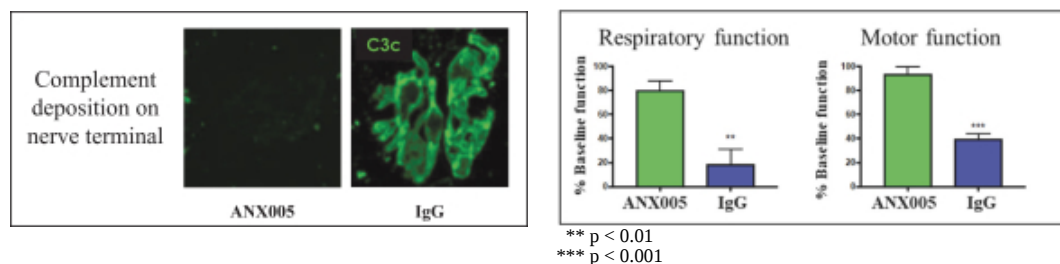
Neurofilament light chain, a marker of neurodegeneration, is highly elevated in GBS

NfL is a well-accepted biomarker of nerve damage in autoimmune disorders characterized by damaged or degenerating nerves, such as GBS, multiple sclerosis, chronic inflammatory demyelinating polyneuropathy and multifocal motor neuropathy, as well as in many chronic neurodegenerative diseases, such as HD, ALS and SMA. In these diseases, elevated NfL levels correlate with current patient disability and predict patient outcomes. Moreover, other treatments that have been clinically effective in neurodegenerative diseases have been shown to reduce NfL levels in patients.

Preclinical Development in GBS

As illustrated below, in a mouse model of severe GBS, ANX005 treatment blocked complement deposition on nerve terminals (left panel) and protected respiratory and motor function (right panel) when compared to an irrelevant immunoglobulin G, or IgG, isotype control antibody. A p-value is a measure of the statistical significance of the observed result. By convention, a p-value lower than 0.05 is considered statistically significant.

Respiratory and motor function



Phase 1a Trial in Healthy Volunteers

ANX005 was initially evaluated in a Phase 1a dose-escalation single-dose trial designed to assess safety, pharmacokinetics and pharmacodynamics. This trial was conducted in 27 healthy volunteers in Australia. The dosing levels of ANX005 delivered in this trial ranged from 1 mg/kg to 8.2 mg/kg. We terminated the trial in healthy volunteers and transitioned our clinical development to test ANX005 directly in patients with GBS.

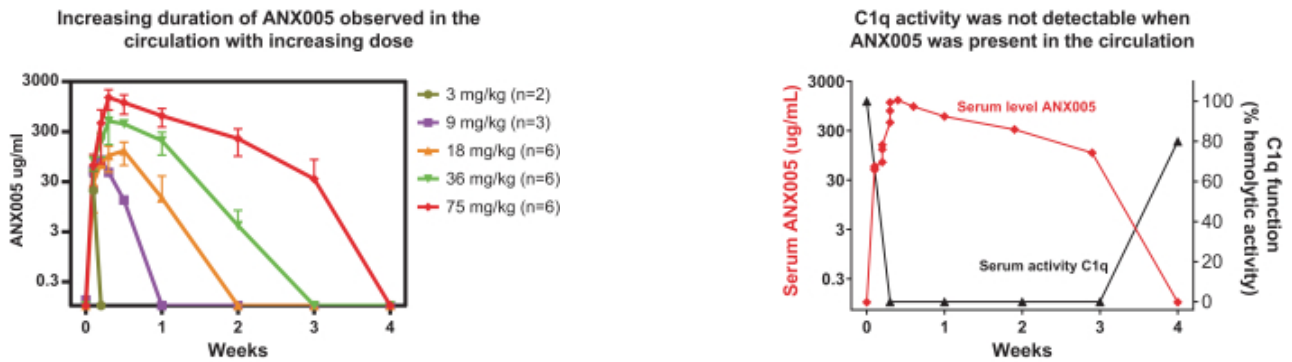
Phase 1b Trial in GBS Patients

We have closely coordinated our clinical efforts with leading researchers of the International GBS Outcomes Study, or IGOS, in pursuing a novel therapy for GBS. In order to achieve the goal of developing a better treatment, practitioners established IGOS, which has collected natural history data from over 1,750 newly-diagnosed GBS patients worldwide. IGOS is a prospective, observational, multicenter cohort trial that aims to identify the clinical and biological determinants and predictors of disease onset as well as the subtype, course and outcome of GBS. IGOS was established to help develop a better understanding of the mechanism of disease progression and recovery and to conduct selective therapeutic trials to improve patient outcomes. This natural history database is an invaluable resource to clinical development, facilitating the design of clinical trials and the optimal selection of endpoints, and has followed GBS patients for over seven years. We initiated our GBS clinical development in Bangladesh, a country where the incidence of GBS is several times higher than in North America and Europe and where 17% of patients die from the disease and 20% suffer permanent disability and are unable to walk. Bangladesh has enrolled more patients in IGOS than any other country, representing approximately 15% of all enrolled patients worldwide.

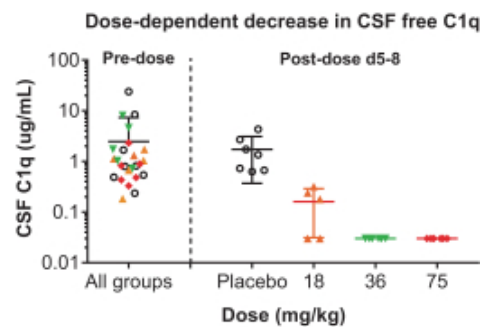
We conducted a Phase 1b placebo controlled, dose escalation trial (n=31) of ANX005 in GBS patients at a tertiary care hospital in Bangladesh, in compliance with good clinical practice, or GCP. The trial objectives included safety and tolerability, dosing levels and target engagement, and included a follow up of eight weeks. ANX005 was well tolerated, and no drug-related serious adverse events or drug-related discontinuations occurred. The most common adverse events were infusion-related reactions, or IRRs, which occurred in the majority of patients and presented as low grade, non-serious, transient skin rash. These IRRs were mitigated by standard anti-inflammatory pre-medications and slowly administering ANX005 until saturation of endogenous C1q was reached.

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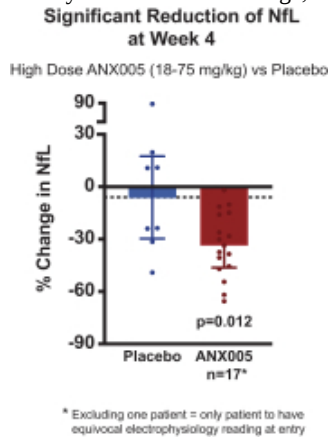
Results from the Phase 1b trial showed increasing serum levels of ANX005 and its duration in the circulation at increasing dose levels, and that the drug was present in the serum for up to three weeks at a dose of 75 mg/kg (left panel). When ANX005 was present in the circulation C1q function was fully inhibited, and rapidly returned to normal levels as ANX005 serum levels declined (right panel showing data from a patient receiving 75 mg/kg).



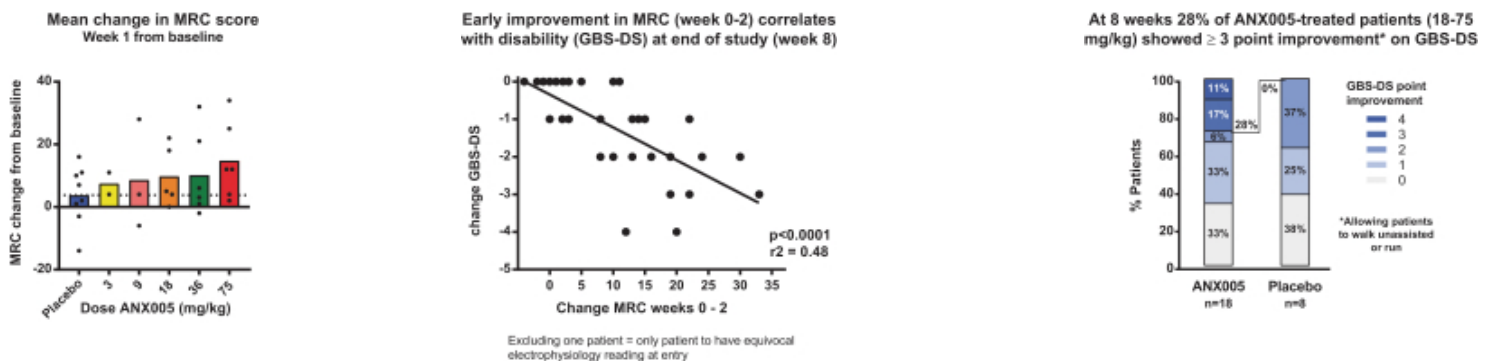
Much of the proximal weakness in GBS patients is due to involvement of peripheral nerve roots that are immersed in CSF as they exit the spinal cord. Hence, we believe product candidate levels and target inhibition in CSF may be an important contributor to efficacy. We observed that ANX005 entered the CSF of GBS patients treated with doses of 18-75 mg/kg of ANX005, resulting in full engagement of C1q inhibition in the CSF (as shown below).



In the Phase 1b trial in GBS patients, ANX005 treatment at doses that engaged C1q in both serum and CSF (i.e., 18-75 mg/kg dose) resulted in an early decline in serum NFL levels compared to placebo (with a statistically significant p-value of 0.012). We believe these results suggest that ANX005 had a rapid impact on the disease process by ameliorating antibody-induced nerve damage, likely within the first two weeks of dosing.



In this Phase 1b trial, we also explored the administration of ANX005 on multiple validated clinical disability measures including GBS-Disability Score, or GBS-DS, Medical Research Council Muscle Strength Scale, or MRC, and Inflammatory Rasch-built Overall Disability Scale, or I-RODS over an eight-week period. Though the trial was not powered for statistically significant improvement for the efficacy measures, treatment with ANX005 resulted in consistent, positive numerical trends. We observed an improvement in the number of days of ventilation, and a dose-dependent improvement in MRC within the first week of treatment as shown below (left panel). Early improvement in MRC is known to have strong prognostic implications on long-term functional recovery (modified Erasmus Outcome Score). In line with this published data, we found that early improvement in MRC correlated significantly ($p < 0.0001$) with patients' disability scores at the end of the Phase 1b trial (GBS-DS at week eight; middle panel). This result is important because GBS-DS is typically used as the primary endpoint in GBS registration studies. In addition, using a responder analysis, 28% of patients treated with high dose ANX005 (18-75 mg/kg) improved by at least three points on GBS-DS compared to 0% of placebo-treated patients (right panel). Patients treated with ANX005 showed a trend of improvement on GBS-DS when using a mean analysis. Both results are promising but not statistically significant. We intend to present the findings from our Phase 1b trial at a future medical meeting.



*r2 is a statistical measure for the correlation of two variables (ranging from 0 for no correlation to 1 for high correlation).

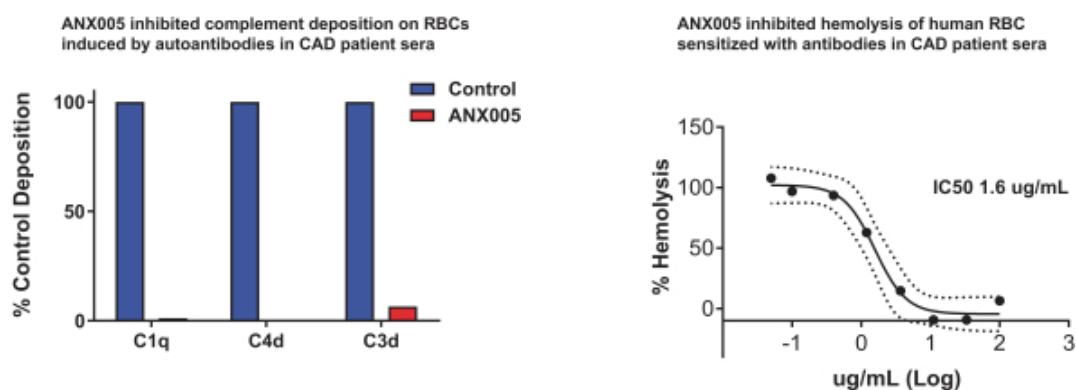
Ongoing Development of ANX005 for GBS

Based on topline results from our Phase 1b trial, we intend to initiate a Phase 2 monotherapy trial of ANX005 in GBS in the first half of 2020. We have initiated a Phase 1b DDI trial of ANX005 with IVIg, in preparation for a global Phase 3 pivotal trial, evaluating the benefit of ANX005 in combination with IVIg. ANX005 has received both Orphan Drug and Fast Track designations from the FDA for the treatment of GBS.

ANX005 for Future Autoimmune Indications

Beyond GBS, we also intend to study ANX005 in specific subsets of patients with autoimmune hemolytic anemias, or AIHA, characterized by the presence of auto-antibodies that bind red blood cells and activate the classical complement pathway. The temperature at which these auto-antibodies agglutinate red blood cells determines whether the hemolytic anemia is labelled “cold” or “warm.” Activated complement components (e.g., C3d, C4d) label red blood cells for removal in the spleen or liver (extra-vascular hemolysis) and less commonly direct lyse red blood cells in the blood vessels by the classical complement generated membrane attack complex (intravascular hemolysis). The “cold” forms of AIHA are known to be complement-mediated disorders, while a subset of patients with the “warm” form of AIHA are hypothesized to have complement-dependent disease. It is estimated that less than 5,000 people have the cold form while approximately 30,000 people have the warm form of AIHA in the United States. There are no approved treatments for AIHA in the United States; however, blood transfusions, steroids, Rituxan, chemotherapies and splenectomies are currently used to treat patients with AIHA. It is estimated that up to 30% of patients require second-line treatment when treated with the standard of care treatment and approximately 11% of cases after symptom onset result in death.

We have found that ANX005 inhibited complement deposition on human red blood cells (left panel) and prevented direct red blood cell lysis (right panel) induced by sera from CAD patients as *ex vivo* models of extravascular and intravascular lysis, respectively.



We have observed in both preclinical studies and in our Phase 1b trial in patients with GBS that treatment with ANX005 resulted in near complete inhibition of complement-mediated hemolysis. Thus, we believe that ANX005 may be able to achieve near complete suppression of complement-mediated hemolysis in patients with wAIHA.

We plan to initiate a Phase 2 trial in wAIHA patients, who are enriched for complement-mediated pathology in 2020. This open label trial will evaluate safety, tolerability, PK, pharmacodynamic impact and efficacy, as measured by biomarkers of hemolysis and changes in hemoglobin. We anticipate data from this trial in 2021.

ANX005 for the Treatment of Huntington's Disease

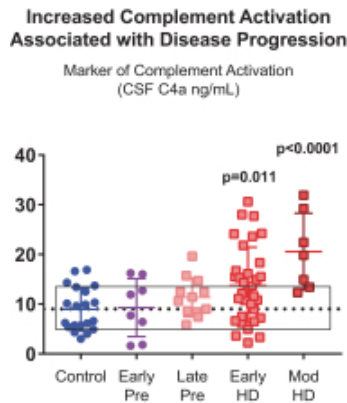
Overview of Huntington's Disease

HD is an orphan hereditary neurodegenerative disease that is fatal and for which there are no approved treatments that can reverse or slow its course of progression. HD symptoms typically begin to manifest between the ages of 30 to 50 and progress as a devastating neurodegenerative disorder characterized by abnormal involuntary movements, known as chorea, spreading to all muscles, progressive dementia and psychiatric manifestations such as depression and psychosis. Ultimately, affected individuals succumb to cardio-respiratory complications. Life expectancy after symptom onset is approximately 10 to 20 years. Some of the symptoms of HD such as chorea and depression can be managed with medications.

Approximately 25,000 to 35,000 people in the United States have HD. Estimates project that approximately 75,000 people in the United States and other major market countries will have HD by 2025. Because HD is a genetic disease in which an individual with a single copy of the dysfunctional gene will develop the disease, every child of a parent with HD has a 50 percent chance of inheriting the faulty gene and developing the disease. There are an estimated 200,000 individuals in the United States who have a 50 percent risk of developing HD because of their family relationship to HD patients. It is estimated that only five to seven percent of these at-risk individuals have voluntarily undergone genetic testing due to the devastating nature of the disease and the lack of any effective treatments. The development of a disease-modifying therapy could encourage at-risk patients to seek out testing and thereby both provide hope to gene carriers and expand the number of patients who may benefit from treatment.

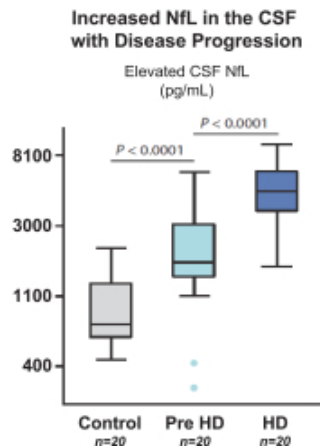
C1q is a key driver of pathogenesis in HD

HD is caused by a mutation in the huntingtin gene, which is thought to produce a mutant neurotoxic protein that promotes the degeneration of neurons. The classical complement cascade is activated in HD patients and is associated with progressive synapse loss. We hypothesize that C1q plays an important role in the degenerative process by tagging weakened synapses and triggering a neuroinflammatory response that leads to aberrant synapse loss and progressive neuronal destruction. As shown below, we observed that increased complement activation was associated with disease progression (as measured by C4a levels in CSF).



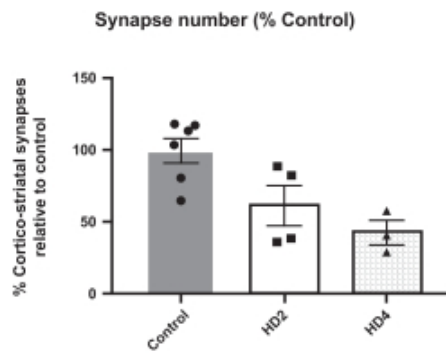
NfL is elevated in HD patients

Both serum and CSF NfL levels were found to be elevated in HD patients compared to healthy controls, consistent with other neurodegenerative diseases. In addition, NfL levels reflected both current disability and future patient outcomes.



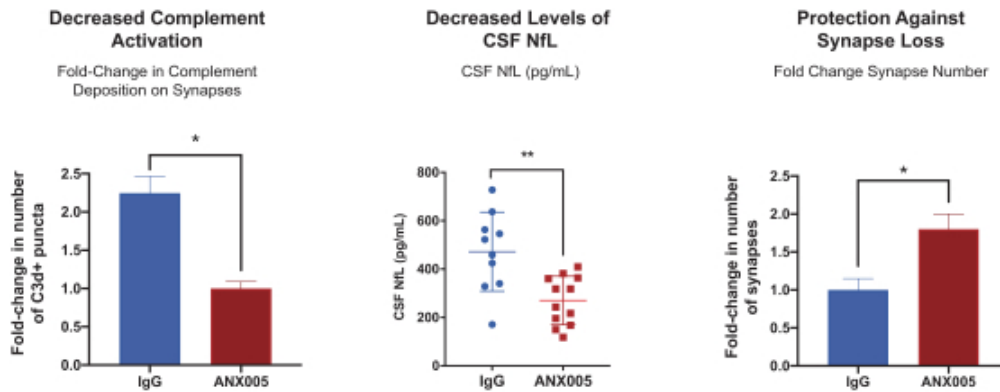
Progressive synapse loss in HD patients

As shown below, researchers observed in post-mortem tissue from HD patients significantly less cortico-striatal synapses than in healthy controls, with patients more advanced in the disease process (Huntington's disease stage 4) showing greater loss of synapses than earlier stage patients (Huntington's disease stage 2).



ANX005 protected against synapse loss and reduced NfL in a preclinical model of HD

In a transgenic mouse model of HD, we assessed the potential of peripherally administered ANX005 to inhibit activation of the classical complement cascade and protect against synapse loss. As shown below, ANX005 treatment reduced the amount of activated complement factor C3d that was deposited on synapses (striatum, left panel), reduced CSF levels of NfL (middle panel), and reduced the loss of synapses (right panel). We believe these three lines of evidence support the hypothesis that ANX005 blocks complement-mediated neurodegeneration in HD and can lead to preservation of neuronal synapses.



* p < 0.05
** p < 0.01

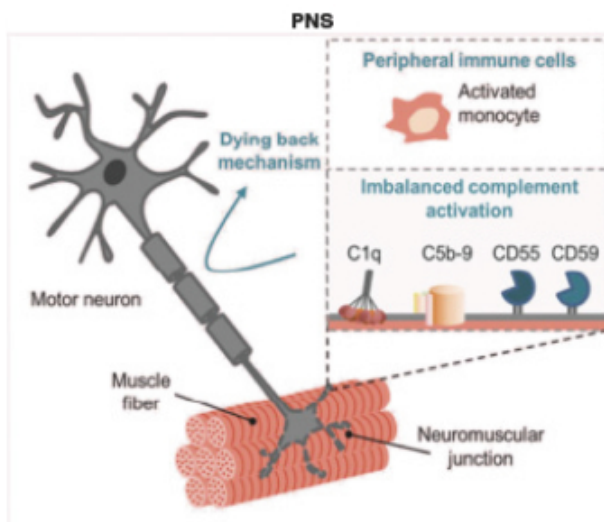
Development of ANX005 in HD

We are planning to file an IND for ANX005 in HD and initiate a three-month Phase 2a trial in HD patients in the first half of 2020. This open-label trial would evaluate ANX005's ability to inhibit C1q in the CSF and to reduce levels of serum and CSF NfL, a marker of neurodegeneration with prognostic significance.

ANX005 for the Treatment of ALS

Overview of ALS

ALS is a devastating neurodegenerative disease with no curative treatment that affects about 30,000 patients worldwide. The disease is a motor neuron disease impacting both the central and peripheral nervous systems. ALS causes progressive weakness of limb, respiratory, swallowing and speaking muscles, and death typically occurs within two to five years after symptom onset. There is evidence that neurodegeneration begins peripherally, at the neuromuscular junction, or NMJ, and then proceeds proximally to involve the peripheral motor nerves, ventral nerve roots, spinal cord and brain motor cortex (“dying back” neurodegeneration). The NMJ is a specialized synapse between peripheral motor nerve and muscle fiber. As illustrated below, “dying back” of the peripheral nerve in ALS is associated with C1q / classical complement deposition on the NMJ.

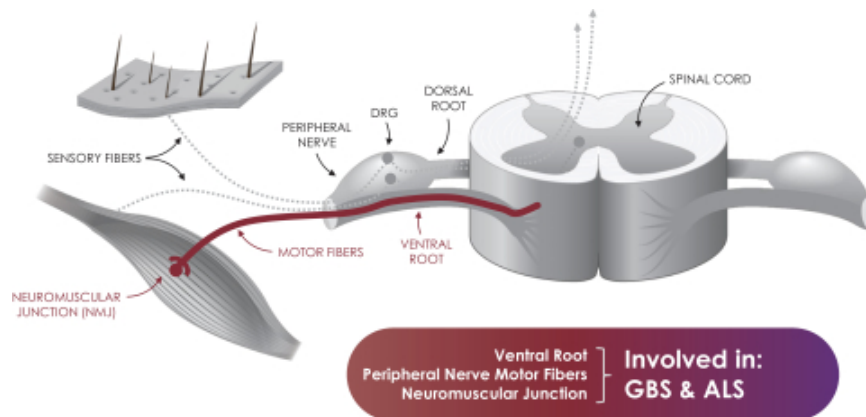


C1q involvement in ALS

C1q and classical pathway activation is elevated in ALS patients. Specifically, C1q deposition has been noted in NMJs and C4d levels are increased in the CSF of ALS patients. In preclinical models of ALS, the amount of C1q deposition in NMJs correlated with weakness of the animals. Our goal with our C1q inhibitor is to prevent loss of NMJs and hence prevent “dying back” neurodegeneration of motor nerves in patients with ALS. Of note, there is significant overlap in the peripheral nerve structures that are involved in both GBS and ALS; therefore, we believe our ANX005 pharmacokinetics and pharmacodynamics data in GBS patients can be extrapolated to ALS patients.

Likewise, in an experimental model of SMA, another peripheral nerve degenerative disease that is pathologically similar to ALS, we found that treatment with anti-C1q antibody (mouse precursor of ANX005) protected against synapse loss and improved motor function. The same peripheral nerve pathway is involved in GBS and ALS, as illustrated below.

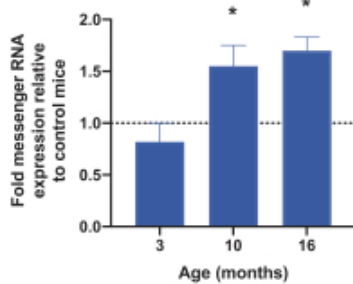
The same peripheral nerve pathway is involved in GBS and ALS



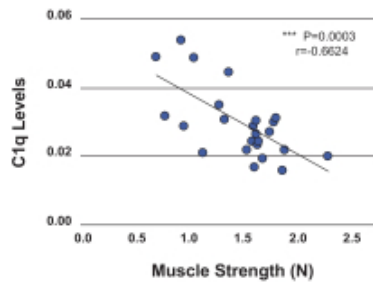
Development of ANX005 in ALS

ALS patients have substantial elevations of NfL in both CSF and serum, and it has been observed that NfL levels in ALS patients correlated both with current disability and future patient outcomes. As shown below, muscle levels of C1q increased with age (left panel) and were observed to correlate with decline in muscle strength (middle panel). The right panel shows that in ALS patients, serum levels of NfL increase in the year prior to onset of disease symptoms.

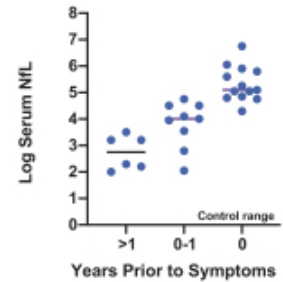
C1q Upregulation in ALS Mouse Muscles with Age



C1q Levels in Muscle Correlate with Muscle Weakness



Serum NfL Elevated in ALS Patients a year prior to symptom onset



* $p < 0.05$

We are planning to initiate a three-month, open-label Phase 2a trial in ALS patients in 2020 to evaluate ANX005's ability to inhibit C1q in the CSF and to reduce NfL levels in serum and CSF in ALS patients. Based on the results of this trial, we will evaluate whether to initiate a potential registrational program for ALS.

If either of the HD or ALS Phase 2a trials are successful, we will consider proof-of-concept studies in other CNS neurodegenerative indications, such as Alzheimer's disease and progressive multiple sclerosis.

Our Second Product Candidate, ANX007

ANX007 is an investigational monoclonal antibody antigen-binding fragment, or Fab, that is designed to potently bind to C1q and inhibit activation of the classical complement cascade. We filed an IND for ANX007 in 2018 and are developing ANX007 as an intravitreal injection for ophthalmic indications such as glaucoma and geographic atrophy. We have conducted a Phase 1b trial of ANX007 in patients with glaucoma, and based on these and preclinical study results, we believe ANX007 may have potential to treat patients with GA.

ANX007 for the Treatment of Ophthalmic Diseases, including Glaucoma and Geographic Atrophy

Overview of Glaucoma

Glaucoma is a major cause of blindness and results from progressive loss of neurons in the retina called Retinal Ganglion Cells, and optic nerve degeneration. A frequent risk factor for glaucoma is elevated intraocular pressure, or IOP, but there are patients with “normotensive” glaucoma who have normal IOP. Patients with glaucoma have progressive loss of peripheral vision, which can eventually result in functional blindness.

It is estimated that over three million people in the United States have glaucoma but only half of these people have been diagnosed. More than 120,000 people in the United States are blind due to glaucoma, accounting for 9 to 12% of all cases of blindness. The worldwide prevalence of glaucoma has been estimated to be over 60 million people. Glaucoma is a disease that is more frequently found in older adults with rates increasing several fold between ages 50 and 70. Similar to other neurodegenerative diseases, the overall prevalence of glaucoma is projected to increase as populations age worldwide.

Glaucoma is one of the largest segments of the global ophthalmic market and has a significant impact on the quality of life. Patients’ ability to perform daily activities becomes increasingly limited as the disease progresses. Individuals with glaucoma are more likely to experience falls, to be involved in motor vehicle collisions, to suffer depression and to require admission to a nursing home.

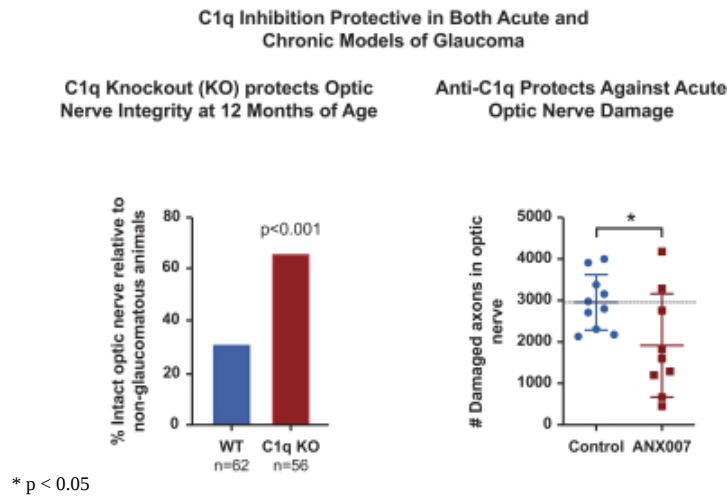
The goal of existing therapies for glaucoma is reduction of IOP. IOP-lowering treatments are typically administered in the form of eye drops, and patients may require surgery to facilitate drainage of fluid in the eye. However, approximately ten percent of people who receive appropriate treatment nevertheless continue to experience progressive vision loss. The optic nerve damage observed in glaucoma is believed to be irreversible, highlighting the need for neuroprotective therapies that can slow or stop the damage to optic nerves.

Role of C1q in Glaucoma

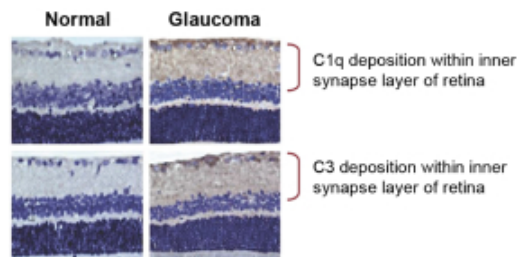
C1q, the initiating molecule of the classical complement cascade, has been implicated in the progression of neurodegenerative disease, including glaucoma. The lab of our scientific founder, Dr. Ben Barres, reported that C1q accumulated on retinal neurons and their synapses early in the disease process in a chronic mouse model of glaucoma, before the onset of other observable changes. C1q accumulation continued as synapses were lost, followed by loss of the optic nerve. Subsequent studies showed that genetic deletion of C1q protected against optic nerve damage in a chronic mouse model of glaucoma at 12 months of age (left panel, figure below).

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Using pharmacological inhibition of C1q with ANX007, we observed these findings in a different mouse model of glaucoma involving acute elevation of IOP. In this model, animals received an intravitreal injection of the M1-Fab murine precursor of ANX007 at the time of IOP elevation, followed by a second dose one week later, and their retinas were examined at week 2. As shown in the right panel of the figure below, intravitreal administration of ANX007 protected against optic nerve damage.



Independent investigators observed elevated levels of C1q and other components of the classical complement cascade in the inner retinal synapse layer of 34 out of 34 human donor eyes from patients with glaucoma, as illustrated below. C1q was not found in donor eyes from individuals who did not have glaucoma.



Overview of Geographic Atrophy

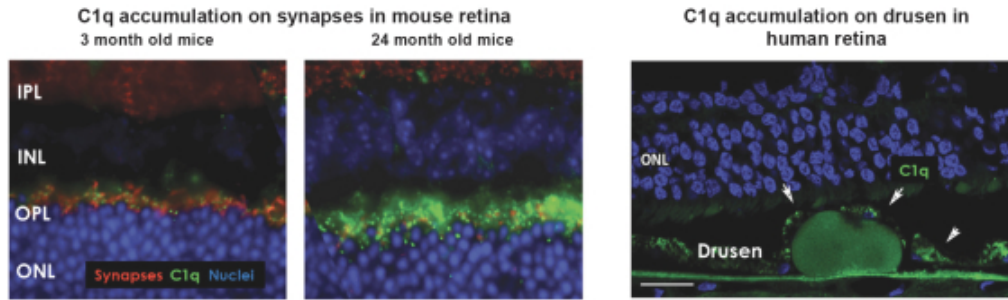
GA is an advanced, vision-threatening form of age-related macular degeneration, or AMD, and is a chronic, progressive disease of the macula that results in loss of central vision. The disease typically affects one eye first, with a high likelihood of it occurring in the second eye over time.

There are two forms of AMD, “dry” AMD and “wet” AMD. Dry AMD is the most common form, representing approximately 85% to 90% of all AMD cases. Geographic atrophy represents the advanced form of dry AMD and is characterized by progressive atrophy of retinal pigment epithelial cells, overlying photoreceptors and underlying choriocapillaries. An early feature of the disease is the presence of drusen, which is comprised of extracellular yellow deposits at the back of the retina.

GA accounts for about ten percent of legal blindness related to AMD. Approximately one million individuals in the United States and five million individuals worldwide suffer from geographic atrophy. As with AMD, the prevalence of geographic atrophy increases with age. There are no approved therapies to prevent either the onset or progression of geographic atrophy.

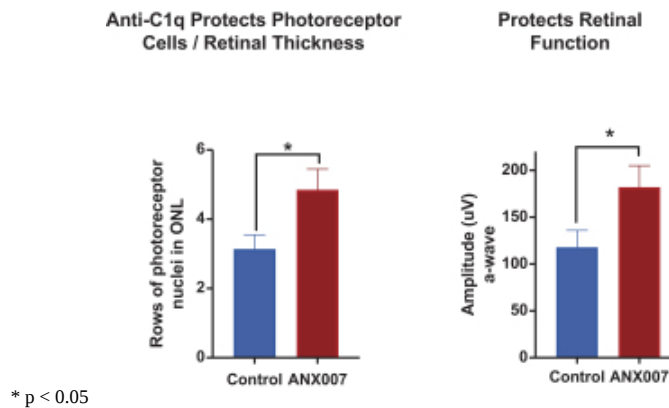
Role of C1q and Complement in Geographic Atrophy

Genome-wide association studies have strongly implicated multiple components of the complement cascade in AMD and geographic atrophy. For example, specific alleles of the gene for C3 can increase the likelihood of developing AMD by 50 percent. Histopathological investigations have also observed the presence of complement components in geographic atrophy. These studies largely point to a role of excessive C3 activity in disease, but do not indicate how C3 is being activated (classical, lectin or alternative pathways). We have identified a potential dual role of C1q and the classical cascade as an important complement-activating system in geographic atrophy. First, we found that C1q strongly accumulated on photoreceptor cell synapses with normal age or disease, as shown below (left panels), implicating C1q's role in excessive synapse pruning and complement-mediated neurodegeneration. Second, C1q and C1q ligands, such as C-reactive protein, also accumulated in the retina below photoreceptor cells in association with drusen (extracellular membrane and protein debris associated with geographic atrophy; right panel). These results suggest that the photoreceptor neurons and pigmented retinal epithelial cells – cell types that are both lost in GA – are sandwiched between deposits of C1q and that the classical complement cascade may have an ongoing and pathogenic role in GA by activating C3.



In support of this hypothesis, we found that either deletion or pharmacologic inhibition of C1q was protective in an animal model of photoreceptor neuron loss induced by photo-oxidation, as shown below. Further, components of the classical complement cascade have been associated with photoreceptor cells in human GA tissue (C4 and C3) and implicated in photoreceptor cell targeting with an *in vitro* assay. Finally, C1q is locally produced within the retina during disease by infiltrating immune cells, indicating that its pathogenic role may be amenable to local inhibition of C1q. As described above, we believe inhibition of C1q would block all key components of the classical cascade, including C1q, C4, C3 involved in immune cell attack and synapse pruning, as well as C5 involved in direct membrane damage.

As shown below, C1q inhibition was protective of photoreceptor cells and retinal function in a model of GA.



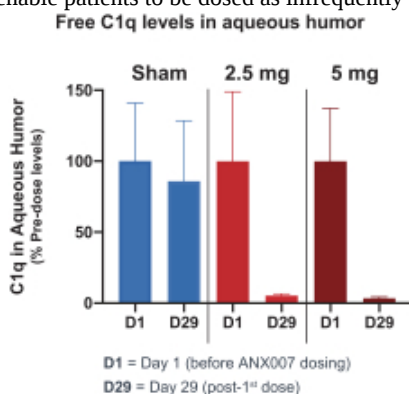
Development of ANX007 for Ophthalmic Diseases

We have completed a Phase 1b trial of ANX007 in patients with glaucoma. Based on our Phase 1b clinical results in glaucoma, our preclinical data showing protection in three retinal neurodegeneration animal models (glaucoma, optic neuritis and GA), and our knowledge of C1q biology in this setting, we are planning a Phase 2 trial in glaucoma or GA in 2020. Our rationale to pursue ANX007 for GA includes:

- The classical complement pathway is implicated in GA by human genetics, as C1q and C4 are associated with pathology in human GA tissue. C1q is produced locally in the eye by infiltrating immune cells and may be more amenable to local inhibition by intravitreal administration of ANX007.
- The potential role of C1q in GA may be dual-purpose, resulting in both complement-mediated neurodegeneration and localized tissue damage unique to the eye. Local administration of ANX007 has been shown to be protective in animal photoreceptor neuron loss and achieved complete C1q inhibition in patients for 1-2 months.
- There is a well-established clinical and regulatory path for development.

Phase 1b Trial in Glaucoma

We completed single ascending dose (n=9) and sham-controlled multiple dose (n=17) studies of intravitreal ANX007 in patients with glaucoma to evaluate safety, tolerability, pharmacokinetics and target engagement. These patients had aqueous humor taps so that ocular fluid could be analyzed for levels of ANX007 and free C1q immediately prior to first dose (day 1) and prior to second dose (day 29). The studies showed that ANX007 was well-tolerated at all doses (1 mg, 2.5 mg, 5 mg) and achieved complete suppression of C1q at 2.5 mg and 5 mg, as illustrated below. We believe these results suggest that ANX007 can be dosed monthly or potentially less frequently in future Phase 2 efficacy trials in glaucoma or geographic atrophy. We are exploring further development of ANX007 that could enable patients to be dosed as infrequently as every six months.



Planned Phase 2 Trial in Glaucoma or Geographic Atrophy

We are planning a randomized, controlled Phase 2 trial in glaucoma or GA patients who are at a high risk of progression. Prior natural history data similar to that found in other recent large Phase 3 trials may provide a wealth of natural history data from nearly 2,000 patients on how to successfully enrich fast progressors of GA to enable an efficacy read-out within a one-year time period. Our Phase 2 GA trial would be designed to show clinical effect on slowing of GA lesion growth, leveraging the natural history data and patient selection criteria of prior GA trials.

Our Third Product Candidate, ANX009

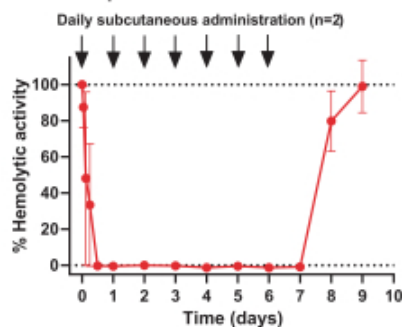
ANX009 is designed to potently bind to C1q and inhibit activation of the classical complement cascade. ANX009 is designed for subcutaneous delivery, and we are currently evaluating the product candidate in preclinical toxicology studies. We intend to advance ANX009 through IND-enabling studies, select our initial lead autoimmune disease indication and commence a FIH clinical trial in healthy volunteers in 2020. We anticipate data from the healthy volunteer trial in 2020 and to initiate a Phase 2 trial in the autoimmune indication in 2021.

Future ANX009 Indications

We are developing ANX009 to potentially enable chronic dosing in autoimmune hemolytic anemias, such as wAIHA and CAD. In addition, we are evaluating ANX009 as a chronic treatment option for a subset of lupus nephritis patients who are at a high risk of renal flare due to pathogenic anti-C1q antibodies in the circulation, and who may likely respond to treatment with our anti-C1q approach.

We have observed that daily subcutaneous administration of ANX009 fully inhibited C1q functional activity in the serum of non-human primates. Its activity occurred rapidly after the first dose and this activity rapidly reversed after dosing was stopped.

Daily subcutaneous administration of ANX009 fully inhibits C1q in the circulation of non-human primates



We believe that ANX009's inhibitory activity and its on/off function may benefit patients with hematological autoimmune disorders.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, new therapeutic approaches and potential indications, and other inventions that are important to our business. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important for the development and implementation of our business. We also rely on the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on confidentiality agreements to protect our interests. We generally require our employees, consultants, scientific advisors and contractors to enter into confidentiality agreements prohibiting the disclosure of confidential information and requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our patent portfolio includes patents and patent applications that are licensed to us in whole or in part from a number of partners, including Stanford University and the University of California, and patents and patent

applications that are owned by us. Our proprietary technology has been primarily developed by in-house research and development programs, and to a lesser extent through acquisitions, relationships with academic research centers and contract research organizations.

For our product candidates, we will, in general, initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including by protecting inventions related to additional methods of use, processes of making, formulation and dosing regimens.

We hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates, which allow us to strategically maximize value from our product portfolio over time. Our patent portfolio includes patent protection for our upstream complement platform and each of our product candidates. In total, our patent portfolio, including patents licensed from our partners, comprises 11 different patent families as of October 31, 2019, filed in various jurisdictions worldwide. Our patent portfolio includes issued patents and patent applications in the United States and in many international countries.

One patent family, which we exclusively license from Stanford University, includes nine granted U.S. patents covering various methods of treating neurodegeneration and related medical conditions by inhibiting the C1 complex or its components, such as by using an anti-C1q antibody. The U.S. patents in this family, which include claims broadly covering uses of ANX005 and ANX007, expire between 2026 and 2030. There are no pending applications or foreign patents in this family.

Two other patent families, which we own, are directed to anti-C1q antibodies and methods of using them. These families include three granted U.S. patents, two pending U.S. patent applications, one granted foreign patent and 30 pending foreign patent applications. The granted patents in these families cover ANX005 and ANX007 and expire between 2034 and 2037. Another patent family that we own, which includes one pending U.S. patent application and 13 pending foreign patent applications, includes claims directed to antibody fragments of anti-C1q antibodies, including ANX007, and methods of using them. Patents that may be issued from these applications would expire in 2036, absent any disclaimers, extensions or adjustments of patent term.

Our patent portfolio also includes five patent families, owned by us solely or jointly with the University of California, directed to the treatment of certain medical conditions using anti-C1q antibodies, including ANX005 and ANX007. These families include five pending U.S. patent applications, one granted foreign patent, and 14 foreign patent applications. Patents that may be issued based on these applications would expire between 2034 and 2040, absent any disclaimers, extensions or adjustments of patent term.

Exclusive (Equity) Agreement with The Board of Trustees of the Leland Stanford Junior University

In November 2011, we and The Board of Trustees of the Leland Stanford Junior University, or Stanford, entered into an exclusive licensing agreement, or the Stanford Agreement. Under the Stanford Agreement, Stanford granted to us an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights, or the Licensed Patents, to make, use, offer for sale, sell, import and otherwise commercialize products covered by the Licensed Patents for human or animal diseases, disorders or conditions. We are required to meet certain development and funding diligence milestones for the licensed products.

Under the Stanford Agreement, we are obligated to pay Stanford an upfront payment, license maintenance fees ranging from the single digit to tens of thousands of dollars per year, and milestone payments totaling up to \$675,000. We also agreed to make royalty payments at a rate equal to a low single-digit percentage of worldwide net sales of licensed products and a portion of certain sublicensing income we receive from sublicensees at a rate in the low double digit percentages, subject to a specified maximum total payment. Additionally, in accordance with the terms of the Stanford Agreement, upon closing our first financing event that raised at least \$2.0 million, we granted Stanford \$150,000 in shares of our redeemable convertible preferred stock. We may also have to pay a fee to Stanford if we assign our rights under the Stanford Agreement to a third party.

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We may terminate the Stanford Agreement in its entirety, or as to a particular Licensed Patent or licensed product, for convenience on thirty days' prior written notice. Stanford may terminate the Stanford Agreement for our breach that remains uncured for forty-five days or if we provide any false report, are delinquent on any report or payment, fail to achieve a milestone or fail to diligently develop and commercialize a licensed product.

Patent Term and Term Extensions

The terms of individual patents are determined based primarily on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the United States Patent and Trademark Office, or USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval for the product covered by that patent. In addition, only one patent applicable to an approved drug may receive the extension, and the extension applies only to coverage for the approved drug, methods for using it and methods of manufacturing it, even if the claims cover other products or product candidates. Where one patent covers multiple products or product candidates, it may only receive an extension for one of the covered products; any extension related to a second product or product candidate must be applied to a different patent. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date of a non-provisional patent application, such as a Patent Cooperation Treaty, or PCT, application. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product by product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Trademarks and Know-How

In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. In addition to patent and trademark protection, we rely upon know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by our employees and through relationships with third parties. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Sales and Marketing

We hold worldwide commercialization rights, including through exclusive licenses, to our product candidates. Given our stage of development, we have not yet established a commercial organization or distribution capabilities. Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs.

Manufacturing

Our success as a company will depend on our ability to deliver reliable, high-quality preclinical and clinical drug supply. We do not currently own or operate facilities for product manufacturing, storage and distribution, or testing. We contract with third parties for the manufacture of our product candidates. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical and quality experience. Our staff has strong project management discipline to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Manufacturing is subject to extensive regulation that imposes various procedural and documentation requirements and that governs record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, and more. Our systems and our contractors are required to be in compliance with these regulations, and compliance is assessed regularly through monitoring of performance and a formal audit program.

Our current supply chains for our lead drug candidates involve several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product manufacturing. We currently operate under work order programs for our drug candidates with master services agreements in place that include specific supply timelines, volume and quality specifications. We intend to establish long-term supply agreements in the future. We believe our current manufacturers have the scale, the system, and the experience to supply our currently planned clinical trials.

We do not currently require commercial manufacturing capabilities. Should our needs change, we will need to scale up our manufacturing processes to enable commercial launch. To ensure continuity in our supply chain, we plan to establish supply arrangements with alternative larger scale suppliers for certain portions of our supply chain, as appropriate.

Competition

The pharmaceutical, biopharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical, biopharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing 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 programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Guillain-Barré Syndrome

There are currently no approved therapies for GBS in the United States. IVIg and plasma exchange are the current standard of care in the Western world and parts of Asia. Hansa Biopharma AB began an open label Phase 2 trial in GBS patients in the second quarter of 2019.

Warm Autoimmune Hemolytic Anemia

There are currently no approved therapies for wAIHA in the United States. Apellis is running a Phase 2 clinical trial using APL-2 in cold agglutinin diseases, or CADs, and wAIHA. Other companies who are running clinical trials in these rare anemias include Alexion in Phase 2 with SYNT001 and Rigel in Phase 3 with Fostamatinib.

Huntington's Disease

There are no known cures for HD. Companies such as Ionis, Takeda, Wave Life Sciences, Voyager Therapeutics, uniQure and Hoffman La Roche are conducting clinical trials with products that are gene silencing in order to attempt to lower the level of the mutant huntingtin protein in patients to investigate whether this will translate to benefits for people with HD.

Amyotrophic Lateral Sclerosis

There are no known cures for ALS. The drug riluzole is currently approved for treatment and has shown modest affect in slowing the progression of the disease. We are aware that Alexion may begin an exploratory Phase 2 trial of Ultomiris, a long acting C5 inhibitor for ALS. There are many companies conducting clinical trials in ALS patients including MediciNova, Astellas, Biogen, Mitsubishi Tanabe, Ono Pharmaceuticals and others.

Glaucoma

There are many approved treatments to relieve increased intraocular pressure in glaucoma. There are no FDA-approved treatments currently available for the retinal degeneration that is observed in glaucoma patients.

Geographic Atrophy

No FDA-approved treatment is currently available for GA. We are aware of a number of companies developing products for the treatment of GA. Those products in clinical development include: CLG561, an anti-properdin monoclonal antibody in Phase 2 trials as a single agent and in combination with LFG316, an anti-C5 antibody being developed by Novartis AG; and Zimura, a C5 inhibitor in Phase 2/3 clinical trials, is being developed by IVERIC bio, previously Ophthotech Corporation. Other products that do not target the complement cascade that are in Phase 2 clinical trials are being developed by Allergan PLC and Regenerative Patch Technologies.

Government Regulation

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

U.S. Biologics Regulation

In the United States, our product candidates are regulated as biologic pharmaceuticals, or biologics. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements, or GLPs;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before clinical trials may begin;
- approval by an institutional review board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application, or BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed products is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the 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

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health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- 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, the side effects associated with increasing doses, and, if possible, to gain early evidence on 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 establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 trials may also be made a condition to approval of the BLA.

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

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product or from a number of alternative sources, including studies and trials initiated by investigators. The submission of a BLA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA is also subject to an annual program fee. A waiver of user fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on BLAs for products designated as Orphan Drugs, unless the product also includes a non-orphan indication.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA

accepts the application for filing. Priority review designation will direct overall attention and resources to the evaluation of applications for products that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions regarding approval.

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 are in compliance with and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter 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 Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase IV post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and

biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. For a Fast Track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. A Fast Track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious disease or condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

In addition, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a product candidate as a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of Fast Track designation.

Fast Track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant Orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000

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individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan Drug designation must be requested before submitting a BLA. After the FDA grants Orphan Drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

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

A designated Orphan Drug may not receive Orphan Drug exclusivity if it is approved for a use that is broader than the indication for which it received Orphan designation. In addition, Orphan Drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with Orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, 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 prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;

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- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

Biosimilars and Exclusivity

The ACA, signed into law in 2010, includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being developed by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. 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.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state fraud and abuse laws, including anti-kickback, false claims, civil monetary penalties laws and consumer protection and transparency laws as well as similar foreign laws in the jurisdictions outside the United States. For example, the federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act and the civil monetary penalties statute. The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; 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 and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or that require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of

which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, additional reporting obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and individual imprisonment.

Data Privacy and Security Laws

Pharmaceutical, biopharmaceutical and biotechnology companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. State laws may be more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than HIPAA, and state laws may differ from each other, which may complicate compliance efforts. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the Department of Health and Human Services, or HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. In addition, California enacted the California Consumer Privacy Act, or CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted.

European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the European Economic Area, or EEA, or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. No uniform policy exists for coverage and reimbursement for products exists among U.S. third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the

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FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our product candidates to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. Furthermore, there can be no assurance that a product will be considered medically reasonable and necessary for a specific indication, that a product will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability to sell a product profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented 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; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated 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 December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the Texas U.S. District Court Judge, as

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well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, it is unclear how this decision, subsequent appeal and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2027 absent additional congressional action. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Further, the Trump Administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Facilities

Our corporate headquarters are located in South San Francisco, California, where we lease approximately 12,300 square feet of office, research and development, engineering and laboratory space pursuant to a lease agreement which commenced on July 1, 2017 and expires on June 30, 2024 with an option to extend for five years. We believe that our existing facilities are sufficient for our near-term needs but expect to need additional space as we grow. We believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Employees

As of September 30, 2019, we had 20 full-time employees, six of whom were primarily engaged in research and development activities. A total of eight employees have an M.D., Ph.D. or Pharm.D. degree. Substantially all of our employees are located in South San Francisco, California. None of our employees is represented by a labor union, and we consider our employee relations to be good.

Legal Proceedings

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation, and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

MANAGEMENT

The following table sets forth information regarding our executive officers and directors as of October 31, 2019:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Executive Officers		
Douglas Love, Esq.	52	President, Chief Executive Officer and Director
Sanjay Keswani, MBBS, BSc, FRCP	50	Executive Vice President and Chief Medical Officer
Jennifer Lew	47	Executive Vice President and Chief Financial Officer
Ted Yednock, Ph.D.	62	Executive Vice President and Chief Scientific Officer
Non-Employee Directors		
William D. Young	75	Chairman and Director
Emmett Cunningham, M.D., Ph.D., M.P.H.	59	Director
Carol Gallagher, Pharm.D.	55	Director
Campbell Murray, M.D.(4)	43	Director
Muneer A. Satter	58	Director
Ricky Sun, Ph.D.	46	Director
Thomas G. Wiggans	67	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

(3) Member of our nominating and corporate governance committee.

(4) Dr. Murray is expected to resign from our Board of Directors prior to the effectiveness of the registration statement of which this prospectus is a part.

Executive Officers

Douglas Love, Esq. has served as our President and Chief Executive Officer and as a member of our board of directors since December 2014. Prior to joining Annexon, from 2008 to April 2013, he served as Head of Operations & Strategic Alliances for Elan Pharmaceuticals, Inc., a biopharmaceutical company, where he led the Tysabri® multiple sclerosis franchise, and Elan's Alzheimer's Immunotherapy Program, which was licensed to Johnson & Johnson. From 2006 to 2008, he served as Head of Strategic Alliances, Business Development & Business Integration for Elan. Prior to joining Elan, Mr. Love served as an associate at the law firm Orrick, Herrington & Sutcliffe LLP, Corporate Counsel at Amgen, Inc. and as Section Corporate Counsel at Genentech, Inc., where he led the BioOncology Healthcare Law Group. Mr. Love received a B.S. in business administration from the University of Southern California and a J.D. with great distinction from McGeorge School of Law. We believe that Mr. Love is qualified to serve on our board of directors due to the valuable expertise and perspective he brings in his capacity as our President and Chief Executive Officer and because of his extensive experience and knowledge of our industry.

Sanjay Keswani, MBBS, BSc, FRCP has served as our Executive Vice President and Chief Medical Officer since June 2019. Prior to that, Dr. Keswani was Chief Executive Officer at Rheos Medicines, Inc., a privately-held biopharmaceutical company, from September 2018 to June 2019. From June 2015 to September 2018, Dr. Keswani was Senior Vice President & Global Head of Neuroscience, Ophthalmology and Rare Diseases for the Roche Pharma Research and Early Development division of F. Hoffmann-La Roche Ltd., a publicly-held pharmaceutical company. Prior to Roche, he was Vice President, Exploratory and Clinical Translational Research at Bristol-Myers Squibb Company, a publicly-held pharmaceutical company, where he was responsible for multiple therapeutic areas including Immunology, Neuroscience, Rare Diseases, Fibrosis and Virology from March 2011 to June 2015. Prior to joining Bristol-Myers Squibb, Dr. Keswani held research and development

leadership roles at Eli Lilly & Company, a publicly-held pharmaceutical company, and Amgen Inc., a publicly-held biopharmaceutical company, and also served as Assistant Professor in Neurology at Johns Hopkins University. Dr. Keswani received his MBBS in medicine at St. Bartholomew's Hospital, London and completed his medical residency in Neurology and fellowships in Neuroimmunology and Neurophysiology at Johns Hopkins University School of Medicine. In addition, Dr. Keswani received a first class honors degree from St. Mary's Hospital, London in Pathology & Basic Medical Sciences (Immunology) and was elected as a Fellow of the Royal College of Physicians.

Jennifer Lew has served as our Executive Vice President and Chief Financial Officer since June 2019. Previously, from October 2013 to May 2019, Ms. Lew held various roles at Aduro Biotech, Inc., a publicly-held immunotherapy company, most recently as Chief Financial Officer. Prior to that, Ms. Lew held various roles at Dynavax Technologies Corporation, a publicly-held biopharmaceutical company, from 2004 to October 2013, most recently as Vice President of Finance and Principal Accounting Officer, where she oversaw accounting and finance operations. Prior to joining Dynavax, Ms. Lew held positions as Assistant Controller and Director of Finance at QRS Corporation, a publicly-held technology company, from 2000 to 2004. Ms. Lew was a member of the audit practice at Ernst & Young LLP from 1994 to 1999. She received a B.A. in Economics/Accounting and Government from Claremont McKenna College and is a Certified Public Accountant (inactive).

Ted Yednock, Ph.D. has served as our Executive Vice President and Chief Scientific Officer since November 2013. Previously, Dr. Yednock was Chief Scientific Officer for Prothena Corporation plc, a publicly-held biotechnology company spun out from Elan Pharmaceuticals, Inc., until 2013, and served in several roles of increasing responsibility from 1996 to 2013 at Elan Pharmaceuticals, Inc., a biopharmaceutical company, including Head of Global Research from 2007 to 2013. From 1990 to 1996, Dr. Yednock was a Scientist at Athena Neurosciences, Inc., a privately-held pharmaceutical company. While at Athena, he was the scientific inventor of Tysabri®, a monoclonal antibody for the treatment of multiple sclerosis. In addition to his work in multiple sclerosis, Dr. Yednock has contributed to the invention or progression of numerous drugs in the areas of Alzheimer's disease, Parkinson's disease, amyloidosis, rheumatoid arthritis, psoriasis and Crohn's disease. Dr. Yednock received his B.S. in biology and chemistry from the University of Illinois and his Ph.D. in anatomy and cell biology from the University of California, San Francisco.

Non-Employee Directors

William D. Young has served as Chairman of our board of directors since March 2017 and as a member of our board of directors since December 2014. Since December 2018, he has been a Senior Advisor at Blackstone Life Sciences, following Blackstone's acquisition of Clarus Ventures, LLC, a healthcare and life sciences venture capital firm where Mr. Young served as Venture Partner since 2010. Mr. Young served from 1999 until 2009 as Chairman of the board of directors and Chief Executive Officer of Monogram Biosciences, Inc., then a publicly-held biotechnology company, which was acquired by Laboratory Corporation of America in June 2009. From 1980 to 1999, Mr. Young was employed at Genentech, Inc., most recently as Chief Operating Officer, where he was responsible for all Product Development, Manufacturing and Commercial functions. Prior to joining Genentech, Mr. Young worked at Eli Lilly & Company for 14 years. Mr. Young has been Chairman of the board of directors of NanoString Technologies, Inc., a publicly-held biotechnology company, since March 2010. He has served as a director of Theravance Biopharma, Inc., a publicly-held biopharmaceutical company, since October 2013 and lead independent director since April 2014. Mr. Young served as a director of Innoviva, Inc., a publicly-held biopharmaceutical company, from April 2001 to June 2014, prior to Theravance's spin-off from Innoviva. In addition, Mr. Young has been a member of the board of directors of Vertex Pharmaceuticals Incorporated, a publicly-held biopharmaceutical company, since May 2014 and is also a member of the board of directors of Praxis Precision Medicines, Inc., a privately-held pharmaceutical company, and SJF Pharmaceuticals Inc., a privately-held pharmaceutical company, both Clarus portfolio companies. He was a member of the board of directors of BioMarin, Inc., a publicly-held biotechnology company, until November 2015 and Biogen Idec Inc., a publicly-held biotechnology company, until June 2014, having served as a director since 1997 and as Chairman of the board of directors since 2010. Mr. Young is also a Trustee of Montage Health, a nonprofit

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company. Mr. Young received his B.S. in Chemical Engineering from Purdue University, his M.B.A. from Indiana University and an honorary Doctorate of Engineering from Purdue University. Mr. Young was elected to The National Academy of Engineering in 2003 for his contributions to biotechnology. We believe that Mr. Young is qualified to serve on our board of directors due to his demonstrated leadership in his field, his experience as an executive and a board member of biotechnology and pharmaceutical companies and his experience as an investor in life sciences companies.

Emmett Cunningham, M.D., Ph.D., M.P.H. has served as a member of our board of directors since December 2014. He is a Senior Managing Director of Blackstone Life Sciences, having joined as part of its acquisition of Clarus Ventures, LLC, in December 2018. Dr. Cunningham was a Managing Director at Clarus from January 2017 to November 2018, where he led investments in the medical technology and biotechnology space including partnerships with pharmaceutical companies, and a Partner from December 2008 to December 2016. Prior to joining Clarus, Dr. Cunningham was the Senior Vice President, Medical Strategy at Eyetech Pharmaceuticals, Inc., a privately-held pharmaceutical company, from February 2004 to December 2005, where he helped lead the team that developed Macugen, a treatment for age-related macular degeneration. Dr. Cunningham is an internationally recognized specialist in infectious and inflammatory eye disease with over 350 publications. Dr. Cunningham previously served as a member of the board of directors of Restoration Robotics, Inc., a publicly-held medical device company. He is also a member of the board of directors of Galera Therapeutics, Inc., a privately-held biotechnology company, Graybug Vision, Inc., a privately-held clinical-stage pharmaceutical company, Lumos Pharma, Inc., a privately-held clinical-stage biopharmaceutical company, and SFJ Pharmaceutical, Inc., a privately-held pharmaceutical company, and serves on the Scientific Advisory Board of Aerie Pharmaceuticals, Inc., a publicly-held ophthalmic pharmaceutical company. Dr. Cunningham is the founder and Chairman of the Ophthalmology Innovation Summit symposium held in conjunction with the annual meetings of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery. Dr. Cunningham received his B.S. in Science from Drexel University and a B.A. in human biology, M.D. and M.P.H. in public health from Johns Hopkins University and a Ph.D. in neuroscience from the University of California, San Diego for work done at The Salk Institute. We believe that Dr. Cunningham is qualified to serve on our board of directors due to his educational background, his medical and scientific expertise, his experience as a board member of biotechnology and pharmaceutical companies and his experience as an investor in life sciences companies.

Carol Gallagher, Pharm.D. has served as a member of our board of directors since October 2018. Since October 2014, Dr. Gallagher has served as a partner with New Enterprise Associates, Inc., a venture capital firm. Prior to joining New Enterprise Associates, Dr. Gallagher served as a venture partner with Frazier Healthcare Partners, a venture capital firm, from October 2013 to July 2014. Dr. Gallagher served as the President and Chief Executive Officer of Calistoga Pharmaceuticals, Inc., a privately-held biopharmaceutical company, from 2008 to 2011, when the company was acquired by Gilead Sciences, Inc. From 2007 to 2008, Dr. Gallagher was the President and Chief Executive Officer of Metastatix, Inc., a privately-held biopharmaceutical company. Prior to that time starting in 1989, she served in various roles at pharmaceutical companies, Eli Lilly & Company, Amgen Inc., Agouron Pharmaceuticals, Inc., Pfizer Inc., Biogen Idec Pharmaceuticals Inc., CancerVax Corp. and Anadys Pharmaceuticals, Inc. Dr. Gallagher also serves as Chairman of the board of directors of Millendo Therapeutics, Inc., a publicly-held biopharmaceutical company, since 2012, lead director at Atara Bio, Inc., a publicly-held immunotherapy company, since 2012, and as a director of Turning Point Therapeutics, a publicly-held oncology company, since August 2019. She also serves as a director to the following private companies: Metacrine, Inc. (since November 2017), PIONYR Immunotherapeutics Inc. (since December 2017), Qpex (since August 2018), XOC Pharmaceuticals (since October 2018) and Chromacode (since December 2018). From November 2011 to March 2018, Dr. Gallagher served as a member of the board of directors of AnaptysBio, Inc., a publicly-held biopharmaceutical company. Dr. Gallagher attended Vanderbilt University and received B.S. and Doctor of Pharmacy degrees from the University of Kentucky. We believe that Dr. Gallagher is qualified to serve on our board of directors due to her educational background, her experience as an executive and a board member of biotechnology and pharmaceutical companies and her experience as an investor in life sciences companies.

Campbell Murray, M.D. has served as a member of our board of directors since December 2014. Dr. Murray has served as a Managing Director at the Novartis Venture Fund since August 2005. Previously, Dr. Murray served as the Director of Special Projects at the Novartis Institutes for BioMedical Research from July 2004 until July 2005. Currently, Dr. Murray serves as a member of the boards of directors of Expansion Therapeutics, Galera Therapeutics, Lemonaid Health, Renovacor and TScan Therapeutics. Dr. Murray received a bachelor of human biology from the University of Auckland Medical School, an M.B.A. from Harvard Business School, an M.P.P. from the John F. Kennedy School of Government, and an MBChB (M.D.) from the University of Auckland Medical School. We believe that Dr. Murray is qualified to serve on our board of directors due to his extensive investment experience in the biotechnology sector. Dr. Murray has notified us that he will resign from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Dr. Murray's resignation is not due to any disagreement with the company or any matters relating to our operations, policies or practices.

Muneer A. Satter has served as a member of our board of directors since December 2014. Mr. Satter has been Founder and Managing Partner of Satter Medical Technology Partners, L.P. since 2016, and Chairman of Satter Investment Management, LLC since 2012, and he also manages the Satter Foundation. Prior to Satter Investment Management, Mr. Satter was a partner at Goldman Sachs where he spent 24 years in various roles, most recently as the Global Head of the Mezzanine Group in the Merchant Banking Division, where he raised and managed over \$30 billion of assets and was also Chairman of the Risk Committee overseeing \$80 billion of assets. He is the Chairman of the board of directors of Aerpio Pharmaceuticals, a publicly-held biopharmaceutical company. Mr. Satter was Chairman of the board of directors of Akebia Therapeutics, Inc. from May 2013 to December 2018 and was Co-Chairman and a director of Vital Therapies, Inc. from October 2012 to October 2018. He also serves as Vice Chairman of the Goldman Sachs Foundation and GS Gives, is a director of World Business Chicago and Accelerate Institute, is on the Board of Advisors of the American Enterprise Institute, is on the board of directors of the Navy SEAL Foundation, Northwestern Medical Group and is on the Board of Trustees of Northwestern University where he is Chairman of the Finance Committee, as well as on the Board of Trustees of the US Olympic and Paralympic Foundation. Mr. Satter received a B.A. in Economics from Northwestern University, a J.D. from Harvard Law School and an M.B.A. from Harvard Business School. We believe that Mr. Satter is qualified to serve on our board of directors due to his experience in the financial industry, his experience as a board member of biotechnology and pharmaceutical companies and his experience as an investor in life sciences companies.

Ricky Sun, Ph.D. has served as a member of our board of directors since December 2018. Since August 2016, Dr. Sun has been a partner at Bain Capital Life Sciences Fund L.P. Prior to joining Bain Capital, he was a Director of Corporate Development and Strategy at Biogen Inc., a publicly-held biotechnology company, from January 2013 to July 2016. Prior to Biogen, Dr. Sun served as a Vice President at BlackRock, Inc., as a member of the Fundamental Equity division of BlackRock's Alpha Strategies Group and senior analyst for BlackRock's Fundamental Large Cap Growth equity team, covering the health care sector. Prior to that, he was a senior healthcare analyst at Citadel LLC and Alyska Investment Group, L.P. in Chicago from May 2010 to December 2011, and worked as a pharmaceuticals equity research analyst on Wall Street from September 2006 to July 2007, spending time at Lehman Brothers Holdings Inc. and Morgan Stanley. Dr. Sun began his career as a senior scientist at Ironwood Pharmaceutical, Inc. from January 2002 to July 2009, where he was involved in the discovery and development of the drug Linzess for irritable bowel syndrome. Dr. Sun received a B.A. in chemistry, *summa cum laude*, from Berea College, an M.B.A. from New York University Stern School of Business, where he was a Mildred Elperin Scholar, and a Ph.D. degree in Chemistry and Chemical Biology from Harvard University. He was also an NIH post-doctoral fellow in Biological Chemistry & Molecular Pharmacology at Harvard Medical School. We believe that Dr. Sun is qualified to serve on our board of directors due to his educational background and his experience in the financial industry.

Thomas G. Wiggans has served as a member of our board of directors since February 2017. Mr. Wiggans founded Demmira, Inc., a publicly-held pharmaceutical company, in August 2010 and has served as its Chief Executive Officer since September 2010 and on its board of directors since October 2014. Mr. Wiggans has also

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served on the boards of various industry organizations, educational institutions and private and public companies, including service on the boards of directors of Onyx Pharmaceuticals from March 2005 until its acquisition by Amgen Inc. in October 2013, Sangamo Biosciences, Inc. from June 2008 until June 2012, Somaxon Pharmaceuticals, Inc. from June 2008 until May 2012 and as Chairman of the board of directors of Excaliard Pharmaceuticals, Inc. from October 2010 until its acquisition by Pfizer, Inc. in December 2011. From October 2007, Mr. Wiggins served as Chairman of the board of directors of Peplin, Inc. and in July 2007, he became its Chief Executive Officer, and he served in these positions until Peplin's acquisition by LEO Pharma A/S in November 2009. Previously, Mr. Wiggins served as Chief Executive Officer of Connetics Corporation from July 1994, and as Chairman of the board of directors of Connetics from January 2006, and he served in these positions until December 2006 when Connetics was acquired by Stiefel Laboratories, Inc. From 1992 to 1994, Mr. Wiggins served as President and Chief Operating Officer of CytoTherapeutics Inc. From 1980 to 1992, Mr. Wiggins served at Ares-Serono S.A. in various management positions including President of its U.S. pharmaceutical operations and Managing Director of its U.K. pharmaceutical operations. Mr. Wiggins began his career with Eli Lilly & Company. In addition, Mr. Wiggins is a member of the board of directors of the Biotechnology Innovation Organization and is a member of the board of trustees of the University of Kansas Endowment Association. Mr. Wiggins received a B.S. in pharmacy from the University of Kansas and an M.B.A. from Southern Methodist University. We believe that Mr. Wiggins is qualified to serve on our board of directors due to his experience as an executive and a board member of biotechnology and pharmaceutical companies.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Board Composition

Director Independence

Our board of directors currently consists of eight members. Our board of directors has determined that all of our directors, other than Mr. Love, qualify as independent directors in accordance with The Nasdaq Stock Market LLC, or Nasdaq, Marketplace Rules or the Nasdaq Listing Rules. Mr. Love is not considered independent by virtue of his position as our President and Chief Executive Officer. Under the Nasdaq Listing Rules, the definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Nasdaq Listing Rules, our board of directors has made a subjective determination as to each independent director that no relationships exists that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's relationships as they may relate to us and our management.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general 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 will be divided among the three classes as follows:

- The Class I directors will be _____, _____ and _____, and their terms will expire at the annual meeting of stockholders to be held in 2021;
- The Class II directors will be _____, _____ and _____, and their terms will expire at the annual meeting of stockholders to be held in 2022; and

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- The Class III directors will be _____, _____ and _____, and their terms will expire at the annual meeting of stockholders to be held in 2023.

We expect that 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.

Voting Arrangements

The election of the members of our board of directors is currently governed by the amended and restated voting agreement that we entered into with certain holders of our common stock and convertible preferred stock and the related provisions of our amended and restated certificate of incorporation. Pursuant to our amended and restated voting agreement and amended and restated certificate of incorporation, our current directors were elected as follows:

- Dr. Cunningham, Dr. Gallagher, Dr. Murray, Mr. Satter and Dr. Sun were elected as the designees of Clarus Lifesciences III, L.P., New Enterprise Associates 15, L.P., Novartis Bioventures Ltd., entities affiliated with Mr. Satter and Bain Capital Life Sciences Fund, L.P., respectively;
- Mr. Love was elected and designated as our then-serving and current Chief Executive Officer; and
- Mr. Wiggins and Mr. Young were elected as the designees of the (i) holders of a majority of the shares of common stock held by stockholders who are our employees, consultants or advisors at the time of such vote and (ii) holders of at least 60% of the shares of our Series A-1 redeemable convertible preferred stock, Series B redeemable convertible preferred stock and Series C redeemable convertible preferred stock on an as-converted basis.

Our amended and restated voting agreement will terminate and the provisions of our current amended and restated certificate of incorporation by which our directors were elected will be amended and restated in connection with this offering. After this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the completion of this offering. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Leadership Structure of the Board

Our amended and restated bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chairman of the board of directors and Chief Executive Officer.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

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

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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. While our board of directors is responsible for monitoring and assessing strategic risk exposure, 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 approves or disapproves any related person transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq Listing Rules, which we will post on our website at www.annexonbio.com upon the completion of this offering. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and pre-approves the audit and non-audit fees and services;
- reviews and approves all related party transactions on an ongoing basis;
- establishes procedures for the receipt, retention and treatment of any complaints received by us regarding accounting, internal accounting controls or auditing matters;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- discusses on a periodic basis, or as appropriate, with our management's policies and procedures with respect to risk assessment and risk management;
- consults with management to establish procedures and internal controls relating to cybersecurity;
- is responsible for reviewing our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;

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- investigates any reports received through the ethics helpline and reports to the board of directors periodically with respect to any information received through the ethics helpline and any related investigations; and
- reviews the audit committee charter and the audit committee’s performance on an annual basis.

Our audit committee consists of _____, _____ and _____. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is _____. Our board of directors has determined that _____ and _____ are each an audit committee financial expert as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our board of directors has also determined that each member of our audit committee can read and understand fundamental consolidated financial statements, in accordance with applicable requirements.

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 (other than our Chief Executive Officer), 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 under our stock plans to our executive officers (other than our Chief Executive Officer). The compensation committee reviews the performance of our Chief Executive Officer and makes recommendations to our board of directors with respect to his compensation, and our board of directors retains the authority to make compensation decisions relative to our Chief Executive Officer. The compensation committee will review and evaluate, on an annual basis, the compensation committee charter and the compensation committee’s performance.

Our compensation committee consists of _____, _____ and _____. Our board of directors has determined that all members are independent under the Nasdaq Listing Rules and are “non-employee directors” as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation committee is _____.

Nominating and Corporate Governance Committee

The 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, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and making recommendations to our board of directors concerning governance matters.

Our nominating and corporate governance committee consists of _____, _____ and _____. Our board of directors has determined that all members of the nominating and corporate governance committee are independent under the Nasdaq Listing Rules. The chair of our nominating and corporate governance committee is _____.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Board Diversity

Upon consummation of this offering, our nominating and corporate governance committee will be 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 held company;
- professional and academic experience relevant to our industry;
- experience as a board member of another publicly held company;
- strength of leadership skills;
- experience in finance and accounting and/or executive compensation practices;
- ability to devote the time required for preparation, participation and attendance at board of directors meetings and committee meetings, if applicable;
- background, gender, age and ethnicity;
- conflicts of interest; and
- ability to make mature business judgments.

Following the consummation of this offering, our board of directors will evaluate each individual in the context of the board of directors as a whole, with the objective of ensuring that the board of directors, as a whole, has the necessary tools to perform its oversight function effectively in light of our business and structure.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a written code of business conduct and ethics that applies to all of our directors, officers and employees, including those officers responsible for financial reporting. The full text of our code of business conduct and ethics will be posted on our website at www.annexonbio.com upon the completion of this offering. Any substantive amendment to, or waiver of, a provision of the code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions will be disclosed on our website.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws, both of which will become effective immediately prior to the completion of this offering, limit our directors' liability, and provide that we may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

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- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the “2019 Summary Compensation Table” below. In 2019, our “named executive officers” and their positions were as follows:

- Douglas Love, our President and Chief Executive Officer;
- Sanjay Keswani, Executive Vice President and Chief Medical Officer; and
- Jennifer Lew, our Executive Vice President and Chief Financial Officer.

Each of Dr. Keswani and Ms. Lew commenced employment with us in June 2019.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion. 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.

2019 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the applicable years shown.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)(2)	All Other Compensation (\$)(3)	Total (\$)
Douglas Love, Esq.	2019						
<i>President and Chief Executive Officer</i>	2018	379,192	—	—	138,352	—	517,544
Sanjay Keswani, M.B.B.S., F.R.C.P.	2019						
<i>Executive Vice President and Chief Medical Officer(4)</i>							
Jennifer Lew(5)	2019						
<i>Executive Vice President and Chief Financial Officer</i>							

- (1) Amounts reflect the full grant-date fair value of option awards granted during 2019 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. In accordance with ASC Topic 718, no amount for Dr. Keswani’s performance-based option has been included because the satisfaction of the required performance condition was not considered probable as of the grant date. Assuming full attainment of the performance condition, the grant date fair value of Dr. Keswani’s performance-based option would have been \$311,000. See Note 9 of the audited financial statements included in this prospectus for the assumptions used in calculating these amounts.
- (2) The annual performance-based cash bonuses earned by our named executive officers for 2019 performance have not yet been determined. It is anticipated that such bonuses will be determined in the first quarter of 2020, at which time the Company will disclose the amounts of such bonuses. Please see the description of the annual performance bonus program under “2019 Bonuses” below.
- (3) Amounts include commuting reimbursements for Mr. Love and relocation reimbursements, consisting of _____ in moving expenses and _____ in closing costs on the sale of his home in Massachusetts, made to Dr. Keswani in connection with the commencement of his employment with us.
- (4) Dr. Keswani commenced employment effective June 17, 2019.
- (5) Ms. Lew commenced employment effective June 3, 2019.

Narrative to the Summary Compensation Table

2019 Salaries

Our named executive officers each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role and responsibilities.

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For fiscal year 2019, Mr. Love's annual base salary was \$397,762, a merit increase of 3.5% over his fiscal 2018 annual base salary. Dr. Keswani's and Ms. Lew's annual base salaries for 2019 were \$380,000 and \$350,000, respectively, each of which were negotiated in connection with the commencement of their employment with the company in June 2019.

2019 Bonuses

We maintain an annual performance-based cash bonus program in which each of our named executive officers participated in 2019. Each named executive officer's target bonus is expressed as a percentage of base salary which can be achieved by meeting certain performance goals discussed below at target level. The 2019 annual bonuses for Mr. Love, Dr. Keswani and Ms. Lew were targeted at 40%, 35% and 35% of their respective base salaries. Mr. Love's target annual bonus was unchanged from his 2018 level. Each of Dr. Keswani's and Ms. Lew's target bonuses were negotiated in connection with the commencement of their employment with the company in June 2019, and will be prorated to reflect the length of their employment during 2019.

For 2019, our named executive officers are eligible to earn annual cash bonuses based on the achievement of certain corporate objectives approved by the compensation committee and the board of directors. The goals under our 2019 bonus program were set with respect to research and development activities and corporate activities. Full achievement of all goals could result in up to 120% of target.

The board of directors has not yet determined the Company's achievement of the applicable performance goals or bonus payments with respect to 2019, but anticipates that such performance assessment will be made in the first quarter of 2020.

Equity Compensation

We have granted stock options to our employees, including our named executive officers, in order to attract and retain them, as well as to align their interests with the interests of our stockholders. In order to provide a long-term incentive, these stock options generally vest over four years subject to continued service to the company.

In January 2019, we granted to Mr. Love an option to purchase 4,738,414 shares of our common stock, which vests as to 1/48th of the shares subject to the option on each monthly anniversary of December 12, 2018, subject to continued service. In June 2019, in connection with their commencement of employment with us, we granted to Dr. Keswani an option to purchase 1,647,045 shares of common stock and Ms. Lew an option to purchase 1,372,537 shares of common stock, each of which vests as to 25% of the shares subject to the option on the first anniversary of the applicable named executive officer's employment commencement date, and as to 1/36th of the remaining shares subject to the option on each monthly anniversary thereafter, subject to continued service. We also granted to Dr. Keswani a performance-based option that vests in full upon the successful completion of a clinical study milestone relating to Guillain-Barre Syndrome or alternative indication approved by our Chief Executive Officer and board of directors, subject to continued service through such date.

We intend to adopt a 2020 Incentive Award Plan, referred to below as the 2020 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable us to obtain and retain services of these individuals, which is essential to our long-term success. The 2020 Plan will be effective on the day prior to the date the registration statement relating to this offering becomes effective. For additional information about the 2020 Plan, please see the section titled "Equity Incentive Plans" below.

Other Elements of Compensation

Retirement Savings and Health and Welfare Benefits

We maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k)

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plan on the same terms as other full-time employees. Currently, we do not match contributions made by participants in the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including: medical, dental and vision benefits; basic and supplemental life and accidental death and dismemberment insurance; and medical and dependent care flexible spending accounts.

Perquisites and Other Personal Benefits

We reimburse the cost of commuting to our offices for Mr. Love. In addition, in connection with the commencement of his employment with us in June 2019, we reimbursed Dr. Keswani for certain relocation expenses, including moving expenses and closing costs on his home in Massachusetts.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding option awards for each named executive officer as of December 31, 2019.

Name and Principal Position	Grant Date	Vesting Commencement Date (1)	Number of Securities Underlying Unexercised Options (Exercisable) (#)	Number of Securities Underlying Unexercised Options (Unexercisable) (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date
Douglas Love, Esq. <i>President and Chief Executive Officer</i>	1/22/2015 8/11/2016 8/11/2016 1/22/2019	12/12/2014(2) 6/8/2016(2) 8/11/2016 12/12/2018	1,224,931 835,627 264,668 1,184,603	— 119,376 52,935 3,553,811	— — — —	0.16 0.21 0.21 0.58	1/22/2025 8/11/2026 8/11/2026 1/22/2029
Sanjay Keswani, M.B.B.S., F.R.C.P. <i>Executive Vice President and Chief Medical Officer</i>	6/21/2019 6/21/2019	6/17/2019(2)(3) —(4)	— —	1,647,045 —	— 411,761	0.85 0.85	6/21/2029 6/21/2029
Jennifer Lew <i>Executive Vice President and Chief Financial Officer</i>	6/21/2019	6/3/2019(2)(3)	—	1,372,537	—	0.85	6/21/2029

- (1) Except as otherwise indicated, 1/48th of the shares subject to each option vest on each monthly anniversary of the vesting commencement date, subject to continued service with us.
- (2) Pursuant to the terms of the named executive officer's offer letter, the shares subject to the option will vest in full in the event of a termination of the executive's employment by us without "cause" or the executive's resignation for "good reason" (each, as defined in the offer letter), in each case, that occurs within 12 months following a "change of control" of us (as defined in the offer letter).
- (3) 25% of the shares subject to the option vest on the 12-month anniversary of the vesting commencement date and 1/36th of the remaining shares subject to the option vest on each monthly anniversary thereafter, subject to continued service with us.
- (4) 100% of the shares subject to the option vest upon the successful achievement of a development milestone, subject to continued service with us.

Executive Compensation Arrangements

Offer Letters

As of December 31, 2019, we were party to offer letters with each of our named executive officers.

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Mr. Love. We entered into an offer letter with Mr. Love in December 2014 setting forth the terms of his employment as our President and Chief Executive Officer, including his initial base salary, target bonus, initial stock option grants and benefit plan participation eligibility. Mr. Love's offer letter provides that in the event that Mr. Love's employment is terminated by us without Cause (as defined in the offer letter), then subject to his execution of a release of claims in favor of us, Mr. Love will receive severance payments equal to nine months of his then-current base salary. In addition, in the event that Mr. Love is terminated by us without Cause or resigns for Good Reason (as defined in the offer letter), in each case, within 12 months following a "change of control" (as defined in the offer letter), his initial option grants will vest in full.

Dr. Keswani and Ms. Lew. We entered into offer letters with Dr. Keswani and Ms. Lew in connection with their commencement of employment with us in June 2019, which provide for initial base salary, target bonus and initial stock option grants as described above. Each of their offer letters also provides that in the event that the named executive officer's employment is terminated by us without Cause (as defined in the offer letter) any time other than during the period commencing three months prior to and ending 12 months following a change in control, then subject to the execution of a release of claims in favor of us, the named executive officer will receive severance payments equal to nine months of his or her then-current base salary and nine months of premium reimbursement for continuing healthcare coverage under COBRA. In addition, in the event that the named executive officer is terminated by us without Cause or resigns for Good Reason (as defined in the offer letter), in each case, during the period commencing three months prior to and ending 12 months following a change in control, the named executive officer will receive severance payments equal to 12 months of the executive's then-current base salary and the executive's target bonus, 12 months of premium reimbursement for continuing healthcare coverage under COBRA, and the executive's initial time-based option will vest in full.

For purposes of our named executive officers' offer letters:

"Cause" means (i) the executive's failure to perform the executive's assigned duties or responsibilities as an officer of us (other than a failure resulting from the executive's Disability (as defined in the offer letter) after notice thereof from us describing the executive's failure to perform such duties or responsibilities, (ii) the executive's engaging in any act of dishonesty, fraud or misrepresentation, (iii) the executive's violation of any federal or state law or regulation applicable to our business or our affiliates, (iv) the executive's breach of any confidentiality agreement or invention assignment agreement between the executive and us (or any affiliate of us), or (v) the executive's commission of, or entering a plea of nolo contendere to, any crime or committing any act of moral turpitude; and

"Good Reason" for the executive to terminate the executive's employment shall mean the occurrence of any of the following events without the executive's consent: (i) a material reduction in the executive's salary or benefits (excluding the substitution of substantially equivalent compensation and benefits), other than as a result of a reduction in compensation affecting our employees, or our successor entity, generally; (ii) a material diminution in the executive's duties or responsibilities, provided however, that, a mere change in title or reporting relationship alone shall not constitute "Good Reason," and (iii) relocation of the executive's place of employment to a location more than 50 miles from our office location. If any of the events set forth above shall occur, the executive shall give prompt written notice of such event to us, or our successor entity, upon becoming aware of such event, and if such event is not cured within thirty (30) days from such notice the executive may exercise his or her rights to resign for Good Reason, provided that if the executive has not exercised such right within forty-five (45) days of the date of such notice the executive shall be deemed to have agreed to the occurrence of such event.

Equity Compensation Plans

The following summarizes the material terms of the 2020 Plan, in which our named executive officers will be eligible to participate following the consummation of this offering, our 2011 Equity Incentive Plan, referred to as the 2011 Plan, under which we have previously made periodic grants of equity and equity-based awards to our

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named executive officers and other key employees and the Employee Stock Purchase Plan that we intend to adopt in connection with the consummation of this offering.

2020 Incentive Award Plan

We intend to adopt the 2020 Plan, which will be effective on the date immediately prior to the date our registration statement relating to this offering becomes effective. The principal purpose of the 2020 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2020 Plan, as it is currently contemplated, are summarized below.

Share Reserve. Under the 2020 Plan, _____ shares of our common stock will be initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, performance bonus awards, performance stock unit awards, dividend equivalents or other stock or cash based awards. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2020 Plan will be increased by (i) the number of shares represented by awards outstanding under our 2011 Plan, or 2011 Plan Awards, that become available for issuance under the counting provisions described below following the effective date and (ii) an annual increase on the first day of each fiscal year beginning in 2021 and ending in 2030, equal to the lesser of (A) _____ % of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than _____ shares of stock may be issued upon the exercise of incentive stock options.

The following counting provisions will be in effect for the share reserve under the 2020 Plan:

- to the extent that an award (including a 2011 Plan Award) expires, lapses or is terminated, converted into an award in respect of shares of another entity in connection with a spin-off or other similar event, exchanged for cash, surrendered, repurchased or canceled, in any case, in a manner that results in the Company acquiring the underlying shares at a price not greater than the price paid by the participant or not issuing the underlying shares, such unused shares subject to the award at such time will be available for future grants under the 2020 Plan;
- to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2020 Plan or 2011 Plan Award, such tendered or withheld shares will be available for future grants under the 2020 Plan;
- to the extent shares subject to stock appreciation rights are not issued in connection with the stock settlement of SARs on exercise thereof, such shares will be available for future grants under the 2020 Plan;
- the payment of dividend equivalents in cash in conjunction with any outstanding awards or 2011 Plan Awards will not be counted against the shares available for issuance under the 2020 Plan; and
- shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2020 Plan.

Administration. The compensation committee of our board of directors is expected to administer the 2020 Plan unless our board of directors assumes authority for administration. The board of directors may delegate its powers to a committee, which, to the extent required to comply with Rule 16b-3, is intended to be comprised of “non-employee directors” for purposes of Rule 16b-3 under the Exchange Act. The 2020 Plan provides that the board or compensation committee may delegate its authority to grant awards other than to individuals subject to Section 16 of the Exchange Act or officers or directors to whom authority to grant awards has been delegated.

Subject to the terms and conditions of the 2020 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and

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conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2020 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2020 Plan. Our board of directors may at any time remove the compensation committee as the administrator and reconstitute itself the authority to administer the 2020 Plan. The full board of directors will administer the 2020 Plan with respect to awards to non-employee directors.

Eligibility. Awards under the 2020 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. However, only employees of our company or certain of our subsidiaries may be granted incentive stock options, or ISOs.

Awards. The 2020 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, performance bonus awards, performance stock units, other stock- or cash-based awards and dividend equivalents, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- *Nonstatutory Stock Options*, or NSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.
- *Incentive Stock Options*, or ISOs, will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2020 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.
- *Restricted Stock* may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock typically may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse; however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.
- *Restricted Stock Units* may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.
- *Stock Appreciation Rights*, or SARs, may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price.

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The exercise price of any SAR granted under the 2020 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. SARs under the 2020 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.

- *Performance Bonus Awards and Performance Stock Units* are denominated in cash or shares/unit equivalents, respectively, and may be linked to one or more performance or other criteria as determined by the administrator.
- *Other Stock- or Cash-Based Awards* are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock- or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The administrator will determine the terms and conditions of other stock- or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.
- *Dividend Equivalents* represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are converted to cash or shares by such formula and such time as determined by the administrator. In addition, dividend equivalents with respect to an awards subject to vesting will either (i) to the extent permitted by applicable law, not be paid or credited or (ii) be accumulated and subject to vesting to the same extent as the related award.

Any award may be granted as a performance award, meaning that the award will be subject to vesting and/or payment based on the attainment of specified performance goals.

Change in Control. In the event of a change in control, unless the administrator elects to terminate an award in exchange for cash, rights or other property, or cause an award to accelerate in full prior to the change in control, such award will continue in effect or be assumed or substituted by the acquirer, provided that any performance-based portion of the award will be subject to the terms and conditions of the applicable award agreement. In the event the acquirer refuses to assume or replace awards granted, prior to the consummation of such transaction, awards issued under the 2020 Plan (other than any portion subject to performance-based vesting) will be subject to accelerated vesting such that 100% of such awards will become vested and exercisable or payable, as applicable. The administrator may also make appropriate adjustments to awards under the 2020 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions.

Adjustments of Awards. The administrator has broad discretion to take action under the 2020 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as “equity restructurings,” the administrator will make equitable adjustments to the 2020 Plan and outstanding awards.

Amendment and Termination. The administrator may terminate, amend or modify the 2020 Plan at any time and from time to time. However, we must generally obtain stockholder approval to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule), and generally no amendment may materially and adversely affect any outstanding award without the affected participant’s consent. Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in

connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

No incentive stock options may be granted pursuant to the 2020 Plan after the tenth anniversary of the effective date of the 2020 Plan, and no additional annual share increases to the 2020 Plan's aggregate share limit will occur from and after such anniversary. Any award that is outstanding on the termination date of the 2020 Plan will remain in force according to the terms of the 2020 Plan and the applicable award agreement.

2011 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, the 2011 Plan effective as of July 31, 2011. The 2011 Plan was subsequently amended on multiple occasions to increase the number of shares issuable thereunder. The 2011 Plan provides for the grant of ISOs, NSOs, SARs, restricted stock, and restricted stock units. As of September 30, 2019, options to purchase 18,336,476 shares of our common stock at a weighted-average exercise price per share of \$0.54 remained outstanding under the 2011 Plan. Following this offering and in connection with the effectiveness of our 2020 Plan, no further awards will be granted under the 2011 Plan. However, all outstanding awards will continue to be governed by their existing terms.

Administration. Our board of directors or a committee thereof appointed by our board of directors has the authority to administer the 2011 Plan and the awards granted under it. The administrator's authority includes the authority to select the service providers to whom awards will be granted under the 2011 Plan, the number of shares to be subject to those awards under the 2011 Plan, and the terms and conditions of the awards granted. The administrator also has the authority to institute and determine the terms and conditions of a program under which all outstanding awards are surrendered or cancelled in exchange for awards of the same or a different type or in exchange for cash, participants would have the opportunity to transfer any outstanding awards to a financial institution or other person selected by the administrator, or the exercise price of the award is reduced or increased. In addition, the administrator has the authority to construe and interpret the 2011 Plan and to adopt rules for the administration, interpretation and application of the 2011 Plan that are consistent with the terms of the 2011 Plan.

Awards. The 2011 Plan provides that the administrator may grant or issue options, including ISOs and NSOs, SARs, restricted stock and restricted stock units to employees, consultants and directors; provided that only employees may be granted ISOs.

- *Stock Options.* The 2011 Plan provides for the grant of ISOs or NSOs. ISOs may be granted only to employees. NSOs may be granted to employees, directors or consultants. The exercise price of ISOs granted to employees who at the time of grant own stock representing more than 10% of the voting power of all classes of our common stock may not be less than 110% of the fair market value per share of our common stock on the date of grant, and the exercise price of ISOs granted to any other employees may not be less than 100% of the fair market value per share of our common stock on the date of grant. The exercise price of NSOs to employees, directors or consultants may not be less than 100% of the fair market value per share of our common stock on the date of grant.
- *Stock Appreciation Rights.* The 2011 Plan provides for the grant of SARs. Each SAR will be governed by a SAR agreement. The exercise price of SARs may not be less than 100% of the fair market value per share of our common stock on the date of grant.
- *Restricted Stock Awards.* The 2011 Plan provides for the grant of restricted stock awards. Each restricted stock award will be governed by a restricted stock award agreement, which will detail the restrictions on transferability, risk of forfeiture and other restrictions the administrator approves. In general, restricted stock may not be sold, transferred, pledged, hypothecated, margined or otherwise encumbered until restrictions are removed or expire. Holders of restricted stock, unlike recipients of other equity awards, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse.

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- *Restricted Stock Units.* The 2011 Plan provides that we may issue restricted stock unit awards which may be settled in either cash or common stock. Each restricted stock unit award will be governed by a restricted stock unit award agreement that will set forth any vesting conditions based on continued employment or service or on performance criteria established by the administrator. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no rights as a stockholder prior to the time when vesting conditions are satisfied.

Adjustments of Awards. In the event of any dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, exchange of shares or other change in the corporate structure of the company affecting shares of common stock, the administrator will make adjustments to the number and class of shares available for issuance under the 2011 Plan and the number, class and price of shares subject to outstanding awards.

Change in Control. In the event of a merger or change in control, the administrator has discretion to determine the treatment of each outstanding award, and may provide that the awards will be assumed or substituted, that the awards will terminate or accelerate in full immediately prior to the change in control, or that the awards will terminate in exchange for cash or other property, or any combination of the foregoing. The administrator is not obligated to treat all outstanding awards in the same manner. In addition, in the event of a change in control where the acquirer does not assume or replace awards, prior to the consummation of such transaction, awards issued under the 2011 Plan will accelerate in full and any awards subject to performance-based vesting will be deemed achieved at 100% of target levels and all other terms and conditions met. Awards will be considered assumed for this purpose if, following the merger or change in control, the award represents the right to purchase or receive the per share consideration received in the merger or change in control by holders of common stock.

Amendment and Termination. Our board of directors may amend or terminate the 2011 Plan at any time, but no amendment will impair the rights of a holder of an outstanding award without the holder's consent. An amendment of the 2011 Plan will be subject to the approval of our stockholders, where such approval by our stockholders of an amendment is required by applicable law. Following this offering and in connection with the effectiveness of our 2020 Plan, no further awards will be granted under the 2011 Plan.

Employee Stock Purchase Plan

We intend to adopt the Employee Stock Purchase Plan, which we refer to as our ESPP, which will be effective on the date immediately prior to the date the registration statement relating to this offering becomes effective. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at periodic intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code. The material terms of the ESPP, as it is currently contemplated, are summarized below.

Administration. Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

Share Reserve. The maximum number of our shares of our common stock which will be authorized for sale under the ESPP is equal to the sum of (i) shares of common stock and (ii) an annual increase on the first day of each year beginning in 2021 and ending in 2030, equal to the lesser of (A) % of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such number of shares of common stock as determined by our board of directors; provided, however, no more than shares of our common stock may be issued under the ESPP. The shares reserved for issuance under the ESPP may be authorized but unissued shares or reacquired shares.

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Eligibility. Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our subsidiaries on the first day of the offering period, or the enrollment date. Our employees (and, if applicable, any employees of our subsidiaries) who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation. Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1% of their compensation but not more than 15% of their compensation. Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount, and the accumulated deductions will be applied to the purchase of shares on each purchase date. However, a participant may not purchase more than 50,000 shares in each offering period and may not accrue the right to purchase shares of common stock at a rate that exceeds \$25,000 in fair market value of shares of our common stock (determined at the time the option is granted) for each calendar year the option is outstanding (as determined in accordance with Section 423 of the Code). The ESPP administrator has the authority to change these limitations for any subsequent offering period.

Offering. Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, the duration and timing of which will be determined by the ESPP administrator. However, in no event may an offering period be longer than 27 months in length.

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time prior to the end of the offering period. Upon cancellation, the participant will have the option to either (i) receive a refund of the participant's account balance in cash without interest or (ii) exercise the participant's option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant's account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant's lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

Adjustments upon Changes in Recapitalization, Dissolution, Liquidation, Merger or Asset Sale. In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock, or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number

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and price of shares which any participant has elected to purchase under the ESPP and the maximum number of shares which a participant may elect to purchase in any single offering period. If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately prior to the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least 10 business days prior to the new exercise date. If we undergo a merger with or into another corporation or sell all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least 10 business days prior to the new exercise date.

Amendment and Termination. Our board of directors may amend, suspend or terminate the ESPP at any time. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws.

Director Compensation

We have not historically maintained a formal non-employee director compensation program. However, we have granted stock options to certain of our directors from time to time, and we provide reimbursement to our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors. In January 2019, we granted to Messrs. Wiggans and Young options to purchase 59,986 and 191,956 shares of common stock, respectively, which vest as to 1/48th of the shares subject to the option on each monthly anniversary of December 12, 2018, subject to continued service. Our non-employee directors received no other compensation from us during the year ended December 31, 2019. Mr. Love receives no additional compensation for his service as director. His compensation as our President and Chief Executive Officer is set forth in the Summary Compensation Table above.

2019 Director Compensation Table

Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Emmett Cunningham, M.D., Ph.D., M.P.H.	—	—	—	—
Carol Gallagher, Pharm.D.	—	—	—	—
Campbell Murray, M.D.	—	—	—	—
Muneer Satter	—	—	—	—
Ricky Sun, Ph.D.	—	—	—	—
Thomas G. Wiggans	—	—	—	—
William Young	—	—	—	—

As of December 31, 2019, Mr. Wiggans held options to purchase an aggregate of shares of our common stock, and Mr. Young held options to purchase an aggregate of shares of our common stock. No other non-employee director held any options to purchase shares of our common stock or any other equity award as of December 31, 2019.

We intend to approve and implement a compensation program for our non-employee directors, or the Director Compensation Program, to be effective in connection with the consummation of this offering.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2016 and any currently proposed transactions to which we were or are expected to be a participant in which (i) the amount involved exceeded or will exceed \$120,000, and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive and Director Compensation.”

Redeemable Convertible Preferred Stock Financings***Series B Redeemable Convertible Preferred Stock Financing***

In June 2016, we entered into a Series B redeemable convertible preferred stock purchase agreement with various investors, pursuant to which we issued an aggregate of 38,778,090 shares of Series B redeemable convertible preferred stock at \$1.15 per share for gross proceeds of approximately \$44.6 million in two closings. The first closing occurred in June 2016, at which time we issued 26,974,965 shares of our Series B redeemable convertible preferred stock for gross proceeds of approximately \$31.0 million. The second closing occurred in February 2018, at which time we issued an additional 11,803,125 shares of our Series B redeemable convertible preferred stock for gross proceeds of approximately \$13.6 million.

The table below sets forth the number of shares of our Series B redeemable convertible preferred stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series B redeemable convertible preferred stock in the table below will convert into one share of our common stock upon the completion of this offering.

Name⁽¹⁾	Series B Redeemable Convertible Preferred Stock (#)	Aggregate Cash Purchase Price (\$)
Entities affiliated with New Enterprise Associates ⁽²⁾	14,039,383	16,145,291
Novartis Bioventures Ltd. ⁽³⁾	8,406,103	9,667,018
Clarus Lifesciences III, L.P. ⁽⁴⁾	8,370,685	9,626,288
Trusts and Other Entities affiliated with Muneer A. Satter ⁽⁵⁾	4,016,573	4,619,059

(1) For additional information regarding these stockholders and their equity holdings, see the section titled “Principal Stockholders.”

(2) Entities affiliated with New Enterprise Associates became beneficial owners of (in the aggregate) more than 5% of our outstanding capital stock upon the closing of the Series B redeemable convertible preferred stock financing. Dr. Carol Gallagher was designated to serve as a member of our board of directors by New Enterprise Associates 15, L.P. Dr. Gallagher is a partner at New Enterprise Associates, Inc.

(3) Novartis Bioventures Ltd. beneficially owned more than 5% of our outstanding capital stock at the time of the Series B redeemable convertible preferred stock financing. Dr. Campbell Murray is currently, and was at the time of the Series B redeemable convertible preferred stock financing, a member of our board of directors. Dr. Murray was designated to serve as a member of our board of directors by Novartis Bioventures Ltd. Dr. Murray is a Managing Director at Novartis Venture Fund, and, in such capacity, employed by a corporation that is an affiliate of Novartis Bioventures Ltd. Dr. Murray is expected to resign from our board of directors prior to the effectiveness of the registration statement of which this prospectus is a part.

(4) Clarus Lifesciences III, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series B redeemable convertible preferred stock financing. Dr. Emmett Cunningham is currently, and was at the time of the Series B redeemable convertible preferred stock financing, a member of our board of directors. Dr. Cunningham was designated to serve as a member of our board of directors by Clarus Lifesciences III, L.P. Dr. Cunningham is a Senior Managing Director of Blackstone Life Sciences, having joined as part of its acquisition of Clarus Ventures, LLC in December 2018. Dr. Cunningham was a Managing Director at Clarus Ventures, LLC from January 2017 to November 2018.

(5) Trusts and other entities affiliated with Muneer A. Satter beneficially owned (in the aggregate) more than 5% of our outstanding capital stock at the time of the Series B redeemable convertible preferred stock financing. Mr. Satter is currently, and was at the time of the Series B redeemable convertible preferred stock financing, a member of our board of directors. Mr. Satter was designated to serve as a member of our board of directors by Satter Medical Technology Partners, L.P. and certain other affiliated entities. Mr. Satter is the founder and managing partner of Satter Medical Technology Partners, L.P. and Chairperson of Satter Investment Management LLC. Mr. Satter also manages the Satter Foundation.

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Series C Redeemable Convertible Preferred Stock Financing

In December 2018, we entered into a Series C redeemable convertible preferred stock purchase agreement with various investors, pursuant to which we issued an aggregate of 55,555,546 shares of Series C redeemable convertible preferred stock at \$1.35 per share for gross proceeds of approximately \$75.0 million in two closings. The first closing occurred in December 2018, at which time we issued 33,333,329 shares of our Series C redeemable convertible preferred stock for gross proceeds of approximately \$45.0 million. The second closing occurred in August 2019, at which time we issued an additional 22,222,217 shares of our Series C redeemable convertible preferred stock for gross proceeds of approximately \$30.0 million.

The table below sets forth the number of shares of our Series C redeemable convertible preferred stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series C redeemable convertible preferred stock in the table below will convert into one share of our common stock upon the completion of this offering.

<u>Name⁽¹⁾</u>	<u>Series C Redeemable Convertible Preferred Stock (#)</u>	<u>Aggregate Cash Purchase Price (\$)</u>
Entities affiliated with Bain Capital Life Sciences ⁽²⁾	22,222,221	29,999,998
Clarus Lifesciences III, L.P. ⁽³⁾	6,148,147	8,299,998
New Enterprise Associates 15, L.P. ⁽⁴⁾	5,925,925	7,999,999
Satter Medical Technology Partners, L.P. ⁽⁵⁾	5,537,036	7,474,999
Novartis Bioventures Ltd. ⁽⁶⁾	4,444,443	5,999,998
Citadel Multi-Strategy Equities Master Fund Ltd.	7,407,406	9,999,998

(1) For additional information regarding these stockholders and their equity holdings, see the section titled “Principal Stockholders.”

(2) Entities affiliated with Bain Capital Life Sciences became beneficial owners of (in the aggregate) more than 5% of our outstanding capital stock upon the closing of the Series C redeemable convertible preferred stock financing. Dr. Ricky Sun was designated to serve as a member of our board of directors by Bain Capital Life Sciences Fund, L.P. Dr. Sun is a partner with Bain Capital Life Sciences Investors, LLC.

(3) Clarus Lifesciences III, L.P. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C redeemable convertible preferred stock financing. Dr. Emmett Cunningham is currently, and was at the time of the Series C redeemable convertible preferred stock financing, a member of our board of directors. Dr. Cunningham was designated to serve as a member of our board of directors by Clarus Lifesciences III, L.P. Dr. Cunningham is a Senior Managing Director of Blackstone Life Sciences, having joined as part of its acquisition of Clarus Ventures, LLC in December 2018. Dr. Cunningham was a Managing Director at Clarus Ventures, LLC from January 2017 to November 2018.

(4) Entities affiliated with New Enterprise Associates 15, L.P. beneficially owned (in the aggregate) more than 5% of our outstanding capital stock at the time of the Series C redeemable convertible preferred stock financing. Dr. Carol Gallagher is currently, and was at the time of the Series C redeemable convertible preferred stock financing, a member of our board of directors. Dr. Gallagher was designated to serve as a member of our board of directors by New Enterprise Associates 15, L.P. Dr. Gallagher is a partner at New Enterprise Associates, Inc.

(5) Trusts and other entities affiliated with Muneer A. Satter beneficially owned (in the aggregate) more than 5% of our outstanding capital stock at the time of the Series C financing. Mr. Muneer Satter is currently, and was at the time of the Series C redeemable convertible preferred stock financing, a member of our board of directors. Mr. Satter was designated to serve as a member of our board of directors by Satter Medical Technology Partners, L.P. and certain other affiliated entities. Mr. Satter is the founder and managing partner of Satter Medical Technology Partners, L.P. and Chairperson of Satter Investment Management LLC. Mr. Satter also manages the Satter Foundation.

(6) Novartis Bioventures Ltd. beneficially owned more than 5% of our outstanding capital stock at the time of the Series C redeemable convertible preferred stock financing. Dr. Campbell Murray is currently, and was at the time of the Series C redeemable convertible preferred stock financing, a member of our board of directors. Dr. Murray was designated to serve as a member of our board of directors by Novartis Bioventures Ltd. Dr. Murray is a Managing Director at Novartis Venture Fund, and, in such capacity, employed by a corporation that is an affiliate of Novartis Bioventures Ltd. Dr. Murray is expected to resign from our board of directors prior to the effectiveness of the registration statement of which this prospectus is a part.

Investors’ Rights Agreement

In June 2016 and December 2018, we entered into an amended and restated investors’ rights agreement with the purchasers of our outstanding redeemable convertible preferred stock, including entities with which certain of

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our directors are affiliated. Following the consummation of this offering, the holders of approximately _____ shares of our common stock, including the shares of common stock issuable upon the conversion of our Series A, Series A-1, Series B and Series C redeemable convertible preferred stock, are entitled to rights with respect to the registration of their shares under the Securities Act. For a more detailed description of these registration rights, see the section titled “Description of Capital Stock—Registration Rights.” The investors’ rights agreement also provides for a right of first refusal in favor of certain holders of redeemable convertible preferred stock with regard to certain issuances of our capital stock. The rights of first refusal will not apply to, and will terminate upon the consummation of, this offering.

Voting Agreement

In June 2016 and December 2018, we entered into an amended and restated voting agreement with certain holders of our common stock and redeemable convertible preferred stock. Upon the conversion of all outstanding shares of redeemable convertible preferred stock into common stock in connection with the consummation of this offering, the amended and restated voting agreement will terminate. For a description of the amended and restated voting agreement, see the section titled “Management—Board Composition—Voting Arrangements.”

Right of First Refusal and Co-Sale Agreement

In June 2016 and December 2018, we entered into an amended and restated right of first refusal and co-sale agreement with certain holders of our common stock and redeemable convertible preferred stock. This agreement provides for rights of first refusal and co-sale relating to the shares of our common stock held by the parties to the agreement. Upon the consummation of this offering, the amended and restated right of first refusal and co-sale agreement will terminate.

Executive Officer and Director Compensation

See the section titled “Executive and Director Compensation” for information regarding the compensation of our directors and named executive officers.

Employment Agreements

We have entered into offer letter agreements with our executive officers that, among other things, provide for certain compensatory and change in control benefits, as well as severance benefits. For a description of these agreements with our named executive officers, see the section titled “Executive and Director Compensation—Executive Compensation Arrangements.”

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors and officers, and intend to enter into new indemnification agreements with each of our current directors and officers before the completion of this offering. Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by applicable law. See the section titled “Management—Limitation on Liability and Indemnification Matters.”

Policies and Procedures for Related Person Transactions

Prior to the consummation of this offering, our board of directors will adopt a written related person transaction policy, to be effective upon the consummation of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, 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

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a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including 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. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth, as of November 30, 2019, information regarding beneficial ownership of our capital stock by:

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

The percentage ownership information under the column titled “Before Offering” is based on 115,569,451 shares of common stock outstanding as of November 30, 2019 assuming the conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 111,748,065 shares of common stock upon the completion of this offering. The percentage ownership information under the column titled “After Offering” is based on the sale of _____ shares of common stock in this offering (assuming an initial public offering price of \$ _____ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus). The percentage ownership information assumes no exercise of the underwriters’ option to purchase additional shares.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security. In addition, shares of common stock issuable upon the exercise of stock options or warrants that are currently exercisable or exercisable within 60 days of November 30, 2019 are included in the following table. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table does not necessarily indicate beneficial ownership for any other purpose. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

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Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Annexon, Inc., 180 Kimball Way, Suite 200, South San Francisco, California 94080.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned	
		Before Offering (%)	After Offering (%)
Greater than 5% Stockholders:			
Entities affiliated with Bain Capital Life Sciences ⁽¹⁾	22,222,221	19.2%	
Clarus Lifesciences III, L.P. ⁽²⁾	20,185,499	17.5%	
Entities affiliated with New Enterprise Associates ⁽³⁾	19,965,308	17.3%	
Novartis Bioventures Ltd. ⁽⁴⁾	18,564,832	16.1%	
Trusts and Other Entities affiliated with Muneer A. Satter ⁽⁵⁾	12,648,847	10.9%	
Citadel Multi-Strategy Equities Master Fund Ltd. ⁽⁶⁾	7,407,406	6.4%	
Named Executive Officers and Directors:			
Douglas Love, Esq. ⁽⁷⁾	3,635,059	3.0%	
Sanjay Keswani, MBBS, BSc, FRCP ⁽⁸⁾	—	*	
Jennifer Lew ⁽⁹⁾	—	*	
William Young ⁽¹⁰⁾	20,575,161	17.7%	
Campbell Murray, M.D. ⁽¹¹⁾	18,564,832	16.1%	
Muneer Satter ⁽¹²⁾	12,648,847	10.9%	
Emmett Cunningham, M.D., Ph.D., M.P.H. ⁽¹³⁾	20,185,499	17.5%	
Carol Gallagher, Pharm.D. ⁽¹⁴⁾	19,965,308	17.3%	
Ricky Sun ⁽¹⁵⁾	—	*	
Thomas G. Wiggans ⁽¹⁶⁾	118,116	*	
All executive officers and directors as a group (11 persons)	76,530,435	63.4%	

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 20,158,775 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock directly held by Bain Capital Life Sciences Fund, L.P., or BC LS, and (ii) 2,063,446 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock directly held by BCIP Life Sciences Associates, LP, or BCIP LS and, together with BC LS, the Bain Capital Life Sciences Entities. Bain Capital Life Sciences Investors, LLC, whose managers are Jeffrey Schwartz and Adam Koppel, is the ultimate general partner of BC LS and governs the investment strategy and decision-making process with respect to investments held by BCIP LS. As a result, each of Bain Capital Life Sciences Investors, LLC, Mr. Schwartz and Dr. Koppel may be deemed to share voting and dispositive power over the shares held by the Bain Capital Life Sciences Entities. The address of the Bain Capital Life Sciences Entities is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, Massachusetts 02116.
- (2) Consists of (i) 5,666,667 shares of common stock issuable upon the conversion of the Series A-1 redeemable convertible preferred stock, (ii) 8,370,685 shares of common stock issuable upon the conversion of the Series B redeemable convertible preferred stock and (iii) 6,148,147 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock, collectively, the Clarus Shares directly held by Clarus Lifesciences III, L.P. The address for Clarus Lifesciences III, L.P. is 101 Main Street, Suite 1210, Cambridge, Massachusetts 02142. Clarus Lifesciences III, L.P. is the record owner of the Clarus Shares. Clarus Ventures III GP, L.P. is the sole general partner of Clarus Lifesciences III, L.P. Blackstone Clarus III L.L.C. is the sole general partner of Clarus Ventures III GP, L.P. The sole member of Blackstone Clarus III L.L.C. is Blackstone Holdings II L.P. The sole general partner of Blackstone Holdings II L.P. is Blackstone Holdings I/II GP L.L.C. The sole member of Blackstone Holdings I/II GP L.L.C. is The Blackstone Group Inc. The sole holder of the Class C common stock of The Blackstone Group Inc. is Blackstone Group Management L.L.C. Blackstone Group Management L.L.C. is wholly-owned by Blackstone's senior managing directors and controlled by its founder, Stephen A. Schwarzman. Each of such entities and Mr. Schwarzman may be deemed to beneficially own the shares beneficially owned by Clarus Lifesciences III, L.P., but each (other than Clarus Lifesciences III, L.P.) disclaims beneficial ownership of such shares.
- (3) Consists of (i) 17,392 shares of common stock issuable upon the conversion of the Series B redeemable convertible preferred stock directly held by NEA Ventures 2016, L.P., or Ventures 16, (ii) 14,021,991 shares of common stock issuable upon the conversion of the Series B redeemable convertible preferred stock directly held by New Enterprise Associates 15, L.P., or NEA 15 and (iii) 5,925,925 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock directly held by NEA 15. The securities directly held by NEA 15 are indirectly held by NEA Partners 15, L.P., or Partners 15, which is the sole general partner of NEA 15; NEA 15 GP, LLC, or NEA 15 LLC, which is the sole general partner of Partners 15; and each of the individual managers of NEA 15 LLC. The individual Managers of NEA 15 LLC, or the NEA 15 Managers, are Peter J. Barris, Forest Baskett, Anthony A. Florence, Mohamad Makhzoumi, Joshua Makower, David M. Mott, Scott D. Sandell and Peter Sonsini. NEA

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Partners 15, NEA 15 LLC and the NEA 15 Managers share voting and dispositive power with regard to the shares owned directly by NEA 15. The securities directly held by Ventures 16 are indirectly held by Karen P. Welsh, the general partner of Ventures 16. All indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein. The address for the above referenced entities is 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

- (4) Consists of (i) 5,714,286 shares of common stock issuable upon the conversion of the Series A-1 redeemable convertible preferred stock, (ii) 8,406,103 shares of common stock issuable upon the conversion of the Series B redeemable convertible preferred stock and (iii) 4,444,443 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock directly held by Novartis Bioventures Ltd. The board of directors of Novartis Bioventures Ltd. has sole voting and investment control and power over such securities. None of the members of its board of directors has individual voting or investment power with respect to such securities and each disclaims beneficial ownership of such securities. Dr. Campbell Murray, a member of our board of directors, is also an employee of a corporation that is affiliated with Novartis Bioventures Ltd. Dr. Murray disclaims beneficial ownership of the securities held by Novartis Bioventures Ltd. except to the extent of his pecuniary interest arising as a result of his employment by such affiliate of Novartis Bioventures Ltd. Novartis Bioventures Ltd. is a Swiss corporation and an indirectly owned subsidiary of Novartis AG. The address for Novartis Bioventures Ltd. is Lichtstrasse 35, CH-4056 Basel.
- (5) Consists of (i) 952,381 shares of common stock issuable upon the conversion of the Series A-1 redeemable convertible preferred stock directly held by the Muneer A. Satter Revocable Trust for which Muneer A. Satter serves as trustee and, in such capacity, has sole voting and dispositive power over all such shares, (ii) 2,142,857 shares of common stock issuable upon the conversion of the Series A-1 redeemable convertible preferred stock directly held by various other trusts and other entities for which Muneer A. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive power over all such shares, (iii) 1,162,022 shares of common stock issuable upon the conversion of the Series B redeemable convertible preferred stock directly held by the Muneer A. Satter Revocable Trust for which Muneer A. Satter serves as trustee and, in such capacity, has sole voting and dispositive power over all such shares, (iv) 2,854,551 shares of common stock issuable upon the conversion of the Series B redeemable convertible preferred stock directly held by various other trusts and other entities for which Muneer A. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive power over all such shares, and (v) 5,537,036 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock directly held by Satter Medical Technology Partners, L.P. for which Muneer A. Satter has sole voting and dispositive power over all such shares collectively, the Satter Investors. Mr. Satter disclaims beneficial ownership of all shares included in clauses (ii), (iv) and (v) of this footnote (5), except to the extent of his pecuniary interest. The address of the Satter Investors is c/o Satter Management Co., L.P., 676 North Michigan Avenue, Suite 4000, Chicago, Illinois 60611.
- (6) Consists of 7,407,406 shares of common stock issuable upon the conversion of the Series C redeemable convertible preferred stock directly held by Citadel Multi-Strategy Equities Master Fund Ltd., or Citadel. Citadel Advisors LLC, or Citadel Advisors, acts as the portfolio manager of Citadel. Citadel Advisors Holdings LP, or CAH, is the sole member of Citadel Advisors, and Citadel GP LLC, or CGP, is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP and may be deemed to share voting and dispositive power over shares held by Citadel. The address for this entity is c/o Citadel Advisors, 601 Lexington Avenue, New York, New York 10022.
- (7) Consists of 3,635,059 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of November 30, 2019.
- (8) Consists of 0 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of November 30, 2019.
- (9) Consists of 0 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of November 30, 2019.
- (10) Consists of 389,662 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of November 30, 2019 and the shares described in footnote (2) above. Mr. Young disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.
- (11) Consists of the shares described in footnote (4) above. Dr. Murray disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.
- (12) Consists of the shares described in footnote (5) above.
- (13) Consists of the shares described in footnote (2) above. Dr. Cunningham disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.
- (14) Dr. Gallagher, a member of our board of directors, is employed as a Partner at New Enterprise Associates, Inc., has no voting or investment power over the shares owned of record by NEA 15 or Ventures 16 referenced in footnote (3) above, and disclaims beneficial ownership of the shares held by NEA 15 and Ventures 16.
- (15) Does not include the shares of common stock held by the Bain Capital Life Sciences Entities described in footnote (1) above. Ricky Sun is a Partner with Bain Capital Life Sciences Investors, LLC.
- (16) Consists of 118,116 shares of common stock that may be acquired pursuant to the exercise of stock options within 60 days of November 30, 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, which will become effective immediately prior to the completion of this offering, the amended and restated investors' rights agreement to which we and certain of our stockholders are parties 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, amended and restated bylaws and amended and restated investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of _____ shares of common stock, par value \$0.001 per share, and _____ shares of preferred stock, par value \$0.001 per share.

Common Stock

Outstanding Shares

As of September 30, 2019, we had 115,569,451 shares of common stock outstanding, held of record by 44 stockholders, assuming the conversion of all of our outstanding shares of redeemable convertible preferred stock into 111,748,065 shares of common stock in connection with the completion of this offering.

Voting Rights

Each holder of 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, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends 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, subject to 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 or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of

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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 and issue 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.

Preferred Stock

Upon the completion of this offering, all of our currently outstanding shares of redeemable convertible preferred stock will convert into common stock and we will not have any shares of preferred stock outstanding. Immediately prior to the completion of this offering, our amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of redeemable convertible preferred stock. From and after the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to _____ 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 our 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 preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock Options

As of September 30, 2019, we had outstanding options to purchase an aggregate of 18,336,476 shares of our common stock, with a weighted-average exercise price of \$0.54 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive and Director Compensation—Equity Incentive Plans.”

Registration Rights

Upon the completion of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our redeemable convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors’ rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will terminate upon the earliest of (i) with respect to each stockholder, such date, on or after the closing of this offering, on which all registrable shares held by such stockholder may immediately be sold during any 90-day period pursuant to Rule 144 of the Securities Act, or Rule 144, and (ii) the occurrence of a deemed liquidation event, as defined in our amended and restated certificate of incorporation, as currently in effect.

Demand Registration Rights

Upon the completion of this offering, holders of up to _____ shares of our common stock issuable upon conversion of outstanding redeemable convertible preferred stock will be entitled to certain demand registration rights. Beginning 180 days following the effectiveness of the registration statement of which this prospectus is a part, certain major investors holding, collectively, 60% of registrable securities may, on not more than two occasions, request that we register all or a portion of their shares, subject to certain specified exceptions. If any of these holders exercises its demand registration rights, then holders of _____ shares of our common stock issuable upon the shares of our redeemable convertible preferred stock in connection with this offering will be entitled to register their shares, subject to specified conditions and limitations in the corresponding offering.

Piggyback Registration Rights

In connection with this offering, holders of up to _____ shares of our common stock issuable upon conversion of outstanding redeemable convertible preferred stock are entitled to their rights to notice of this offering and to include their shares of registrable securities in this offering. The requisite percentage of these stockholders are expected to waive all such stockholders' rights to notice of this offering and to include their shares of registrable securities in this offering. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 Registration Rights

Upon the completion of this offering, the holders of _____ shares of our common stock issuable upon conversion of outstanding redeemable convertible preferred stock will initially be entitled to certain Form S-3 registration rights. Certain major investors holding at least 30% of registrable securities may, on not more than two registrations on Form S-3 within any 12-month period, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds \$1.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

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

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective immediately prior to the completion of this offering contain provisions that 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-held 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 will make 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 effect a change in control of our company. 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 certificate of incorporation will provide that a special meeting of stockholders may be called at any time by our board of directors, but such special meetings may not be called by the stockholders or any other person or persons.

Requirements for Advance Notification of Stockholder Nominations and Proposals

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

Classified Board; Election and Removal of Directors; Filling Vacancies

Effective upon the consummation of this offering, our board of directors will be divided into three classes, divided as nearly as equal in number as possible. 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 will provide for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock. For more information on the classified board, see the section titled “Management—Board Composition.” Furthermore, 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.

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This system of electing and removing directors and filling vacancies 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 certificate of incorporation and amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws (as either may be amended from time to time); or any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws preclude stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware, or a Foreign Action, in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation and amended and restated bylaws will 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.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Amendment of Charter Provisions

The amendment of any of the above provisions 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 on Liability and Indemnification

For a discussion of limitation on liability and indemnification, see the section titled “Management—Limitation on Liability and Indemnification Matters.”

Nasdaq Global Market Listing

We intend to apply to list our common stock on the Nasdaq Global Market under the trading symbol “ANNX.”

Transfer Agent and Registrar

Upon completion of this offering, the transfer agent and registrar for our common stock will be . The transfer agent and registrar’s address is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of our common stock, including shares issued upon the exercise of outstanding options, in the public market after the completion of this offering, or the perception that those sales may occur, could adversely affect the prevailing market price for our common stock from time to time or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of September 30, 2019, upon the closing of this offering and (i) assuming the conversion of all of our outstanding redeemable convertible preferred stock into an aggregate of 111,748,065 shares of our common stock in connection with the completion of this offering, (ii) assuming no exercise of the underwriters' option to purchase additional shares of common stock and (iii) assuming no exercise of outstanding options, we will have outstanding an aggregate of approximately _____ shares of common stock. Of these shares, all of the _____ shares of common stock to be sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act, or Rule 144, or subject to lock-up agreements. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be "restricted securities," as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 of the Securities Act, or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701, based on the number of shares of our common stock outstanding (calculated as of September 30, 2019 on the basis of the assumptions described above), the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

<u>Approximate Number of Shares</u>	<u>First Date Available For Sale Into Public Market</u>
shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2020 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Rule 144

Under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, and we are current in our Exchange Act reporting at the time of sale, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our “affiliates” for purposes of Rule 144 at any time during the 90 days preceding a sale and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our “affiliates,” is entitled to sell those shares in the public market (subject to the lock-up agreement referred to below, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than “affiliates,” then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to below, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our “affiliates,” as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months, are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately _____ shares of common stock immediately upon the completion of this offering (calculated as of September 30, 2019 on the basis of the assumptions described above); or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and requirements related to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) and who are not our “affiliates” as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Persons who are our “affiliates” may resell those shares beginning 90 days after the date of this prospectus without compliance with minimum holding period requirements under Rule 144 (subject to the terms of the lock-up agreement referred to below, if applicable).

Lock-Up Agreements

In connection with this offering, we, our directors, our executive officers and holders of substantially all of our other outstanding shares of common stock or securities convertible into or exchangeable for shares of our common stock outstanding upon the completion of this offering, have agreed, subject to certain limited

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exceptions, with the underwriters not to directly or indirectly offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of or hedge any shares of our common stock or any options to purchase shares of our common stock, or any securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC, and certain other limited exceptions. These agreements are described in the section titled “Underwriting.”

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors’ rights agreement, our standard form of option agreement, our standard form of restricted stock agreement and our standard form of restricted stock purchase agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration Rights

Upon the completion of this offering, the holders of up to 111,748,065 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described under “—Lock-Up Agreements” above. 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, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. The requisite percentage of these stockholders will waive all such stockholders’ rights to notice of this offering and to include their shares of registrable securities in this offering. See the section titled “Description of Capital Stock—Registration Rights.”

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under our 2020 Plan and our ESPP. Such registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the 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 purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that 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 not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(1)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation 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 that (i) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled “Dividend Policy,” we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions 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. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable tax treaties.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below regarding backup withholding, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is 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
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by certain U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the Non-U.S. Holder certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above or the Non-U.S. Holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA), on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

<u>Name</u>	<u>Number of Shares</u>
J.P. Morgan Securities LLC	
BofA Securities, Inc.	
Cowen and Company, LLC	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ _____ per share. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to _____ additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ _____ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	<u>Without Option to Purchase Additional Shares Exercise</u>	<u>With Full Option to Purchase Additional Shares Exercise</u>
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ _____. We have agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount up to \$ _____.

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

We have agreed that we will not, subject to certain exceptions, (i) offer, pledge, announce the intention to sell, 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, hedge, or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended, or the Securities Act, relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap, hedging, or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC for a period of 180 days after the date of this prospectus.

Our directors and executive officers, and substantially all of our securityholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC, (i) offer, pledge, announce the intention to sell, 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, hedge, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) or (ii) enter into any swap, hedging, or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or (iii) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for our common stock.

The restrictions described in the immediately preceding paragraph do not apply to, subject to certain additional limitations, among other items:

- (i) the securities to be sold by the securityholder pursuant to the underwriting agreement for this offering;
- (ii) transfers of securities as a bona fide gift or gifts;
- (iii) transfers or dispositions of securities to any trust for the direct or indirect benefit of the securityholder or the immediate family of the securityholder;
- (iv) transfers or dispositions of securities to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the securityholder or the immediate family of the securityholder;
- (v) transfers or dispositions of securities by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the securityholder;
- (vi) redeemable distributions of securities to partners, members or stockholders of the securityholder;

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- (vii) transfers to the securityholder's affiliates or to any investment fund or other entity controlled or managed by, controlling or managing, or under common control with, the securityholder; and
- (viii) transfers pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of our common stock and involving a change of control of our company approved by the board of directors of our company, provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the securities owned by the securityholder shall remain subject to the restrictions contained in the lock-up agreement;

provided that in the case of any transfer or distribution pursuant to clauses (ii), (iii), (iv), (v), (vi) or (vii) above, each transferee, donee or distributee shall execute and deliver to the representatives a lock-up agreement; and provided, further, that in the case of any transfer, disposition or distribution pursuant to clauses (ii), (iii), (iv), (v), (vi) or (vii) above, no filing by any party under Section 16 of the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution and any such transfer or distribution shall not involve a disposition for value.

Furthermore, securityholders may, subject to certain additional limitations, without the prior written consent of J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC (i) exercise on a cash basis of any option to purchase shares of common stock granted under any stock incentive plan or stock purchase plan, provided that the underlying shares of common stock shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement; (ii) establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of common stock, provided that such plan does not provide for any transfers of common stock during the lock-up period; (iii) transfer or dispose of shares of common stock acquired in this offering or on the open market following this offering; (iv) transfer or surrender to us shares of common stock (or any security convertible into common stock) (A) pursuant to a right of first refusal described in this prospectus with respect to transfers of such shares of common stock or other securities, or (B) to us for purposes of exercising or settling (including for the payment of tax withholdings due as a result of such exercise or settlement) on a "net exercise," "net settlement" or "cashless" basis any equity award, provided such equity award was granted under our stock incentive plan or stock purchase plan; and (v) transfer or dispose of securities by operation of law pursuant to a qualified domestic order or in connection with a divorce settlement or other court order.

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

We intend to apply to list our shares of common stock on the Nasdaq Global Market under the trading symbol "ANNX."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. 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 that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

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The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other Relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area, or each, a “Member State,” no shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation), except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- (i) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- (iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000 (as amended).

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in 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.

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Pursuant to section 3A.3 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.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the Dubai International Financial Centre, or DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to Prospective Investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to Prospective Investors in Australia

This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;

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- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, or Exempt Investors.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, 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 resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (ii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the CO or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

Notice to Prospective Investors in 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

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invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares 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, as modified or amended from time to time including by any subsidiary legislation as may be applicable at the relevant time, or together, the SFA, (ii) to a relevant person pursuant to Section 275(1), 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 the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (i) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) 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 of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (A) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (B) where no consideration is or will be given for the transfer;
- (C) where the transfer is by operation of law; or
- (D) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended (the "CMA Regulations"). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to Prospective Investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Company. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to Prospective Investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to Prospective Investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The shares have not been listed on any of the securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to Prospective Investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to Prospective Investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through

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a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to Prospective Investors in South Africa

Due to restrictions under the securities laws of South Africa, no “*offer to the public*” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted), or the South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a “*registered prospectus*” (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96(1) applies:

Section 96(1)(a)	the offer, transfer, sale, renunciation or delivery is to: (i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent; (ii) the South African Public Investment Corporation; (iii) persons or entities regulated by the Reserve Bank of South Africa; (iv) authorised financial service providers under South African law; (v) financial institutions recognised as such under South African law; (vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or (vii) any combination of the person in (i) to (vi); or
Section 96(1)(b)	the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as “*advice*” as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Notice to Prospective Investors in Israel

We have not taken any action to permit a public offering of our shares outside the United States. Solicitation of our shares, however, will be made in certain countries in a manner that will not require the publication of a prospectus under the laws of the country. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to the offering of our shares and the distribution of this prospectus outside the United States.

Notwithstanding the above, the offering of our shares is available to investors listed in the First Supplement of the Israeli Securities Law of 1968, as amended. A prospectus has not been prepared or filed, and will not be prepared or filed, in Israel relating to the shares offered hereunder. The shares cannot be resold in Israel other than to investors listed in the First Supplement of the Israeli Securities Law of 1968, as amended purchasing for their own account and not for distribution or resale purposes. No action will be taken in Israel that would permit

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an offering of the shares offered hereunder, or the distribution of any offering document or any other material to the public in Israel. This registration statements has not been reviewed or approved by the Israel Securities Authority. Any materials provided to an investor in Israel may not be reproduced or used for any other purpose, nor be furnished to any other person other than those to whom copies have been provided directly by the Issuer or the Dealer(s). The shares will not be traded on the TASE. Nothing in the above should be considered as the rendering of a recommendation or advice, including investment advice or investment marketing under the Israeli Law For Regulation of Investment Advice, Investment Marketing and Investment Portfolio Management, 1995, to purchase any shares and in purchasing the shares, the investors acknowledge that they have expertise and experience in financial and business matters so as to be capable of evaluating the risks and merits of the purchase of the shares.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Cooley LLP, San Diego, California.

EXPERTS

The consolidated financial statements of Annexon, Inc. as of December 31, 2017 and 2018, and for each of the years in the two-year period ended December 31, 2018, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website referred to above. We also maintain a website at www.annexonbio.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only.

ANNEXON, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Annexon, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Annexon, Inc. (the Company) as of December 31, 2017 and 2018, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2018, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

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

San Francisco, California
August 27, 2019

ANNEXON, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	<u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,966	\$ 44,175
Prepaid expenses and other current assets	1,927	1,531
Total current assets	4,893	45,706
Property and equipment, net	2,816	2,345
Other long-term assets	112	98
Total assets	<u>\$ 7,821</u>	<u>\$ 48,149</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,524	\$ 1,271
Accrued liabilities	1,074	1,713
Deferred rent, current	318	342
Total current liabilities	2,916	3,326
Deferred rent	2,145	1,803
Redeemable convertible preferred stock liability	—	5,140
Total liabilities	<u>5,061</u>	<u>10,269</u>
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, \$0.001 par value, 56,192,520 and 119,155,472 shares authorized as of December 31, 2017 and 2018, respectively; 44,389,394 and 89,525,848 shares issued and outstanding as of December 31, 2017 and 2018, respectively; liquidation preference of \$49,240 and \$107,814 as of December 31, 2017 and 2018, respectively	48,971	102,082
Stockholders' Deficit:		
Common stock, \$0.001 par value; 69,000,000 and 150,000,000 shares authorized as of December 31, 2017 and 2018, respectively; 3,140,526 and 3,808,699 shares issued and outstanding as of December 31, 2017 and 2018, respectively	3	4
Additional paid-in capital	905	1,257
Accumulated other comprehensive loss	(26)	(66)
Accumulated deficit	(47,093)	(65,397)
Total stockholders' deficit	<u>(46,211)</u>	<u>(64,202)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 7,821</u>	<u>\$ 48,149</u>

See accompanying notes to consolidated financial statements.

ANNEXON, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2017	2018
Operating expenses:		
Research and development	\$ 17,853	\$ 15,528
General and administrative	2,624	3,619
Total operating expenses	<u>20,477</u>	<u>19,147</u>
Loss from operations	(20,477)	(19,147)
Gain on remeasurement of redeemable convertible preferred stock liability	—	260
Other income, net	1,770	584
Net loss before taxes	(18,707)	(18,303)
Provision for income taxes	1	1
Net loss	(18,708)	(18,304)
Accretion on redeemable convertible preferred stock	87	176
Net loss attributable to common stockholders	<u>\$ (18,795)</u>	<u>\$ (18,480)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (6.16)</u>	<u>\$ (5.21)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>3,051,792</u>	<u>3,548,177</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		<u>\$</u>
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		<u></u>

See accompanying notes to consolidated financial statements.

ANNEXON, INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended	
	December 31,	
	<u>2017</u>	<u>2018</u>
Net loss	\$(18,708)	\$(18,304)
Other comprehensive loss:		
Foreign currency translation adjustment	(24)	(40)
Comprehensive loss	<u>\$(18,732)</u>	<u>\$(18,344)</u>

See accompanying notes to consolidated financial statements.

ANNEXON, INC.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Cost	Shares	Cost				
Balances as of December 31, 2016	44,389,394	\$ 48,884	2,911,610	\$ 3	\$ 549	\$ (2)	\$ (28,385)	\$ (27,835)
Accretion on redeemable convertible preferred stock	—	87	—	—	(87)	—	—	(87)
Stock option exercises	—	—	228,916	—	42	—	—	42
Stock-based compensation	—	—	—	—	401	—	—	401
Foreign currency translation adjustment	—	—	—	—	—	(24)	—	(24)
Net loss	—	—	—	—	—	—	(18,708)	(18,708)
Balances as of December 31, 2017	44,389,394	48,971	3,140,526	3	905	(26)	(47,093)	(46,211)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$22	11,803,125	13,552	—	—	—	—	—	—
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of \$217 and redeemable convertible preferred stock liability of \$5.4 million	33,333,329	39,383	—	—	—	—	—	—
Accretion on redeemable convertible preferred stock	—	176	—	—	(176)	—	—	(176)
Stock option exercises	—	—	668,173	1	120	—	—	121
Stock-based compensation	—	—	—	—	408	—	—	408
Foreign currency translation adjustment	—	—	—	—	—	(40)	—	(40)
Net loss	—	—	—	—	—	—	(18,304)	(18,304)
Balances as of December 31, 2018	<u>89,525,848</u>	<u>\$ 102,082</u>	<u>3,808,699</u>	<u>\$ 4</u>	<u>\$ 1,257</u>	<u>\$ (66)</u>	<u>\$ (65,397)</u>	<u>\$ (64,202)</u>

See accompanying notes to consolidated financial statements.

ANNEXON, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended	
	December 31,	
	2017	2018
Operating activities:		
Net loss	\$(18,708)	\$(18,304)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	271	488
Stock-based compensation	401	408
Gain on remeasurement of redeemable convertible preferred stock liability	—	(260)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,645)	396
Other long-term assets	(17)	14
Accounts payable	144	(253)
Accrued liabilities	196	639
Deferred rent	98	(318)
Net cash used in operating activities	<u>(19,260)</u>	<u>(17,190)</u>
Investing activities:		
Purchases of property and equipment	(567)	(17)
Net cash used in investing activities	<u>(567)</u>	<u>(17)</u>
Financing activities:		
Proceeds from the exercise common stock options	42	121
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	58,335
Net cash provided by financing activities	<u>42</u>	<u>58,456</u>
Net (decrease) increase in cash and cash equivalents	(19,785)	41,249
Effect of exchange rate changes on cash and cash equivalents	(24)	(40)
Cash and cash equivalents at beginning of year	22,775	2,966
Cash and cash equivalents at end of year	<u>\$ 2,966</u>	<u>\$ 44,175</u>
Supplemental disclosure of non-cash investing and financing activities:		
Cash paid for income taxes	<u>\$ 1</u>	<u>\$ 1</u>
Recognition of fair value of redeemable convertible preferred stock liability upon issuance of redeemable convertible preferred stock	<u>\$ —</u>	<u>\$ 5,400</u>
Accretion on redeemable convertible preferred stock	<u>\$ 87</u>	<u>\$ 176</u>
Cash paid by landlord for tenant improvements	<u>\$ 2,365</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

ANNEXON, INC.
Notes to Consolidated Financial Statements

1. Organization

Annexon, Inc. (the “Company”) is a clinical-stage biopharmaceutical company targeting C1q and initiating molecules of the classical complement pathway to develop transformative therapies for autoimmune and neurodegenerative disorders of the body, eye and brain. The Company is located in South San Francisco, California and was incorporated in Delaware in March 2011.

The Company’s wholly-owned subsidiary, Annexon Biosciences Australia Pty Ltd (the “Subsidiary”), is a proprietary limited company incorporated in 2016 and domiciled in Australia. The Subsidiary is also engaged in research and development activities in support of its parent company.

Liquidity

Since inception, the Company has been involved primarily in performing research and development activities, conducting clinical trials, hiring personnel, and raising capital to support and expand these activities. The Company has experienced losses and negative cash flows from operations since its inception and, as of December 31, 2018, had an accumulated deficit of \$65.4 million and cash and cash equivalents of \$44.2 million.

In December 2018, the Company completed a Series C redeemable convertible preferred stock financing raising \$75.0 million with the first closing of \$45.0 million occurring on December 7, 2018 and the second closing to occur subject to the Company achieving defined milestones (Note 8). During the third quarter of 2019, the Company achieved the defined milestones, triggering the obligation to fund the second closing of \$30.0 million. The Company intends to raise additional capital through the issuance of additional equity, and potentially through strategic alliances with partner companies and/or debt financing. If financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Based on projected activities, management projects that cash and cash equivalents on hand and the funds associated with the Series C second closing are sufficient to support operations for at least the next 12 months following issuance of these financial statements. Management expects to continue to incur losses and negative cash flows from operations for at least the next several years.

2. Basis of Presentation and Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including but not limited to the fair value of common stock, redeemable convertible preferred stock, redeemable convertible preferred stock liability, and stock options, income taxes, and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the operations of Annexon, Inc. and its wholly owned subsidiary and include the results of operations and cash flows of these entities. All intercompany balances and transactions have been eliminated in consolidation.

ANNEXON, INC.
Notes to Consolidated Financial Statements

Segments

The Company's chief operating decision maker is its Chief Executive Officer. The Chief Executive Officer reviews financial information on an aggregate basis for the purposes of evaluating financial performance and allocating the Company's resources. Accordingly, the Company has determined that it operates in one segment.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with an original maturity of three months or less at time of purchase to be cash equivalents. Cash equivalents, which includes amounts invested in money market funds, are stated at fair value.

Property and Equipment, Net

Property and equipment are carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations in the period realized.

The useful lives of the property and equipment are as follows:

Laboratory equipment	5 years
Office and computer equipment	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of these asset may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. When indications of impairment are present and the estimated undiscounted future cash flows from the use of these assets is less than the assets' carrying value, the related assets will be written down to fair value. There were no impairments of the Company's long-lived assets for the periods presented.

Commitments and Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred.

Redeemable Convertible Preferred Stock Liability

The obligation to issue additional shares of the Company's Series C redeemable convertible preferred stock at a future date was determined to be a freestanding financial instrument that should be accounted for as a liability. At initial recognition, the Company recorded the redeemable convertible preferred stock liability on the balance sheet at its estimated fair value. The liability is subject to remeasurement at each balance sheet date, with changes in fair value recognized as gain (loss) on remeasurement of redeemable convertible preferred stock

ANNEXON, INC.
Notes to Consolidated Financial Statements

liability on the statement of operations. Upon settlement of the redeemable convertible preferred stock liability, the Company remeasures the liability and then reclassifies the final value associated with the redeemable convertible preferred stock liability to the carrying value of the Series C redeemable convertible preferred stock.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred taxes to the amounts expected to be realized.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merit, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Translation of Foreign Currencies

The Company's reporting currency is the U.S. dollar. The functional currency of the Company's subsidiary located in Australia is the Australian Dollar. Balance sheets prepared in the functional currencies are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders' equity accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using a weighted-average rate during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the accompanying consolidated balance sheets. Foreign exchange translation losses for the years ended December 31, 2017 and 2018 totaled \$24,000 and \$40,000, respectively.

Gains and losses resulting from exchange rate changes on transactions denominated in a currency other than the local currency are included in earnings as incurred.

Research and Development Expense

Research and development costs are expensed as incurred. Research and development costs consist primarily of direct and indirect development expenses incurred for the development of the Company's product candidates. Direct expenses include (i) agreements with third party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities; (ii) fees paid to contract manufacturers and costs to produce clinical trial materials; (iii) costs associated with discovery, preclinical and clinical testing of the product candidate costs; and (iv) laboratory supplies and materials. Indirect expenses include compensation and personnel-related expenses and stock-based compensation for personnel contributing to research and development and facilities and other expenses including depreciation and amortization. Payments made to third parties are under agreements that are generally cancelable by the Company. Advance payments for research and development activities are deferred as prepaid expenses. The prepaid amounts are expensed as the related services are performed.

ANNEXON, INC.
Notes to Consolidated Financial Statements

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In accruing service fees, the Company estimates the period over which services will be performed and the level of effort to be expended in each period. These estimates are based on the Company's communications with the third-party service providers and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies significantly from the estimate, the Company will adjust the accrual accordingly to reflect the best information available at the time of the financial statement issuance. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employee directors and consultants using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards to employees on the date of grant using the Black-Scholes option pricing model. The fair value of awards to non-employees is estimated at each measurement date, which is the date on which the award vests. Total expenses for non-employee share based awards has been immaterial to date.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating the fair value of the underlying common stock, expected term, expected stock price volatility, risk-free interest rate and dividend yield. The Company accounts for forfeitures as they occur.

Accounting for Non-Recurring Grant Income

Non-recurring grant income is recognized when the research and development activities have been undertaken and the Company has completed its assessment of whether such activities meet the relevant qualifying criteria. Grants received from government and other agencies in advance of the specific research and development costs to which they relate are deferred and recognized in the consolidated statement of operations in the period they are earned and when the related research and development costs are incurred. Non-recurring grant income recognized in other income, net for the years ended December 31, 2017 and 2018 was \$1.4 million and \$35,000, respectively.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. As the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders because the effects of potentially dilutive securities are antidilutive.

Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

In contemplation of the initial public offering ("IPO"), the Company has presented the unaudited pro forma basic and diluted net loss per share attributable to common stockholders, which has been computed to give effect

ANNEXON, INC.
Notes to Consolidated Financial Statements

to the conversion of the redeemable convertible preferred stock into shares of common stock. The unaudited pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received from the IPO. The unaudited pro forma net loss per share attributable to common stockholders for the year ended December 31, 2018 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates if later. The net loss attributable to common stockholders was adjusted to exclude the impact of the remeasurement of the redeemable convertible preferred stock liability and accretion on the redeemable convertible preferred stock as the underlying shares would have converted into common stock upon an IPO.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash. The Company's cash is deposited with high credit quality financial institutions. At times such deposits may be in excess of the Federal Depository Insurance Corporation insured limits.

Subsequent Events

The Company evaluated its consolidated financial statements for subsequent events through August 27, 2019, the date the consolidated financial statements were available to be issued.

Emerging Growth Company Status

The Company is expected to be an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which supersedes the guidance in former ASC 840, *Leases*. This standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. This standard is effective for annual reporting periods, and interim periods within those years, for public entities beginning after December 15, 2018 and for private entities beginning after December 15, 2019. Originally, a modified retrospective transition approach was required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued guidance to permit an alternative transition method for Topic 842, which allows transition to the new lease standard by

ANNEXON, INC.
Notes to Consolidated Financial Statements

recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Entities may elect to apply either approach. There are also a number of optional practical expedients that entities may elect to apply. The Company is currently assessing the impact of this standard on its consolidated financial statements. The Company expects to record a material right-of-use asset and lease liability in connection with adopting this standard as of January 1, 2020.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07). This standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Some of the areas of simplification apply only to nonpublic entities. This guidance is effective for annual reporting periods, and interim periods within those years, for public entities beginning after December 15, 2018. For all other entities, the amendments are effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted for any entity in any interim or annual period for which financial statements have not been issued or made available for issuance, but not before an entity adopts ASC 606. The Company is currently assessing the impact of this standard on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13), which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for all entities for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently assessing the impact of this standard on its consolidated financial statements.

3. Fair Value Measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- *Level 1 Inputs:* Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- *Level 2 Inputs:* Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- *Level 3 Inputs:* Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

On a recurring basis, the Company measures certain financial assets and liabilities at fair value. The following tables summarize the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2017			Total
	Level 1	Level 2	Level 3	
Assets:				
Money market funds	\$2,409	\$ —	\$ —	\$2,409
Total assets	<u>\$2,409</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$2,409</u>

ANNEXON, INC.
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	December 31, 2018			Total
	Level 1	Level 2	Level 3	
Assets:				
Money market funds	\$43,680	\$ —	\$ —	\$43,680
Total assets	<u>\$43,680</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$43,680</u>
Liabilities:				
Redeemable convertible preferred stock liability	\$ —	\$ —	\$5,140	\$ 5,140
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$5,140</u>	<u>\$ 5,140</u>

The Company has an operating account invested in money market funds with maturities of less than three months and is classified as cash and cash equivalents on the Company's balance sheet. The money market funds are valued using Level 1 inputs that are based on quoted prices in active markets for identical assets.

For the years ended December 31, 2017 and 2018, the Company recognized no material realized gains or losses on financial instruments.

The Company's Level 3 liabilities include the redeemable convertible preferred stock liability. The Company estimates the fair value of this liability using the Black-Scholes option pricing model with an expected term of 0.58 to 0.65 years, the estimated fair value of the Series C redeemable convertible preferred stock of \$1.19 to \$1.20, volatility of 77.7% and risk-free interest rates ranging from 2.47% to 2.56% during 2018. On the first closing of the Company's Series C redeemable convertible preferred stock financing in December 2018, the Company recorded the initial fair value of the redeemable convertible preferred stock liability of \$5.4 million. The liability was remeasured as of December 31, 2018, and the Company recorded a gain of \$260,000 in the consolidated statements of operations for the change in the fair value of the liability.

The changes in the carrying value of the liability were as follows (in thousands):

Fair value as of December 31, 2017	\$ —
Fair value at issuance	5,400
Change in fair value	(260)
Fair value as of December 31, 2018	<u>\$5,140</u>

There were no transfers between Levels 1, 2 or 3 for the periods presented.

4. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2017	2018
Prepaid research and development costs	\$1,071	\$1,127
Prepaid expenses	274	179
Other receivables	582	225
Total prepaid expenses and other current assets	<u>\$1,927</u>	<u>\$1,531</u>

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5. Property and Equipment, Net

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

	December 31,	
	2017	2018
Leasehold improvements	\$2,564	\$2,564
Laboratory equipment	413	429
Furniture and fixtures	136	136
Computer equipment and software	25	27
Total property and equipment, gross	<u>3,138</u>	<u>3,156</u>
Less: accumulated depreciation	(322)	(811)
Total property and equipment, net	<u>\$2,816</u>	<u>\$2,345</u>

Total depreciation expense recognized for the years ended December 31, 2017 and 2018 was \$271,000 and \$488,000, respectively.

6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2017	2018
Accrued research and development expenses	\$ 578	\$ 766
Accrued compensation	421	766
Accrued professional services	14	65
Other accrued expenses	61	116
Total accrued liabilities	<u>\$1,074</u>	<u>\$1,713</u>

7. Commitments and Contingencies**Leases**

In December 2016, the Company entered into a 7-year noncancelable facility lease agreement for its offices and laboratory occupying 12,316 square feet in South San Francisco, California. The lease commencement date was January 1, 2017. The lease agreement included a tenant improvement allowance of up to \$2.4 million that was accounted for as a tenant improvement asset with a corresponding increase to the deferred rent liability. The tenant improvement asset is being depreciated over the lease term, its assessed useful life. The lease has a 5-year renewal option prior to expiration and includes rent adjustment clauses throughout the lease term. Rent expense is recognized on a straight-line basis over the non-cancelable term of the lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability on the accompanying balance sheet.

Total rent expense was \$467,000 and \$353,000 for the years ended December 31, 2017 and 2018, respectively.

ANNEXON, INC.
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Future minimum lease payments under noncancelable operating leases as of December 31, 2018 were as follows (in thousands):

2019	\$ 696
2020	720
2021	743
2022	769
2023 and thereafter	1,157
Total	<u>\$4,085</u>

Sponsored Research Agreement

In December 2016, the Company entered into a Sponsored Research Agreement with a not-for-profit entity to perform research on multiple sclerosis. Under the terms of the Sponsored Research Agreement, the Company may receive up to \$693,000 in funding. If within 15 years of the end of the Sponsored Research Agreement the Company files a marketing authorization application for a product treating multiple sclerosis, the Company will be obligated to pay milestone payments up to four times the amounts received under the Sponsored Research Agreement. In the year ended December 31, 2017, the Company had received \$231,000, representing the total amount received to that date under the Sponsored Research Agreement, which was recorded as other income. No funding was received in 2018.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2018, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

8. Redeemable Convertible Preferred Stock and Stockholder's Deficit

Redeemable Convertible Preferred Stock

As of December 31, 2017, redeemable convertible preferred stock consisted of the following:

	<u>Shares Authorized</u>	<u>Shares Outstanding</u>	<u>Net Carrying Value (in thousands)</u>	<u>Liquidation Preference (in thousands)</u>
Series A	1,015,434	1,015,434	\$ 994	\$ 1,000
Series A-1	16,398,995	16,398,995	17,098	17,219
Series B	38,778,091	26,974,965	30,879	31,021
Total	<u>56,192,520</u>	<u>44,389,394</u>	<u>\$ 48,971</u>	<u>\$ 49,240</u>

ANNEXON, INC.
Notes to Consolidated Financial Statements

As of December 31, 2018, redeemable convertible preferred stock consisted of the following:

	Shares Authorized	Shares Outstanding	Net Carrying Value (in thousands)	Liquidation Preference (in thousands)
Series A	1,015,434	1,015,434	\$ 996	\$ 1,000
Series A-1	16,398,995	16,398,995	17,142	17,219
Series B	38,778,091	38,778,090	44,484	44,595
Series C	62,962,952	33,333,329	39,460	45,000
Total	<u>119,155,472</u>	<u>89,525,848</u>	<u>\$ 102,082</u>	<u>\$ 107,814</u>

In December 2018, the Company issued 33,333,329 shares of Series C redeemable convertible preferred stock for \$1.35 per share in the first closing of its Series C redeemable convertible preferred stock financing. Investors in the Series C redeemable convertible preferred stock financing also received freestanding rights to purchase an additional 22,222,217 shares of Series C redeemable convertible preferred stock on the same terms as the first closing upon completion of certain defined milestones or waiver of the milestones by the holders of at least 60% of the outstanding redeemable convertible preferred stock, voting as a single class on an as-converted basis, including certain Series C investors. Additionally, the investors had the right to purchase their second closing shares upon providing notice to the Company prior to July 31, 2019. If the milestones are met by July 31, 2019 then the investors are obligated to participate in the second closing on the same terms as the first closing. In August 2019, the term was extended to August 31, 2019. The investors' rights to purchase Series C redeemable convertible preferred stock represent a freestanding financial instrument accounted for as a liability measured at fair value at inception and remeasured at fair value each reporting date. Changes in fair value are recognized in the statement of operations. The proceeds from the initial closing of the Series C redeemable convertible preferred stock of \$44.8 million were allocated to the redeemable convertible preferred stock liability at its fair value of \$5.4 million and to the carrying value of the Series C redeemable convertible preferred stock.

In June 2016, the Company issued 26,974,965 shares of Series B redeemable convertible preferred stock for \$1.15 per share to a group of investors in the first closing of its Series B redeemable convertible preferred stock financing. In February 2018, the Company issued 11,803,125 additional shares of Series B redeemable convertible preferred stock in a second closing on the same terms as the initial closing in June 2016.

Significant provisions of the redeemable convertible preferred stock are as follows:

Dividends—The holders of Series A-1, Series B and Series C redeemable convertible preferred stock are entitled to receive noncumulative dividends, in preference to any dividends payable to holders of Series A redeemable convertible preferred stock or common stock, at the annual dividend rate of \$0.063 per share for Series A-1 redeemable convertible preferred stock, \$0.069 per share for Series B redeemable convertible preferred stock and \$0.081 per share for Series C redeemable convertible preferred stock, as adjusted for any stock splits, stock dividends, recapitalization, or the like, if declared by the Board of Directors.

The holders of Series A redeemable convertible preferred stock are entitled to receive noncumulative dividends, in preference to any dividends payable to holders of common stock, if declared by the Board of Directors.

The holders of redeemable convertible preferred stock are also entitled to participate in dividends on common stock, when and if declared by the Board of Directors, based on the outstanding redeemable convertible preferred stock (on an as-if converted to common stock basis) and common stock.

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Notes to Consolidated Financial Statements

Conversion—At the option of the holder, each share of redeemable convertible preferred stock is convertible, one-for-one, subject to adjustment for anti-dilution protection, into shares of common stock. Each share automatically converts into the number of shares of common stock into which the shares are convertible at the then applicable conversion ratio upon (i) the closing of the sale of the Company's common stock in a public offering provided the offering price per share is not less than \$2.70 (as adjusted for recapitalization), and the aggregate net proceeds are greater than \$50 million ("Qualified Public Offering") or (ii) upon receipt of the written consent of the holders of at least 60% of the outstanding redeemable convertible preferred stock, voting as a single class on an as-converted basis, including certain Series C investors, for the conversion of all then outstanding redeemable convertible preferred stock.

Liquidation—In the event of any liquidation, dissolution or winding up of the Company, including a merger or acquisition where the beneficial owners of the Company's common and redeemable convertible preferred stock own less than majority of the surviving entity, or a sale of all or substantially all assets, the holders of Series C, Series B and Series A-1 redeemable convertible preferred stock will be entitled to receive a per share amount equal to \$1.35, \$1.15 and \$1.05 for Series C, Series B and Series A-1 redeemable convertible preferred stock, respectively (subject to adjustment for recapitalizations, stock dividends or the like), plus all declared but unpaid (if any). The holders of Series C redeemable convertible preferred stock are also entitled to an additional amount per share if the liquidation event occurs before a certain date.

After payment of the full liquidation preference of Series C, Series B and Series A-1 redeemable convertible preferred stock, the holders of Series A redeemable convertible preferred stock will be entitled to receive an amount equal to \$0.9848 per share, as adjusted, plus all declared but unpaid dividends prior to and in preference to any distribution to the holders of common stock.

After payment of the full liquidation preference of Series C, Series B, Series A-1 and Series A redeemable convertible preferred stock, distributions by the Company shall be distributed with equal priority, subject to the proviso outlined below, among holders of the redeemable convertible preferred stock and common stock, with redeemable convertible preferred stock being treated on an as converted basis. Upon receipt by the Series C, Series B, Series A-1 and Series A redeemable convertible preferred stock holders of their per share aggregate distribution threshold amounts of \$1.35, \$2.30, \$2.10 and \$1.9696 for holders of Series C, Series B, Series A-1 and Series A redeemable convertible preferred stock, respectively, any remaining proceeds available for distribution will be distributed among holders of common stock in proportion to the number of common shares held by them.

Voting—The holders of redeemable convertible preferred stock are entitled to the number of votes equal to the number of shares of common stock into which each share of Series C, Series B, Series A-1 and Series A redeemable convertible preferred stock could be converted on the record date for the vote or consent of the stockholders, except as otherwise required by law, and have voting rights and powers equal to the voting rights and powers of the common stockholders.

The holders of Series C redeemable convertible preferred stock, voting as a separate class, are entitled to elect one member of the Board of Directors. The holders of Series B redeemable convertible preferred stock, voting as a separate class, are entitled to elect one member of the Board of Directors. The holders of Series A-1 redeemable convertible preferred stock, voting as a separate class, are entitled to elect three members of the Board of Directors. The holders of common stock, voting as a separate class, are entitled to elect one member of the Board of Directors. Any additional members of the Board of Directors shall be elected by the holders of common stock and redeemable convertible preferred stock voting together as a single class.

Redemption—All redeemable convertible preferred stock shall be redeemed at the election of the holders of at least 60% of the then outstanding shares of redeemable convertible preferred stock, voting as a single class on

ANNEXON, INC.
Notes to Consolidated Financial Statements

an as-converted basis, including certain Series C investors, at any time after the fifth anniversary of the date of the filing of the Fifth Amended and Restated Certificates of Incorporation. The Company shall redeem the outstanding shares of redeemable convertible preferred stock by paying in cash, in three equal annual installments, an amount per share equal to the Series C original issue price, with respect to Series C redeemable convertible preferred stock, Series B original issue price, with respect to Series B redeemable convertible preferred stock, Series A-1 original issue price, with respect to the Series A-1 redeemable convertible preferred stock, and the Series A original issue price, with respect to the Series A redeemable convertible preferred stock, plus an amount equal to all declared and unpaid dividends thereon, whether or not earned. Funds available for such redemption shall be used to redeem all shares of Series C, Series B and Series A-1 redeemable convertible preferred stock, on a pari passu basis, before any shares of Series A redeemable convertible preferred stock are redeemed.

Classification—The Company has classified the redeemable convertible preferred stock as mezzanine equity on the consolidated balance sheets as the stock is contingently redeemable with passage of time or upon deemed liquidation events, such as a change in control. Because the redeemable convertible preferred stock becomes redeemable at any time after the fifth anniversary of the issuance dates at the election of the holders of at least 60% of the then outstanding shares of redeemable convertible preferred stock, voting as a single class on an as-converted basis, including certain Series C investors, the carrying values of the redeemable convertible preferred stock are adjusted to redemption value over the period from the date of issuance to the earliest redemption date using the effective interest rate method.

Common Stock

The holders of the Company's common stock have one vote for each share of common stock. Common stockholders are entitled to dividends when, as, and if declared by the Board of Directors, subject to the prior rights of the redeemable convertible preferred stockholders. The holders have no preemptive or other subscription rights and there are no redemption or sinking fund provisions with respect to such shares. As of December 31, 2018, no dividends had been declared by the Board of Directors.

The Company reserved the following shares of common stock for issuance as follows:

	December 31,	
	2017	2018
Redeemable convertible preferred stock outstanding on an as-converted basis	44,389,394	89,525,848
Options issued and outstanding	7,228,413	6,216,272
Options available for future grant	2,771,020	15,480,692
Total common stock reserved	<u>54,388,827</u>	<u>111,222,812</u>

9. Equity Incentive Plan

In 2011, the Company adopted the 2011 Equity Incentive Plan (the "Plan"). The Plan provides for granting stock options, stock bonuses, and rights to acquire restricted stock to employees, directors and consultants. As of December 31, 2018, there were 22,705,663 shares authorized under the Plan. Both incentive and nonqualified stock options can be granted under terms of the Plan and conditions established by the Board of Directors. Incentive stock options can only be granted to employees. The exercise price for incentive stock options cannot be less than the fair market value of the related common stock on the grant date. Stock options granted under the Plan generally vest over four years and expire no later than 10 years from the date of grant. The exercise price for rights to acquire restricted stock cannot be less than the fair market value of the related common stock on the grant date. The terms and conditions governing restricted stock is at the sole discretion of the Company.

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Stock option activity under the Plan was as follows:

	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balances as of December 31, 2016	2,397,599	6,184,575	\$ 0.18	8.21	\$ 1,515
Additional shares authorized	1,646,175	—			
Stock options granted	(1,891,617)	1,891,617	0.32		
Stock options exercised	—	(228,916)	0.19		
Stock options cancelled	618,863	(618,863)	0.19		
Balances as of December 31, 2017	2,771,020	7,228,413	\$ 0.22	8.24	\$ 1,888
Additional shares authorized	12,365,704	—			
Stock options granted	(756,822)	756,822	0.48		
Stock options exercised	—	(668,173)	0.18		
Stock options cancelled	1,100,790	(1,100,790)	0.38		
Balances as of December 31, 2018	<u>15,480,692</u>	<u>6,216,272</u>	\$ 0.23	7.23	\$ 2,199
Exercisable as of December 31, 2018		<u>4,125,391</u>	\$ 0.18	6.71	\$ 1,635

The total intrinsic value of options exercised during the years ended December 31, 2017 and 2018 was \$60,000 and \$200,000, respectively. The intrinsic value is the difference between the estimated fair value of the Company's common stock at the time of exercise, as determined by the Board of Directors, and the exercise price of the stock option.

The weighted-average grant date fair value of options granted to employees during the years ended December 31, 2017 and 2018 was \$0.33 per share.

Stock Options Granted to Employees

To determine the value of stock option awards for stock-based compensation purposes, the Company uses the Black-Scholes option-pricing model and the assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

Fair Value of Common Stock—The grant date fair market value of the shares of common stock underlying stock options has historically been determined by the Company's Board of Directors. Because there has been no public market for the Company's common stock, the Board of Directors exercises reasonable judgment and considers a number of objective and subjective factors to determine the best estimate of the fair market value, which include contemporaneous valuations performed by an independent third-party, important developments in the Company's operations, sales of redeemable convertible preferred stock, the rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock, lack of marketability of its common stock, actual operating results, financial performance, the progress of clinical development, the likelihood of achieving a liquidity event for the Company's security holders, the trends, development and conditions in the life sciences and biotechnology sectors, the economy in general, the stock price performance and volatility of comparable public companies.

Expected Term—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

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Expected Volatility—Because the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life science companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in the life cycle, or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend Yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of each award issued during the years ended December 31, 2017 and 2018 was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2017	2018
Expected term (in years)	5.89-6.08	6.08
Expected volatility	77%-79%	76%-77%
Risk-free interest rate	2.04%-2.20%	2.49%-2.87%
Dividend yield	—	—

As of December 31, 2018, the total unrecognized stock-based compensation cost related to outstanding unvested employee stock options that are expected to vest was \$579,000, which the Company expects to recognize over an estimated weighted-average period of 1.3 years.

Stock-Based Compensation Expense

The total stock-based compensation recognized for options granted was as follows (in thousands):

	December 31,	
	2017	2018
Research and development	\$165	\$118
General and administrative	236	290
Total stock-based compensation expense	<u>\$401</u>	<u>\$408</u>

10. Income Taxes

The provision for income taxes was immaterial for the years ended December 31, 2017 and 2018. The Company has not reflected any benefit of net operating loss carryforwards in the financial statements.

ANNEXON, INC.
Notes to Consolidated Financial Statements

Reconciliation of income tax computed at federal statutory rates to the reported provision for income taxes was as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Tax provision at U.S. statutory rate	\$(6,360)	\$(3,844)
State income taxes, net of federal benefit	1	1
Stock-based compensation	116	67
R&D tax credits	(718)	(541)
Change in valuation allowance	623	4,309
Change in federal statutory rate	5,785	—
Other	554	9
Provision for income tax	<u>\$ 1</u>	<u>\$ 1</u>

Deferred Tax Assets and Liabilities

The tax effects of temporary differences that give rise to significant portions of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2017	2018
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 10,743	\$ 16,176
Research and development credits	2,080	3,074
Other intangibles	8	7
Accruals and reserves	149	219
Stock-based compensation	96	73
Other	84	7
Tenant improvement allowances	457	389
Total gross deferred tax assets	<u>13,617</u>	<u>19,945</u>
Less: valuation allowance	(13,149)	(19,545)
Total deferred tax assets, net	<u>\$ 468</u>	<u>\$ 400</u>
Deferred Tax Liabilities:		
Fixed assets	(468)	(400)
Total gross deferred tax liabilities	<u>(468)</u>	<u>(400)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2018, the Company had \$60.8 million of federal and \$36.6 million of state net operating loss carryforwards available to offset future taxable income. If not utilized, these carryforward losses will expire in various amounts for federal and state tax purposes beginning in 2031 and 2031, respectively. Under the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), net operating losses generated after December 31, 2017 will be carried forward indefinitely with the yearly net operating loss utilization limited to 80 percent of taxable income.

ANNEXON, INC.
Notes to Consolidated Financial Statements

As of December 31, 2018, the Company had \$2.1 million of federal and \$1.8 million of state credit carryforwards available to offset future taxable income. If not utilized, these credit carryforwards will expire in various amounts for federal purposes beginning in 2031. The state credits do not expire.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some or all of the deferred tax assets will not be realized. Management believes that, based on available evidence, both positive and negative, it is more likely than not that the deferred tax assets will not be utilized; therefore, a full valuation allowance has been recorded. The Company's valuation allowance increased by \$2.8 million and \$6.4 million for the years ended December 31, 2017 and 2018, respectively. The change in the 2017 valuation allowance was primarily due to the addition of the current year loss carryforwards and change in federal tax rate; the change in the 2018 valuation allowance was primarily due to the addition of the current year loss carryforwards.

Utilization of the net operating loss carryforwards and credits may be subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. Any annual limitation may result in the expiration of net operating losses and credits before utilization.

Uncertain Tax Benefits

The Company has the following activity relating to the gross amount of unrecognized tax benefits (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Beginning balance	\$285	\$503
Additions based on tax positions related to prior year	—	31
Additions based on tax positions related to current year	218	249
Ending balance	<u>\$503</u>	<u>\$783</u>

None of these uncertain tax positions will impact the Company's effective tax rate if assessed. The Company's policy is to classify interest and penalties associated with unrecognized tax benefits as income tax expense. The Company had no interest or penalty accruals associated with uncertain tax benefits in its consolidated balance sheet and consolidated statement of operations for fiscal year 2018. The tax years 2011 through 2018 remain effectively open for examination by the Internal Revenue Service and most state tax authorities.

Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next twelve months due to tax examination changes, settlement activities, expirations of statute of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar activities, the Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months. During the years ended December 31, 2017 and 2018, no interest or penalties were required to be recognized relating to unrecognized tax benefits.

Tax Law Changes

The Tax Act was enacted on December 22, 2017. Among other provisions, the Tax Act reduces the top U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of

ANNEXON, INC.
Notes to Consolidated Financial Statements

certain foreign subsidiaries that were previously tax deferred, changes the rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017, and creates new taxes on certain foreign sourced earnings. The Company has reflected the changes resulting from the Tax Act in the financial statements for the period of enactment, the year ended December 31, 2017. The change in corporate tax rate resulted in a \$5.8 million decrease in the Company's gross deferred tax assets, with an offsetting decrease in valuation allowance of the same amount as of December 31, 2017. No change in the Company's gross tax assets is required from the corporate tax rate change as of December 31, 2018. The Company has established a policy to account for tax liability arising from Global Intangible Low-Taxed Income ("GILTI"), if any, as a period cost. In 2018, there was no GILTI inclusion from the foreign subsidiary.

11. Net Loss and Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Year Ended December 31,	
	2017	2018
Redeemable convertible preferred stock on an as-converted basis	44,389,394	89,525,848
Stock options to purchase common stock	7,228,413	6,216,272
Total	51,617,807	95,742,120

Unaudited Pro forma Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of unaudited pro forma basic and diluted net loss per share during the year ended December 31, 2018 (in thousands, except share and per share amounts):

	Year Ended December 31, 2018 (unaudited)
Numerator:	
Net loss attributable to common stockholders	\$ (18,480)
Gain on remeasurement of the redeemable convertible preferred stock liability	(260)
Accretion to redemption value on redeemable convertible preferred stock	176
Net loss used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	\$ (18,564)
Denominator:	
Weighted-average shares of common stock used in computing net loss per share attributable to common stockholders	3,548,177
Pro forma adjustment to reflect conversion of redeemable convertible preferred stock	—
Weighted-average shares of common stock used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	—
Pro forma net loss per share attributable to common stockholders, basic and diluted	—

ANNEXON, INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)

	December 31, 2018	September 30, 2019	Pro Forma September 30, 2019
Assets			
Current assets:			
Cash and cash equivalents	\$ 44,175	\$ 53,662	
Prepaid expenses and other current assets	1,531	1,040	
Total current assets	45,706	54,702	
Property and equipment, net	2,345	2,204	
Other long-term assets	98	1,694	
Total assets	<u>\$ 48,149</u>	<u>\$ 58,600</u>	
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit			
Current liabilities:			
Accounts payable	\$ 1,271	\$ 2,564	
Accrued liabilities	1,713	2,200	
Deferred rent, current	342	360	
Total current liabilities	3,326	5,124	
Deferred rent	1,803	1,531	
Redeemable convertible preferred stock liability	5,140	—	\$
Total liabilities	<u>10,269</u>	<u>6,655</u>	
Commitments and contingencies (Note 7)			
Redeemable convertible preferred stock, \$0.001 par value, 119,155,472 shares authorized as of December 31, 2018 and September 30, 2019; 89,525,848 and 111,748,065 shares issued and outstanding as of December 31, 2018 and September 30, 2019, respectively; liquidation preference of \$107,814 and \$137,814 as of December 31, 2018 and September 30, 2019, respectively, no shares issued and outstanding as of September 30, 2019, pro forma			
	102,082	143,704	\$
Stockholders' Deficit:			
Common stock, \$0.001 par value; 150,000,000 shares authorized as of December 31, 2018 and September 30, 2019; 3,808,699 and 3,821,386 shares issued and outstanding as of December 31, 2018 and September 30, 2019, respectively; 115,569,451 shares issued and outstanding as of September 30, 2019, pro forma	4	4	
Additional paid-in capital	1,257	1,958	
Accumulated other comprehensive loss	(66)	(83)	
Accumulated deficit	(65,397)	(93,638)	
Total stockholders' deficit	<u>(64,202)</u>	<u>(91,759)</u>	<u>\$</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 48,149</u>	<u>\$ 58,600</u>	

See accompanying notes to these unaudited condensed consolidated financial statements.

ANNEXON, INC.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	Nine Months Ended September 30,	
	2018	2019
Operating expenses:		
Research and development	\$ 11,591	\$ 17,729
General and administrative	2,576	5,660
Total operating expenses	14,167	23,389
Loss from operations	(14,167)	(23,389)
Loss on remeasurement of redeemable convertible preferred stock liability	—	(5,670)
Other income, net	525	821
Net loss before taxes	(13,642)	(28,238)
Provision for income taxes	1	3
Net loss	(13,643)	(28,241)
Accretion on redeemable convertible preferred stock	75	815
Net loss attributable to common stockholders	\$ (13,718)	\$ (29,056)
Net loss per share attributable to common stockholders, basic and diluted	\$ (3.96)	\$ (7.61)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	3,460,382	3,818,365
Pro forma net loss per share attributable to common stockholders, basic and diluted		\$
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted		

See accompanying notes to these unaudited condensed consolidated financial statements.

ANNEXON, INC.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(in thousands)

	Nine Months Ended	
	September 30,	
	2018	2019
Net loss	\$(13,643)	\$(28,241)
Other comprehensive loss:		
Foreign currency translation adjustment	(43)	(17)
Comprehensive loss	<u>\$(13,686)</u>	<u>\$(28,258)</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

ANNEXON, INC.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(unaudited)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Cost	Shares	Cost				
Balances as of December 31, 2017	44,389,394	\$48,971	3,140,526	\$ 3	\$ 905	\$ (26)	\$ (47,093)	\$ (46,211)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$22	11,803,125	13,552	—	—	—	—	—	—
Accretion on redeemable convertible preferred stock	—	75	—	—	(75)	—	—	(75)
Stock option exercises	—	—	668,173	1	120	—	—	121
Stock-based compensation	—	—	—	—	309	—	—	309
Foreign currency translation adjustment	—	—	—	—	—	(43)	—	(43)
Net loss	—	—	—	—	—	—	(13,643)	(13,643)
Balances as of September 30, 2018	<u>56,192,519</u>	<u>\$62,598</u>	<u>3,808,699</u>	<u>\$ 4</u>	<u>\$ 1,259</u>	<u>\$ (69)</u>	<u>\$ (60,736)</u>	<u>\$ (59,542)</u>

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Cost	Shares	Cost				
Balances as of December 31, 2018	89,525,848	\$102,082	3,808,699	\$ 4	\$ 1,257	\$ (66)	\$ (65,397)	\$ (64,202)
Issuance of Series C redeemable convertible preferred stock, including the value of the redeemable convertible preferred stock liability of \$10,810, net of issuance costs of \$3	22,222,217	40,807	—	—	—	—	—	—
Accretion on redeemable convertible preferred stock	—	815	—	—	(815)	—	—	(815)
Stock option exercises	—	—	12,687	—	3	—	—	3
Stock-based compensation	—	—	—	—	1,513	—	—	1,513
Foreign currency translation adjustment	—	—	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	—	—	(28,241)	(28,241)
Balances as of September 30, 2019	<u>111,748,065</u>	<u>\$143,704</u>	<u>3,821,386</u>	<u>\$ 4</u>	<u>\$ 1,958</u>	<u>\$ (83)</u>	<u>\$ (93,638)</u>	<u>\$ (91,759)</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

ANNEXON, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended	
	September 30,	
	2018	2019
Operating activities:		
Net loss	\$(13,643)	\$(28,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	371	364
Stock-based compensation	309	1,513
Loss on remeasurement of redeemable convertible preferred stock liability	—	5,670
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	988	491
Other long-term assets	13	—
Accounts payable	23	885
Accrued liabilities	(151)	3
Deferred rent	(236)	(254)
Net cash used in operating activities	<u>(12,326)</u>	<u>(19,569)</u>
Investing activities:		
Purchases of property and equipment	(18)	(168)
Net cash used in investing activities	<u>(18)</u>	<u>(168)</u>
Financing activities:		
Proceeds from the exercise common stock options	121	3
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	13,552	29,997
Payment of deferred offering costs	—	(759)
Net cash provided by financing activities	<u>13,673</u>	<u>29,241</u>
Net increase in cash and cash equivalents	1,329	9,504
Effect of exchange rate changes on cash and cash equivalents	(43)	(17)
Cash and cash equivalents at beginning of period	2,966	44,175
Cash and cash equivalents at end of period	<u>\$ 4,252</u>	<u>\$ 53,662</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment included in accounts payable	<u>\$ —</u>	<u>\$ 55</u>
Accretion on redeemable convertible preferred stock	<u>\$ 75</u>	<u>\$ 815</u>
Deferred offering costs included in accounts payable and accrued liabilities	<u>\$ —</u>	<u>\$ 837</u>
Reclassification of redeemable convertible preferred stock liability to redeemable convertible preferred stock	<u>\$ —</u>	<u>\$ 10,810</u>

See accompanying notes to these unaudited condensed consolidated financial statements.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization

Annexon, Inc. (the “Company”) is a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, eye and brain. The Company is located in South San Francisco, California and was incorporated in Delaware in March 2011.

The Company’s wholly-owned subsidiary, Annexon Australia Pty Ltd (the “Subsidiary”), is a proprietary limited company incorporated in 2016 and domiciled in Australia. The Subsidiary is also engaged in research and development activities in support of the Company.

Liquidity

Since inception, the Company has been involved primarily in performing research and development activities, hiring personnel, and raising capital to support and expand these activities. The Company has experienced losses and negative cash flows from operations since its inception and, as of September 30, 2019, had an accumulated deficit of \$93.6 million and cash and cash equivalents of \$53.7 million.

The Company has historically funded its operations through the issuance of shares of its redeemable convertible preferred stock. The Company intends to raise additional capital through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. If financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Based on projected activities, management projects that cash and cash equivalents on hand is sufficient to support operations for at least the next 12 months following issuance of these condensed consolidated financial statements. Management expects to continue to incur losses and negative cash flows from operations for at least the next several years.

2. Basis of Presentation and Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including but not limited to the fair value of common stock, redeemable convertible preferred stock, redeemable convertible preferred stock liability, and stock options, income taxes, and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the operations of Annexon, Inc. and its wholly-owned subsidiary and include the results of operations and cash flows of these entities. All intercompany balances and transactions have been eliminated in consolidation.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated balance sheet as of September 30, 2019, and the interim condensed consolidated statements of operations, comprehensive loss, changes in redeemable convertible preferred stock and stockholders' deficit and cash flows for the nine months ended September 30, 2018 and 2019 are unaudited. These unaudited interim condensed consolidated financial statements have been prepared on a basis consistent with the Company's audited consolidated financial statements and include, in the opinion of management, all adjustments (consisting only of normal recurring adjustments) that management considers necessary for a fair presentation of the Company's consolidated financial information. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the nine-month periods are also unaudited. The condensed consolidated results of operations for the nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2018 included herein was derived from the audited consolidated financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included elsewhere in this prospectus.

Unaudited Pro Forma Consolidated Balance Sheet Information

In contemplation of the Company's planned initial public offering ("IPO"), the unaudited pro forma stockholders' equity in the condensed consolidated balance sheet reflects shares of the Company's common stock outstanding as of September 30, 2019 and assumes the conversion of outstanding shares of redeemable convertible preferred stock into common stock immediately prior to the completion of the IPO. The shares of common stock issuable and the proceeds expected to be received in the IPO are excluded from such pro forma financial information.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and filing fees relating to an IPO, are capitalized. The deferred offering costs will be offset against offering proceeds upon the completion of the offering. In the event the offering is terminated or delayed, deferred offering costs will be expensed. As of September 30, 2019, \$1.6 million of deferred offering costs were capitalized, which are included in other long-term assets in the accompanying condensed consolidated balance sheets. No amounts were deferred as of December 31, 2018.

Redeemable Convertible Preferred Stock Liability

The obligation to issue additional shares of the Company's Series C redeemable convertible preferred stock at a future date was determined to be a freestanding financial instrument that should be accounted for as a liability. At initial recognition, the Company recorded the redeemable convertible preferred stock liability on the balance sheet at its estimated fair value. The liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized as a gain (loss) on remeasurement of convertible redeemable preferred stock liability on the statement of operations. Upon settlement of the redeemable convertible preferred stock liability in August 2019, the Company remeasured the liability and then reclassified the final value associated with the redeemable convertible preferred stock liability to the carrying value of the Series C redeemable convertible preferred stock.

Translation of Foreign Currencies

The Company's reporting currency is the U.S. dollar. The functional currency of the Company's subsidiary located in Australia is the Australian Dollar. Balance sheets prepared in the functional currencies are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders'

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
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equity accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using a weighted-average rate during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the accompanying consolidated balance sheets. Foreign exchange translation losses for the nine months ended September 30, 2018 and 2019 totaled \$43,000 and \$17,000, respectively.

Gains and losses resulting from exchange rate changes on transactions denominated in a currency other than the local currency are included in earnings as incurred.

Research and Development Expense

Research and development costs consist primarily of direct and indirect development expenses incurred for the development of the Company's product candidates.

Research and development expenses consist primarily of direct and indirect costs incurred for the development of the Company's product candidates.

Direct expenses include (i) preclinical and clinical outside service costs associated with discovery, preclinical and clinical testing of the Company's product candidates; (ii) professional services agreements with third-party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities on the Company's behalf; (iii) contract manufacturing costs to produce clinical trial materials; and (iv) laboratory supplies and materials. Indirect expenses include (A) compensation and personnel-related expenses (including stock-based compensation), (B) allocated expenses for facilities and depreciation; and (C) other indirect costs.

Research and development costs are expensed as incurred. Payments made to third parties are under agreements that are generally cancelable by the Company. Advance payments for research and development activities are deferred as prepaid expenses. The prepaid amounts are expensed as the related services are performed.

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In accruing service fees, the Company estimates the period over which services will be performed and the level of effort to be expended in each period. These estimates are based on the Company's communications with the third-party service providers and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies significantly from the estimate, the Company will adjust the accrual accordingly to reflect the best information available at the time of the financial statement issuance. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employee directors and consultants using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards to employees on the date of grant using the Black-Scholes option pricing model. The fair value of awards to non-employees is estimated at each measurement date, which is the date on which the award vests. Total expenses for non-employee share based awards has been immaterial to date.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
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The Company grants certain employees performance-based stock options. For awards that include performance conditions, no compensation cost is recognized until the performance goals are probable of being met, at which time the cumulative compensation expense from the service inception date would be recognized.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating the fair value of the underlying common stock, expected term, expected stock price volatility, risk-free interest rate and dividend yield. The Company accounts for forfeitures as they occur.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. As the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders because the effects of potentially dilutive securities were antidilutive.

Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

In contemplation of the IPO, the Company has computed the unaudited pro forma basic and diluted net loss per share attributable to common stockholders, to give effect to the conversion of the redeemable convertible preferred stock into shares of common stock. The unaudited pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received from the IPO. The unaudited pro forma net loss per share attributable to common stockholders for the nine months ended September 30, 2019 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates if later. The net loss attributable to common stockholders was adjusted to exclude the impact of the remeasurement of the redeemable convertible preferred stock liability and accretion on the redeemable convertible preferred stock as the underlying shares would have converted into common stock upon an IPO.

Subsequent Events

The Company evaluated its condensed consolidated financial statements for subsequent events through December 6, 2019, the date the condensed consolidated financial statements were available to be issued.

Emerging Growth Company Status

The Company is expected to be emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
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Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases* (Topic 842), which supersedes the guidance in former ASC 840, *Leases*. This standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. This standard is effective for annual reporting periods, and interim periods within those years, for public entities beginning after December 15, 2018 and for private entities beginning after December 15, 2020. Originally, a modified retrospective transition approach was required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued guidance to permit an alternative transition method for Topic 842, which allows transition to the new lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Entities may elect to apply either approach. There are also a number of optional practical expedients that entities may elect to apply. The Company is currently assessing the impact of this standard on its consolidated financial statements. The Company expects to record a material right-of-use asset and lease liability in connection with early adopting this standard as of January 1, 2020.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”). This standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Some of the areas of simplification apply only to nonpublic entities. This guidance is effective for annual reporting periods, and interim periods within those years, for public entities beginning after December 15, 2018. For all other entities, the amendments are effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted for any entity in any interim or annual period for which financial statements have not been issued or made available for issuance, but not before an entity adopts ASC 606. The Company is currently assessing the impact of this standard on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”), which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for all entities for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently assessing the impact of this standard on its consolidated financial statements.

3. Fair Value Measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
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Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

On a recurring basis, the Company measures certain financial assets and liabilities at fair value. The following tables summarize the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	December 31, 2018			Total
	Level 1	Level 2	Level 3	
Assets:				
Money market funds	\$43,680	\$ —	\$ —	\$43,680
Total assets	<u>\$43,680</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$43,680</u>
Liabilities:				
Redeemable convertible preferred stock liability	\$ —	\$ —	\$ 5,140	\$ 5,140
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,140</u>	<u>\$ 5,140</u>
	September 30, 2019			Total
	Level 1	Level 2	Level 3	
Assets:				
Money market funds	\$53,220	\$ —	\$ —	\$53,220
Total assets	<u>\$53,220</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$53,220</u>

The Company has an operating account invested in money market funds with maturities of less than three months and is classified as cash and cash equivalents on the Company's balance sheet. The money market funds are valued using Level 1 inputs that are based on quoted prices in active markets for identical assets.

For the nine months ended September 30, 2018 and 2019, the Company recognized no material realized gains or losses on financial instruments.

The Company's Level 3 liabilities include the redeemable convertible preferred stock liability. The Company initially estimated the fair value of the redeemable convertible preferred stock liability using the Black-Scholes option pricing model with an expected term of 0.65 years, the fair value of the Series C redeemable convertible preferred stock of \$1.19, expected volatility of 77.7% and risk-free interest rate of 2.47% as of December 7, 2018. The liability was remeasured at December 31, 2018 using the Black-Scholes option pricing model with an expected term of 0.58 years, the fair value of the Series C redeemable convertible preferred stock of \$1.20, expected volatility of 77.7% and risk-free interest rate 2.56%.

In August 2019, the redeemable convertible preferred stock liability was settled upon the completion of the second closing of the Company's Series C redeemable convertible preferred stock financing. In light of the Company's progress towards an IPO, the liability was remeasured at the settlement date using a probability-weighted expected return method ("PWERM") whereby the Company's total equity value was estimated under various exit scenarios and allocated to the Company's different classes of equity. The PWERM included two scenarios, IPO or staying private, that considered an estimate of the timing of each scenario and were weighted

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
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based on the Company's estimate of the probability of each event occurring. The equity value under the IPO scenario was based on recent IPO values of comparable companies and weighted 50%. The equity value under the staying private scenario was based on the recent Series C redeemable convertible preferred stock financing and was weighted 50%. The liability was remeasured to its fair value of \$10.8 million upon settlement and the carrying value of the liability was reclassified to the carrying value of the Series C redeemable convertible preferred stock. The Company recorded a loss of \$5.7 million in the condensed consolidated statements of operations for the nine months ended September 30, 2019 for the change in the fair value of the liability.

The changes in the carrying value of the liability were as follows (in thousands):

Fair value as of December 31, 2018	\$ 5,140
Change in fair value	5,670
Reclassification to redeemable convertible preferred stock upon settlement	<u>(10,810)</u>
Fair value as of September 30, 2019	<u>\$ —</u>

There were no transfers between Level 1, 2 or 3 for the periods presented.

4. Prepaid Expenses and Other Current Assets

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

	December 31, 2018	September 30, 2019
Prepaid research and development costs	\$ 1,127	\$ 495
Prepaid expenses	179	383
Other receivables	225	162
Total prepaid expenses and other current assets	<u>\$ 1,531</u>	<u>\$ 1,040</u>

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2018	September 30, 2019
Accrued compensation	\$ 766	\$ 856
Accrued research and development expenses	766	693
Accrued professional services	65	569
Other accrued expenses	116	82
Total accrued liabilities	<u>\$ 1,713</u>	<u>\$ 2,200</u>

6. Commitments and Contingencies

Leases

The Company leases its offices and laboratory in South San Francisco, California under a 7-year noncancelable lease agreement that ends in June 2024 with a 5-year renewal option. Rent expense is recognized on a straight-line basis over the non-cancelable term of the lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability on the accompanying balance sheet.

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Total rent expense was \$265,000 and \$264,000 for the nine months ended September 30, 2018 and 2019, respectively.

License and Other Agreements

In November 2011, the Company entered into an exclusive licensing agreement (the “Stanford Agreement”) with the Leland Stanford Junior University (“Stanford”) whereby the Company was granted an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights (the “Licensed Patents”), to make, use, offer for sale, sell, import and otherwise commercialize products covered by the Licensed Patents for human or animal diseases, disorders or conditions. Under the Stanford Agreement, the Company made an upfront payment and is obligated to pay Stanford annual license maintenance fees, potential future milestone payments totaling up to \$600,000, and royalty payments at a rate equal to a low single-digit percentage of worldwide net sales of licensed products.

In December 2016, the Company entered into a Sponsored Research Agreement with a not-for-profit entity to perform research on multiple sclerosis. Under the terms of the Sponsored Research Agreement, the Company may receive up to \$693,000 in funding. If within 15 years of the end of the Sponsored Research Agreement the Company files a marketing authorization application for a product treating multiple sclerosis, the Company will be obligated to pay milestone payments up to four times the amounts received under the Sponsored Research Agreement. No funding was received during the nine months ended September 30, 2018. For the nine months ended September 30, 2019, the Company received \$190,000, representing the final amount received under the Sponsored Research Agreement, which was recorded as other income.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2019, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

7. Redeemable Convertible Preferred Stock and Stockholder’s Deficit

Redeemable Convertible Preferred Stock

As of December 31, 2018, redeemable convertible preferred stock consisted of the following:

	<u>Shares Authorized</u>	<u>Shares Outstanding</u>	<u>Net Carrying Value (in thousands)</u>	<u>Liquidation Preference (in thousands)</u>
Series A	1,015,434	1,015,434	\$ 996	\$ 1,000
Series A-1	16,398,995	16,398,995	17,142	17,219
Series B	38,778,091	38,778,090	44,484	44,595
Series C	62,962,952	33,333,329	39,460	45,000
Total	<u>119,155,472</u>	<u>89,525,848</u>	<u>\$ 102,082</u>	<u>\$ 107,814</u>

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

As of September 30, 2019, redeemable convertible preferred stock consisted of the following:

	Shares Authorized	Shares Outstanding	Net Carrying Value (in thousands)	Liquidation Preference (in thousands)
Series A	1,015,434	1,015,434	\$ 1,000	\$ 1,000
Series A-1	16,398,995	16,398,995	17,142	17,219
Series B	38,778,091	38,778,090	44,499	44,595
Series C	62,962,952	55,555,546	81,063	75,000
Total	<u>119,155,472</u>	<u>111,748,065</u>	<u>\$ 143,704</u>	<u>\$ 137,814</u>

In August 2019, upon achieving certain defined milestones, the Company completed the second closing (“Second Closing”) of its Series C redeemable convertible preferred stock financing and issued 22,222,217 shares of Series C redeemable convertible preferred stock at \$1.35 per share for net proceeds of \$30.0 million. The redeemable convertible preferred stock liability was settled upon the Second Closing and the fair value of the liability of \$10.8 million was reclassified to the carrying value of the Series C redeemable convertible preferred stock.

Common Stock

The Company reserved the following shares of common stock for issuance as follows:

	September 30, 2019
Redeemable convertible preferred stock outstanding on an as-converted basis	111,748,065
Options issued and outstanding	18,336,476
Options available for future grant	3,347,801
Total common stock reserved	<u>133,432,342</u>

8. Equity Incentive Plan

Stock option activity under the 2011 Equity Incentive Plan (the “Plan”) was as follows:

	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balances as of December 31, 2018	15,480,692	6,216,272	\$ 0.23	7.23	\$ 2,199
Stock options granted	(13,276,801)	13,276,801	0.69		
Stock options exercised	—	(12,687)	0.21		
Stock options cancelled	1,143,910	(1,143,910)	0.52		
Balances as of September 30, 2019	<u>3,347,801</u>	<u>18,336,476</u>	\$ 0.54	8.53	\$ 17,945
Exercisable as of September 30, 2019		<u>6,063,095</u>	\$ 0.28	6.91	\$ 7,538

The total intrinsic value of options exercised during the nine months ended September 30, 2018 and 2019 was \$200,000 and \$8,000, respectively. The intrinsic value is the difference between the estimated fair value of the Company’s common stock at the time of exercise, as determined by the Company’s Board of Directors (the “Board of Directors”), and the exercise price of the stock option.

The weighted-average grant date fair values of options granted to employees during the nine months ended September 30, 2018 and 2019 were \$0.33 per share and \$0.63 per share, respectively.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

In June 2019, the Company granted options to purchase 411,761 shares of the Company's common stock to one of its officers that will vest if the Company achieves a certain developmental milestone related to its product candidate. The total grant date fair value of this award was \$311,000 and no associated expense was recognized during the nine months ended September 30, 2019 as the achievement of the performance condition was not considered probable.

Stock-Based Compensation Expense

The total stock-based compensation expense recognized for options granted was as follows (in thousands):

	Nine Months Ended September 30,	
	2018	2019
Research and development	\$ 88	\$ 391
General and administrative	221	1,122
Total stock-based compensation expense	<u>\$ 309</u>	<u>\$ 1,513</u>

As of September 30, 2019, the total unrecognized stock-based compensation cost related to outstanding unvested employee stock options that are expected to vest was \$7.1 million, which the Company expects to recognize over an estimated weighted-average period of 2.5 years.

To determine the value of stock option awards for stock-based compensation purposes, the Company uses the Black-Scholes option-pricing model and the assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

Fair Value of Common Stock—The grant date fair market value of the shares of common stock underlying stock options has historically been determined by the Board of Directors. Because there has been no public market for the Company's common stock, the Board of Directors exercises reasonable judgment and considers a number of objective and subjective factors to determine the best estimate of the fair market value, which include contemporaneous valuations performed by an independent third-party valuation firm, important developments in the Company's business, sales of the Company's redeemable convertible preferred stock, the rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock, lack of marketability of its common stock, actual operating results, financial performance, the progress of clinical development, the likelihood of achieving a liquidity event for the Company's securityholders, the trends, developments and conditions in the life sciences and biotechnology industry sectors, the economy in general and the stock price performance and volatility of comparable public companies.

Expected Term—The expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility—Because the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life science companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in the life cycle, or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Dividend Yield—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

The fair value of each award issued during the nine months ended September 30, 2018 and 2019 was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2018	2019
Expected term (in years)	6.08	6.02-6.08
Expected volatility	76%-77%	76%-77%
Risk-free interest rate	2.49%-2.87%	1.87%-2.61%
Dividend yield	—	—

9. Income Taxes

For each of the nine months ended September 30, 2018 and 2019, the Company incurred insignificant amounts for an income tax provision. The U.S. federal and California deferred tax assets generated from the Company's net operating losses have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized.

10. Net Loss and Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Nine Months Ended September 30,	
	2018	2019
Redeemable convertible preferred stock on an as-converted basis	56,192,519	111,748,065
Stock options to purchase common stock	6,232,585	18,336,476
Total	<u>62,425,104</u>	<u>130,084,541</u>

ANNEXON, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of unaudited pro forma basic and diluted net loss per share during the nine months ended September 30, 2019 (in thousands, except share and per share amounts):

	<u>Nine Months Ended</u> <u>September 30, 2019</u>
Numerator:	
Net loss attributable to common stockholders	\$ (29,056)
Loss on remeasurement of the redeemable convertible preferred stock liability	5,670
Accretion to redemption value on redeemable convertible preferred stock	815
Net loss used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$ (22,571)</u>
Denominator:	
Weighted-average shares of common stock used in computing net loss per share attributable to common stockholders	3,818,365
Pro forma adjustment to reflect conversion of redeemable convertible preferred stock	
Weighted-average shares of common stock used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	<u></u>
Pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$</u>

Shares

ANNEXON

biosciences

Common Stock

Prospectus

J.P. Morgan

BofA Securities

Cowen

, 2020

Through and including , 2020 (the 25th day after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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 Annexon, Inc., or the Registrant, in connection with the sale of our common stock being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the Nasdaq Global Market, or Nasdaq, listing fee.

ITEM	Amount Paid or to be Paid
SEC registration fee	\$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and amended and restated 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, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; 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 may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;

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- we may advance expenses to our directors, officers and employees in connection with a legal proceeding 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.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against certain 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 or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

We have purchased and currently intend to maintain insurance on behalf of each and every person who is or was a director or officer of the company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The form of underwriting agreement for this initial public offering provides for indemnification by the underwriters of us and our officers and directors who sign this registration statement for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

Since June 30, 2016, we have made the following sales of unregistered securities:

Equity Plan-Related Issuances

1. Since June 30, 2016, we have granted to our directors, employees and consultants options to purchase 19,657,160 shares of our common stock with per share exercise prices ranging from \$0.21 to \$1.52 under our 2011 Equity Incentive Plan, as amended, or the 2011 Plan.
2. Since June 30, 2016, we have issued to certain of our directors, employees and consultants an aggregate of 834,776 shares of our common stock at per share purchase prices ranging from \$0.16 to \$0.21 pursuant to exercises of options under the 2011 Plan for an aggregate purchase price of \$150,088.
3. Since June 30, 2016, we have issued to our consultants 75,000 shares of restricted common stock at a price per share of \$0.21 (including non-cash issuances as consideration for services) under the 2011 Plan for an aggregate purchase price \$15,750.

Sale of Preferred Stock

4. Between June 2016 and February 2018, we issued and sold an aggregate of 38,778,090 shares of Series B redeemable convertible preferred stock to 17 accredited investors at \$1.15 per share for gross proceeds of approximately \$44.6 million.
5. Between December 2018 and August 2019, we issued and sold an aggregate of 55,555,546 shares of Series C redeemable convertible preferred stock to 10 accredited investors at \$1.35 per share for gross proceeds of approximately \$75.0 million.

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The offers, sales and issuances of the securities described in paragraphs (1) through (3) were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraphs (4) through (5) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access to information about us. No underwriters were involved in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

The exhibits listed below are filed as part of this registration statement.

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>Date</u>	<u>Number</u>	
1.1*	Form of Underwriting Agreement				
3.1	Amended and Restated Certificate of Incorporation, as amended, currently in effect				
3.2*	Form of Amended and Restated Certificate of Incorporation, to be in effect immediately prior to the completion of this offering				
3.3	Bylaws, currently in effect				
3.4*	Form of Amended and Restated Bylaws, to be in effect immediately prior to the completion of this offering				
4.1	Reference is made to Exhibits 3.1 through 3.4				
4.2*	Form of Common Stock Certificate				
5.1*	Opinion of Latham & Watkins LLP				
10.1	Amended and Restated Investors' Rights Agreement, dated December 4, 2018, by and among the Registrant and the investors listed therein				
10.2†	Exclusive (Equity) Agreement, dated November 21, 2011, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University				
10.3	Lease, dated December 19, 2016, by and between the Registrant and Bayside Acquisition, LLC				
10.4(a)#	2011 Equity Incentive Plan, as amended				
10.4(b)#	Form of Stock Option Agreement under 2011 Equity Incentive Plan				

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<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			<u>Filed Herewith</u>
		<u>Form</u>	<u>Date</u>	<u>Number</u>	
10.5(a)#*	2020 Incentive Award Plan				
10.5(b)#*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2020 Incentive Award Plan				
10.5(c)#*	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2020 Incentive Award Plan				
10.5(d)#*	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2020 Incentive Award Plan				
10.6#*	Employee Stock Purchase Plan				
10.7#*	Employment Agreement by and between the Registrant and Douglas Love, Esq.				
10.8#*	Employment Agreement by and between the Registrant and Sanjay Keswani, MBBS, BSc, FRCP				
10.9#*	Employment Agreement by and between the Registrant and Jennifer Lew				
10.10#*	Employment Agreement by and between the Registrant and Ted Yednock, Ph.D.				
10.11#*	Non-Employee Director Compensation Program				
10.12*	Form of Indemnification Agreement for directors and officers				
21.1	List of subsidiaries				
23.1*	Consent of KPMG LLP, independent registered public accounting firm				
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)				
24.1*	Power of Attorney (reference is made to the signature page to the Registration Statement)				

* To be filed by amendment.

Indicates management contract or compensatory plan.

† Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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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 SEC 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 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 of 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 a 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.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California on _____, 2020.

ANNEXON, INC.

By: _____
Douglas Love, Esq.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Douglas Love and Jennifer Lew, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with 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 and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
_____ Douglas Love, Esq.	President, Chief Executive Officer and Director (<i>Principal Executive Officer</i>)	, 2020
_____ Jennifer Lew	Executive Vice President and Chief Financial Officer (<i>Principal Financial and Accounting Officer</i>)	, 2020
_____ William D. Young	Chairman of the Board of Directors	, 2020
_____ Emmett Cunningham, M.D., Ph.D., M.P.H.	Director	, 2020
_____ Carol Gallagher, Pharm.D.	Director	, 2020
_____ Campbell Murray, M.D.	Director	, 2020
_____ Muneer A. Satter	Director	, 2020

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<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
_____ Ricky Sun, Ph.D.	Director	, 2020
_____ Thomas G. Wiggans	Director	, 2020