UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO_____

Commission File Number 001-38295

ARSANIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-3181608**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
950 Winter Street, Suite 4500 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-5704

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	**The Nasdaq Global Market**

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

None

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market on June 29, 2018, was $27,036,480.

As of March 1, 2019, the registrant had 14,643,737 shares of Common Stock, $0.001 par value per share, outstanding.

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We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. Other trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- our plans and expectations regarding the merger with X4 Pharmaceuticals, Inc., including the expected completion of the merger;
- the strategies, goals, prospects, plans, expectations, forecasts or objectives of us, X4 Pharmaceuticals, Inc. or the combined company;
- our plans to seek potential collaboration or out-licensing opportunities for ASN100;
- the initiation, timing, progress and results of any current and future preclinical studies and clinical trials of ASN500;
- the planned reductions in our workforce;
- our estimates regarding expenses, future revenue, capital requirements and need for additional financing;
- our expectations regarding our ability to fund our operating expenses, capital expenditure requirements and debt service payments with our existing cash and cash equivalents;
- our estimates regarding the potential market opportunity for ASN500;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for any product candidates;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to obtain additional funding; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company that has historically focused on applying monoclonal antibody, or mAb, immunotherapies to address serious infectious diseases. We possess a deep understanding of the pathogenesis of infection paired with access to what we believe to be some of the most advanced mAb discovery techniques and platforms available today. Our pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including *Staphylococcus aureus* (*S. aureus*) and respiratory syncytial virus, or RSV.

On June 28, 2018, we announced the discontinuation of our Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients following the completion of a planned interim analysis of unblinded trial data for 118 patients by an independent data review committee, or DRC. Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued. During the third quarter of 2018, we completed follow-up visits on patients dosed in the trial per the study protocol, and during the fourth quarter of 2018, we completed our analysis of the complete dataset from the 154 patients that were enrolled in the trial. We are currently exploring potential collaborations or out-licensing opportunities for the potential continued development of ASN100.

Following our discontinuation of ASN100 clinical development, in August 2018 we announced that we were considering strategic options that may potentially result in changes to our business strategy and future operations and our board of directors approved a reduction in workforce to reduce operating costs and better align our workforce with the needs of our business following our discontinuation of the clinical development of ASN100. As part of this planned reduction in workforce, we eliminated 28 positions across the company, representing approximately 65% of our workforce, through March 1, 2019.

Following an extensive process of evaluating strategic alternatives for the company and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on November 26, 2018, we entered into an Agreement and Plan of Merger, as amended, or the Merger Agreement, with X4 Pharmaceuticals, Inc., or X4, pursuant to which a wholly owned subsidiary of the company will merge with and into X4, with X4 continuing as a wholly owned subsidiary of the company and the surviving corporation of the merger. We expect to devote significant time and resources to completion of this proposed transaction, which we refer to as the Merger. However, there can be no assurance that such activities will result in the completion of the Merger. Further, the completion of the Merger ultimately may not deliver the anticipated benefits or enhance shareholder value.

X4 has expressed interest in retaining certain members of our staff including our scientific team in Vienna, Austria, a team which has deep expertise in the research of virally-mediated infections.

Our Programs

ASN100

ASN100 is a combination of two fully human mAbs that are co-administered intravenously to neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis. Only recently has it become fully understood that *S. aureus* bacteria propagate disease in the lung through the production of up to six pathogenic cytotoxins that damage human lung tissue and destroy human immune cells. Antibiotics do not address these cytotoxins and can actually increase their production. ASN100 was developed by us specifically to neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis, a scientific advancement that has not previously been achieved.

In 2016, we successfully completed a Phase 1 single ascending dose clinical trial in 52 healthy volunteers to assess the safety, tolerability and pharmacokinetics of ASN100, both in the bloodstream and the lung. ASN100 was well tolerated across all doses tested and no dose-limiting toxicities were observed. ASN100 plasma half-life exceeded three weeks and lung concentrations were above levels required for cytotoxin neutralization based on pharmacokinetic and pharmacodynamic modeling. In 2017, we initiated the ASN100 Phase 2 clinical trial, a double-blind, placebo-controlled superiority trial evaluating the efficacy and safety of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. The primary efficacy endpoint of the trial was the proportion of patients who develop *S. aureus* pneumonia through 21 days after dosing. The trial was designed to detect a 50% reduction in the occurrence of *S. aureus* pneumonia in the ASN100 arm when compared to placebo. On June 28, 2018, we announced the discontinuation of the Phase 2 trial following the completion of a planned interim analysis of unblinded trial data for 118 patients by the DRC. Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued.

During the fourth quarter of 2018, we completed our analysis of the complete dataset from the 154 patients that were enrolled in the Phase 2 trial, and the modified intent to treat population included 76 patients in the ASN100 arm and 76 patients in the placebo arm. The trial failed to achieve the primary efficacy endpoint, as there was no statistical difference in the occurrence of *S. aureus* pneumonia prior to Day 22 between the ASN100 (5/76, 6.6%) and placebo arms (7/76, 9.2%).

ASN500

ASN500 is a mAb targeting RSV, a virus that can cause serious respiratory tract infections in young children and elderly and immunocompromised patients. We believe ASN500, which we are developing for the prevention of RSV infection, will have the potential to offer benefits over existing preventive therapies in terms of potency, dosing strategy, manufacturing and route of administration, to better serve both new and existing target populations. The ASN500 program is currently in preclinical development and Phase 1 clinical trials are expected to commence in the first half of 2020. This program has been principally funded to date under grant agreements between us and the Bill & Melinda Gates Foundation, or the Gates Foundation.

Gram-Negative Programs: ASN300 and ASN200

Our preclinical stage Gram-negative mAb programs, ASN300 for *Klebsiella pneumoniae* and ASN200 for *Escherichia coli*, were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018. In December 2018, we entered into a patent license and option agreement with Janssen Pharmaceuticals, Inc., or Janssen, pursuant to which we granted to Janssen (i) a non-exclusive license to specified patents in our portfolio related to the ASN200 *E. coli* program, and (ii) an option for Janssen to acquire these patents in the future if specified conditions are met.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and government agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Some of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources and significantly greater experience in the discovery and development of product candidates, obtaining U.S. Food and Drug Administration, or FDA, and other regulatory approvals of treatments and commercializing those treatments. These same competitors may invent technology that competes with our product candidates.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject 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.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, health-economic benefit, convenience of administration and delivery, price, the level of generic or biosimilar competition and the availability of adequate reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that any products, if approved, would be priced at a premium over competitive generic products and our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

ASN500

If approved for the prevention of RSV infection, ASN500 would compete with palivizumab, which is marketed by MedImmune as Synagis®, the only approved therapy in this indication. ASN500 may also compete with other product candidates currently in clinical development in this indication, including MedImmune's MEDI8897, which is in Phase 2 clinical development, and Merck's MK-1654, which is in Phase 1 clinical development.

Sales and Marketing

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. We have retained worldwide commercial rights for our ASN100 and ASN500 product candidates. If either of these product candidates receive marketing approval, we plan to commercialize them in the United States and potentially in Europe with our own focused, specialty sales force. We would expect to conduct most of the build-out of this organization following the approval of a biologics license application, or BLA, in the United States or similar marketing authorization in Europe of any of our product candidates. We would expect to explore commercialization of our product candidates in certain markets outside the United States, including the European Union, utilizing a variety of collaboration, distribution and other marketing arrangements with one or more third parties.

Manufacturing

We currently contract with third parties for the manufacture of our product candidates for preclinical studies and clinical trials and intend to do so in the future. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers. Although we rely on contract manufacturers, we have personnel with manufacturing experience to oversee our relationships with contract manufacturers.

Our current product candidates are mAbs. Therefore, the manufacturing process involves the genetic engineering of a parental host cell line to isolate a cell that produces the antibody. Once the cell or clone (colony of cells derived from a single cell) is isolated, a cell bank is produced under prescribed and documented conditions. The cell bank, preserved frozen, is tested as required by regulations to demonstrate that the engineered cell line is free from potentially harmful impurities and contaminants, such as viruses.

The drug substance manufacturing process begins with the thaw of vials from the cell bank and growth of these cells in established media until sufficient cells are cultured to inoculate a production bioreactor. The cells in the production bioreactor are grown in media and under controlled and monitored conditions that stimulate the production of the antibody into the culture media. The production bioreactor is cultured for an established time period and is then harvested by filtration to remove the cells from the culture media.

The antibody solution is purified through a number of steps to remove known process- and product-derived impurities. The technologies employed include ultrafiltration and column and membrane chromatography. Additional steps are performed to inactivate or remove viruses. The final step of the drug substance process adjusts the antibody concentration and produces the final formulation to be used for drug product production. The drug substance is tested to meet pre-established criteria for purity, potency and safety, and is then periodically tested to demonstrate stability upon storage as required by regulations. The drug substance is stored at prescribed temperatures, typically refrigerated or frozen.

The drug product is produced by sterilization filtration of the drug substance solution, followed by aseptic filling into glass vials and then stoppered. The drug product is subjected to release testing for purity, potency and safety according to pre-established specifications. Drug product lots are periodically tested to demonstrate stability over the established storage expiry period. The drug product is stored and shipped under temperature-controlled conditions, typically refrigerated, to sites designated for clinical trial testing, or eventually to commercial pharmaceutical logistics providers.

Intellectual Property

Our success depends significantly on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and certain non-U.S. patent applications related to our product candidates, proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of March 1, 2019, our patent portfolio included:

- Our ASN100 patent portfolio, which includes seven patent families that we solely own:
  - The first family consists of patents and patent applications with composition of matter claims covering antibodies directed against specified targets and includes granted patents in the United States, Europe, Japan, China, Mexico and Australia, and five pending patent applications in other jurisdictions, including Brazil, Canada, India, Israel, and Russia. We expect that any patents that issue in this first family will expire in April 2033.
  - The second family consists of patent applications with composition of matter claims covering antibodies directed against a specified target and includes one pending patent application in the United States, one pending patent application in Europe and 10 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Mexico, New Zealand and Russia. We expect that any patents that issue in this second family will expire in May 2034.
  - The third family consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe, one granted patent in Japan, one granted patent in South Africa and 10 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Korea, Mexico, New Zealand and Russia. We expect that any patents that issue in this third family will expire in October 2034.
  - The fourth family consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe, one granted patent in South Africa and 11 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand and Russia. We expect that any patents that issue in this fourth family will expire in December 2034.
  - The fifth family consists of patent applications with method and kit claims covering diagnostics for predicting VAP using a specified biomarker of methicillin-susceptible *S. aureus* and includes one pending patent application in the United States, one pending patent application in Europe and three pending patent applications in other jurisdictions, including Australia, Canada and Japan. We expect that any patents that issue in this fifth family will expire in August 2035.
  - The sixth family consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe and 10 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico and Russia. We expect that any patents that issue in this sixth family will expire in April 2036.
  - The seventh family consists of patent applications with composition of matter claims covering a specified combination of antibodies and includes one pending patent application in the United States, one pending patent application in Europe and 10 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico and Russia. We expect that any patents that issue in this seventh family will expire in April 2036.
- Our ASN500 patent portfolio, which includes two patent families that we have an exclusive option to license from Adimab, LLC. Each family includes one pending Patent Cooperation Treaty, or PCT, application with composition of matter claims covering antibodies with specified antibody sequences. We expect that any patents that issue from these families will expire in October 2037.
- Our ASN300 patent portfolio, which includes three patent families that we solely own and two patent families that are co-owned by Max Planck Gesellschaft, from which we have exclusively licensed rights to develop and commercialize therapeutic and diagnostic products under such patent families.
  - The first solely owned family consists of patent applications with composition of matter claims covering antibodies directed against a specified target and includes one pending patent application in the United States, one pending patent application in Europe and 12 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand, Russia and South Africa. We expect that any patents that issue in this first solely owned family will expire in June 2036.
  - The second solely owned family consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe and 10 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico and Russia. We expect that any patents that issue in this second solely owned family will expire in November 2035.

- The third solely owned family consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe and 12 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand, Russia and South Africa. We expect that any patents that issue in this third solely owned family will expire in October 2036.
- The fourth family, which is a co-owned family, consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe and one pending patent application in Japan. We expect that any patents that issue in this fourth co-owned family will expire in August 2037.
- The fifth family, which is a co-owned family, consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one pending patent application in the United States, one pending patent application in Europe and one pending patent application in Japan. We expect that any patents that issue in this fifth co-owned family will expire in August 2037.

- Our ASN200 patent portfolio, which includes two patent families that we solely own.
  - The first family consists of patent applications with composition of matter claims covering antibodies directed against a specified target and includes two granted patents and one pending patent application in the United States, two granted patent applications in Europe, one granted and one pending patent application in Australia, one granted patent in South Africa and 13 pending patent applications in other jurisdictions, including Brazil, Canada, China, India, Israel, Japan, Mexico, New Zealand and Russia. We expect that any patents that issue in this first family will expire in January 2034.
  - The second family consists of patent applications with composition of matter claims covering antibodies with specified antibody sequences and includes one granted patent in Europe, one granted patent in South Africa, one pending patent application in the United States and 11 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand and Russia. We expect that any patents that issue in this second family will expire in December 2034.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, what the duration of such extension may be.

Similar provisions are available in the European Union and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or non-U.S. regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us. However, we cannot provide any assurances that any such patent term extension of a non-U.S. patent will be obtained and, if obtained, the duration of such extension.

Trade Secrets

In addition to patents, we rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Collaboration and License Agreements

Adimab, LLC

We are developing antibodies discovered by Adimab, LLC, or Adimab, in our ASN100 and ASN500 monoclonal antibody programs.

Adimab Collaboration Agreement. In May 2011, we entered into a collaboration agreement with Adimab, which, as amended, and together with certain applicable option exercise letters we have sent to Adimab, we refer to as the Adimab Collaboration Agreement. We are developing antibodies discovered under the Adimab Collaboration Agreement in our ASN100 monoclonal antibody program.

Under the Adimab Collaboration Agreement, the company and Adimab were required to use reasonable efforts to conduct certain research, which we funded, to discover and optimize antibodies directed against targets selected by us. Intellectual property arising from the research is generally owned by the party that invents or creates the applicable intellectual property, although certain categories of intellectual property are specifically assigned to one party or the other. For example, patent rights relating to improvements to Adimab's background platform technology or specifically covering the sequence of an antibody that, in each case, are invented in the course of the research are assigned to Adimab. Prior to our exercise of an option (as described in the next paragraph), (1) we and Adimab each grant the other a non-exclusive license to the relevant intellectual property we own to allow each party to carry out its rights and obligations in connection with the research, and (2) except for Adimab's retained right to continue using and licensing its own libraries (as described further below), each party agrees not to practice or license the patents arising out of the research that it owns for any purpose other than to carry out its rights and obligations in connection with the research.

With respect to each target that was the subject of the research, we had an exclusive option to obtain, with respect to a specified number of antibodies directed against such target and discovered or optimized by Adimab, (1) ownership of certain patent rights relating to such antibodies (including patent rights specifically covering the sequences of such antibodies) and (2) exclusive and non-exclusive licenses, with the right to grant sublicenses, in all human therapeutic, prophylactic and diagnostic areas, which we refer to as the licensed field, under certain patent rights and know-how (including non-exclusive licenses to certain patent rights and know-how covering or relating to Adimab's background platform technology), to research, develop, make, have made, use, sell, offer to sell, import and export such antibodies and products based on such antibodies (but not for antibody discovery purposes). In addition, upon exercise of each option, certain contractual restrictions on our ability to prosecute, practice and license certain patents owned by us that arose out of the research were eliminated. All of our options under the Adimab Collaboration Agreement have expired, or are in the process of being exercised, or, with respect to multiple targets and hundreds of antibodies, have already been exercised. The assigned and exclusively and non-exclusively licensed patent rights resulting from these option exercises are described in more detail above under *" —Intellectual Property."*

Under the Adimab Collaboration Agreement, for each target for which we have exercised an option, we are required to use commercially reasonable efforts to develop and commercialize at least one product in major markets. If we do not fulfill these diligence obligations, Adimab may consider it a material breach, allowing Adimab to terminate the Adimab Collaboration Agreement with respect to such target and all associated products.

Regardless of the assignments and licenses granted by Adimab under the Adimab Collaboration Agreement, Adimab is not required to remove any antibodies from its libraries or to restrict itself from either adding any antibodies to its libraries or providing those libraries to third parties (even if those libraries contain antibodies for which we have exercised an option). Adimab may also freely disclose to third parties certain information (including information received from us) regarding certain attributes of the antibodies discovered or optimized under the research program. Accordingly, Adimab retains a non-exclusive, royalty-free, sublicensable right under certain patents created under the research program to transfer to third parties' libraries that may include antibodies discovered under the research program (including antibodies for which we have exercised our option) and to conduct any activity with respect to antibodies for which we do not exercise our option.

Under the Adimab Collaboration Agreement, as of December 31, 2018, we had paid Adimab approximately $4.3 million in the aggregate, consisting of upfront payments and reimbursement for research conducted by Adimab. We are obligated to pay Adimab royalties at a mid-single-digit percentage of net sales, made by us or our affiliates, of products based on antibodies for which we have exercised our option, or products that use or are based on any antibody discovered or optimized under the agreement, any derivative or modified version of any such antibody, or any sequence information as to any such antibody.

If we (or one of our affiliates with rights under the agreement) undergo a change in control and, at the time of such change in control, we have not sold or licensed to third parties all of our rights in antibodies for which we are obligated to pay Adimab royalties under the agreement (which rights we refer to as undesignated rights), then we are obligated to either pay Adimab a percentage, in the mid double digits of the payments we receive from that change in control that are reasonably attributable to those undesignated rights and certain patents arising from the collaboration, or require our acquirer and all of its future third party collaborators to pay to Adimab the royalties described in the preceding paragraphs with respect to net sales of all products based on those undesignated rights. If the Merger is successfully consummated, the transaction will result in this royalty election being made. If we grant rights to a third party under certain patents that are not directed to the antibodies for which we are obligated to pay Adimab royalties (as described above), we are also obligated to pay Adimab, in place of royalties or a percentage of payments received from the third party, a lump sum in the high six digits.

If we sell or license to any third party, or otherwise grant rights to any third party to, any of the products for which we are obligated to pay Adimab royalties (as described above), either alone or as part of a package including specified patents not directed to these antibodies, we are obligated to pay Adimab either the same royalties on net sales of such products by such third party, or a percentage, ranging from the low double digits to a maximum of less than 30%, of the payments we receive from such third parties that are attributable to such grant of rights. In April 2017, we entered into a letter agreement with the Gates Foundation (described in more detail below), pursuant to which we licensed to the Gates Foundation certain rights under our ASN100 program.

Notwithstanding the payment obligations described in the preceding paragraphs, we have no payment obligations under the Adimab Collaboration Agreement with respect to sales of certain antibody products if they are sold at cost in developing countries under our April 2017 letter agreement with the Gates Foundation. However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess over cost will be subject to the royalty payment obligations described above.

Under the Adimab Collaboration Agreement, each party generally controls the prosecution and maintenance of the intellectual property it owns, but we control the prosecution and maintenance of patents covering antibodies for which we have exercised our option (except to the extent that such patents cover Adimab's background platform technology or any improvements to that technology), which we refer to as the antibody patents, regardless of which party owns those patents. After we exercise an option, we must use commercially reasonable efforts to conduct such prosecution and maintenance, including by filing and maintaining, in the major markets and all other countries where it is commercially reasonable to do so, at least one patent directed to the antibodies for which we have exercised our option, and must collaborate with Adimab with respect to such prosecution and maintenance. We have the first right to enforce the antibody patents against infringers in the licensed field, though our right to settle such infringement cases is limited.

If we or any of our affiliates challenges the validity, enforceability or scope of any of the licensed patents, then our payment obligations under the Adimab Collaboration Agreement increase, Adimab obtains the right to prosecute, maintain and enforce all of the exclusively licensed patents, and we must reimburse Adimab for its legal costs in connection with such challenge.

Under the Adimab Collaboration Agreement, we are solely responsible for searching for, identifying and evaluating any third party intellectual property that may be infringed or misappropriated by any antibody discovered or optimized under the agreement, or any derivative or modified version of such an antibody, and must indemnify Adimab for any third party claims arising from any such infringement or misappropriation.

The Adimab Collaboration Agreement will expire on a country-by-country basis twelve years after the first commercial sale in such country of the last product for which we are obligated to pay Adimab royalties in such country under the Adimab Collaboration Agreement. We have the right to terminate the Adimab Collaboration Agreement for any reason by providing Adimab with a specified amount of prior written notice. Adimab has the right to terminate the Adimab Collaboration Agreement if we materially breach the agreement and fail to cure such breach within a specified cure period, including, as discussed above, for our failure to use commercially reasonable efforts to develop and commercialize at least one product directed at a target for we have exercised an option in major markets. If Adimab terminates the Adimab Collaboration Agreement for our breach, or if we terminate the agreement for our convenience, then we must transfer or license to Adimab certain rights and assets relating to targets and antibodies for which we exercised our option. Adimab is then obligated to make payments to us with respect to these targets and antibodies that are similar to the payments we were required to make to Adimab during the term of the agreement. Certain of our payment obligations relating to specified products and patents arising from the agreement survive expiration or termination of the agreement.

Certain disputes under the Adimab Collaboration Agreement must be resolved through binding arbitration.

Adimab Option and License Agreement. In February 2017, we entered into an option and license agreement with Adimab, which we refer to as the Adimab Option Agreement. We are developing antibodies discovered under the Adimab Option Agreement in our ASN500 monoclonal antibody program.

Under the Adimab Option Agreement, Adimab has provided to us certain proprietary antibodies against RSV, which we refer to as the initial RSV antibodies, for our evaluation during a specified option period and has granted us an exclusive, non-sublicensable license under certain Adimab patent rights and know-how during the option period to create, research, optimize, make, have made and use the initial RSV antibodies and modified or derivative forms of the initial RSV antibodies. Adimab has performed affinity maturation of a limited number of the initial RSV antibodies for us and provided us with a specified number of higher-affinity RSV antibodies resulting from those activities. In addition, we are conducting our own research program with respect to these RSV antibodies.

Under the Adimab Option Agreement, we have an exclusive option, exercisable during the option period upon payment of an option fee to Adimab, to require Adimab to assign to us all rights in up to a specified number of RSV antibodies selected by us, which we refer to as the selected RSV antibodies, and certain patent rights owned by Adimab that cover these antibodies, and to obtain from Adimab a non-exclusive license, with the right to grant sublicenses, under certain other patent rights and know-how owned by Adimab, to research, develop, have developed, make, have made, use, sell, offer to sell, import and export products based on the selected RSV antibodies and modified or derivative forms of the selected RSV antibodies, for all indications and uses except for certain diagnostic uses. This license would not include any right or license to use the licensed patent rights or know-how to discover or optimize antibodies. We have agreed not to use the patent rights or know-how assigned or licensed to us for the purpose of researching, developing, manufacturing or commercializing RSV antibodies that are not licensed by us.

If we exercise our option under the Adimab Option Agreement, we are required to use commercially reasonable efforts to develop and commercialize at least one product based on a licensed RSV antibody in major markets. If we materially breach these diligence obligations, Adimab will have the right to terminate the Adimab Option Agreement.

Under the Adimab Option Agreement, regardless of the assignments and licenses granted by Adimab, Adimab is not required to remove any antibodies from its libraries or to restrict itself from either adding any antibodies to its libraries or providing those libraries to third parties (even if those libraries include RSV antibodies that have been licensed or assigned to us). Under the Adimab Option Agreement, Adimab may also freely disclose to third parties certain information regarding certain attributes of the initial RSV antibodies and modified or derivative forms of the initial RSV antibodies created by Adimab (but not modified or derivative forms created by us). However, Adimab and its affiliates may not provide any third party any isolated RSV antibody that has been licensed or assigned to us or grant any third party any license under any patent to the extent it covers any such antibody. If any third party receives a library containing an RSV antibody that has been licensed or assigned to us and requests intellectual property rights, nucleic acid or amino acid sequences, or additional physical materials with respect to such antibody, Adimab must inform such third party that it cannot grant such rights or provide such information or materials.

Under the Adimab Option Agreement, as of December 31, 2018, we had incurred costs paid to Adimab of approximately $0.2 million in the aggregate, consisting of reimbursement for affinity maturation work performed by Adimab and for certain patent prosecution costs incurred by Adimab. If we wish to exercise our option under the Adimab Option Agreement, we are obligated to pay Adimab an option fee of $0.3 million and make clinical and regulatory milestone payments of up to $24.4 million. We are obligated to pay Adimab royalties at a mid-single-digit percentage of net sales of products based on the initial RSV antibodies (including modified or derivative forms of those antibodies created by or for the company) by us or any of our affiliates, licensees or sublicensees, regardless of whether these products practice any of the assigned or licensed patents or know-how. If we obtain a license under a third party's patent in order to avoid potential claims of patent infringement based on the way in which Adimab discovered an initial RSV antibody or a modified or derivative form of an initial RSV antibody using Adimab's platform technology, then we have the right to offset a portion of the royalties we pay to the third party against our royalty payment obligations to Adimab with respect to such antibody, subject to certain limitations. If we obtain a license under any third-party patent other than as described in the preceding sentence, we have no right to offset any portion of the royalties we pay to the third party against our royalty payment obligations to Adimab. If there is a specified level of biosimilar competition with respect to any product on which we are obligated to pay Adimab running royalties, the royalties owed to Adimab will be reduced with respect to such product, subject to certain limitations.

Notwithstanding the royalty payment obligations described in the preceding paragraph, we have no payment obligations under the Adimab Option Agreement with respect to sales of products based on licensed RSV antibodies to the extent they are sold at cost in developing countries under the February 2017 Gates Foundation grant agreement, as amended and restated in August 2018, and the August 2018 Gates Foundation grant agreement (which are described in further detail below). However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess will be subject to the royalty payment obligations described in the preceding paragraph.

After exercising our option under the Adimab Option Agreement, we control prosecution, maintenance, enforcement and defense of the assigned patents (with obligations to collaborate with Adimab on such prosecution and maintenance) at our cost, and Adimab controls prosecution, maintenance, enforcement and defense of the licensed patents at its cost.

Under the Adimab Option Agreement, we are solely responsible for searching for, identifying and evaluating any third party intellectual property that may be infringed or misappropriated by any licensed RSV antibody, or any derivative or modified version of such an antibody, and must indemnify Adimab for any third party claims arising from any such infringement or misappropriation.

If we do not exercise our option, the Adimab Option Agreement will expire on our achievement of specified preclinical milestones under our grant agreements with the Gates Foundation, but in any event no later than mid-2019. If we do exercise our option, the Adimab Option Agreement will expire on the last-to-expire royalty term (defined, on a product-by-product and country-by-country basis, as the period ending on the later of twelve years after the first commercial sale of such product in such country and the expiration of the last of a specified set of patents and patent applications covering such product in such country) for any and all products for which we are obligated to pay Adimab royalties under the Adimab Option Agreement. We have the right to terminate the Adimab Option Agreement for any reason by providing Adimab with a specified amount of prior written notice. Adimab has the right to terminate the Adimab Option Agreement if we materially breach the agreement and fail to cure such breach within a specified cure period, including, as discussed above, for our failure to use commercially reasonable efforts to develop and commercialize at least one product based on a licensed RSV antibody in major markets. If Adimab terminates the Adimab Option Agreement for our breach, if we terminate the agreement for our convenience or if the agreement expires before we exercise our option, then we must return or destroy certain know-how, including all initial RSV antibodies, and all modified or derivative forms of those antibodies, in our possession other than those for which we have made all payments required under the Adimab Option Agreement, assign certain patents covering certain RSV antibodies to Adimab, grant Adimab a non-exclusive, royalty-free license under certain other patents, and grant Adimab a time-limited right of first negotiation to obtain an exclusive license to certain patents and know-how and the transfer and assignment of certain regulatory filings and approvals and other related assets related to products based on licensed RSV antibodies. Certain of our payment obligations relating to specified products arising from the agreement survive expiration or termination of the agreement.

Certain disputes under the Adimab Option Agreement must be resolved through binding arbitration.

The Bill & Melinda Gates Foundation

February 2017 Grant Agreement and August 2018 Amended and Restated Gates Foundation Grant Agreement. In February 2017, we entered into a grant agreement with the Gates Foundation pursuant to which the Gates Foundation granted us up to $9.3 million to conduct preclinical development of monoclonal antibodies for the prevention of RSV infection in newborns, which we refer to as the RSV project. In return, we agreed to conduct the RSV project in a manner that ensures that the knowledge and information gained from the project will be promptly and broadly disseminated, and that the products, technologies, materials, processes and other intellectual property resulting from the RSV project (which we collectively refer to as the funded developments) will be made available and accessible at an affordable price to people most in need within developing countries. These obligations survive any expiration or termination of the grant agreement.

To this end, we granted the Gates Foundation a non-exclusive, perpetual, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the funded developments and, to the extent incorporated into a funded development or required to use a funded development, any other technology created outside of the RSV project that was used as part of the RSV project, for the benefit of people in developing countries. We also agreed to seek prompt publication of data and results developed under the RSV project under “open access” terms and conditions. This license and these publication obligations survive any expiration or termination of the grant agreement.

The grant agreement expires on October 31, 2019. The Gates Foundation can modify, suspend or discontinue any payment under the grant agreement, or terminate the grant agreement, if it is not reasonably satisfied with our progress on the RSV project; if there are significant changes to our leadership or other factors that the Gates Foundation reasonably believes may threaten the RSV project’s success; if we undergo a change in control; if there is a change in our tax status; if the RSV project is no longer aligned with the Gates Foundation’s programmatic strategy; or if we fail to comply with the grant agreement. Any grant funds that have not been used for, or committed to, the RSV project upon the expiration or termination of the agreement must be returned to the Gates Foundation or otherwise used as directed by the Gates Foundation.

In August 2018, we amended and restated the February 2017 grant agreement. The amended and restated grant agreement includes amendments to conform to current Gates Foundation audit, reporting, and other administrative requirements, as well as to make the perpetual Gates Foundation license grant described above irrevocable.

August 2018 Gates Foundation Grant Agreement. In August 2018, we entered into an additional grant agreement with the Gates Foundation pursuant to which the Gates Foundation granted to us up to $1.1 million to conduct preclinical development activities for the RSV project that were not included in the February 2017 grant agreement, as amended and restated in August 2018. In return, we agreed to conduct the RSV project in a manner that ensures that the knowledge and information gained from the project will be promptly and broadly disseminated, and that the products, technologies, materials, processes and other intellectual property resulting from the RSV project (collectively referred to as the funded developments) will be made available and accessible at an affordable price to people most in need within developing countries. These obligations survive any expiration or termination of the grant agreement.

To this end, we granted to the Gates Foundation a non-exclusive, perpetual, irrevocable, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the funded developments and, to the extent incorporated into a funded development or required to use a funded development, any other technology created outside of the RSV project that was used as part of the RSV project, for the benefit of people in developing countries. We also agreed to seek prompt publication of data and results developed under the RSV project under "open access" terms and conditions. This license and these publication obligations survive any expiration or termination of the grant agreements.

The August 2018 grant agreement expired during the year ended December 31, 2018.

Gates Foundation Letter Agreement and Investment. In April 2017, we entered into a letter agreement with the Gates Foundation. In connection with the letter agreement, the Gates Foundation purchased $8.0 million of shares of our Series D convertible preferred stock as a program-related investment, and we committed to use the proceeds from the investment by the Gates Foundation solely to advance the development of a specified monoclonal antibody program, which we refer to as the funded program, that involves the monoclonal antibodies ASN-1, ASN-2 and ASN-3 and our product candidate ASN100. The Gates Foundation's primary objective in making the investment was to further the accomplishment of its charitable purposes, including the relief of the poor, distressed and underprivileged, the advancement of science, and the promotion of health by supporting the development of low-cost drugs to address diseases that have a disproportionate impact on people within developing countries, and to ensure that the knowledge gained using the Gates Foundation's funding is promptly and broadly disseminated and the products developed with such funding are made available and accessible at affordable prices to people most in need within developing countries. We refer to the specific obligations that we assumed in the letter agreement that are intended to further this objective as our global access commitments.

We agreed to diligently generate and test, in preclinical animal studies, a product candidate for the prevention of neonatal sepsis caused by *S. aureus* in accordance with an agreed-upon research program. The Gates Foundation has a right to continue funding to develop and launch a final product for the prevention of neonatal sepsis caused by *S. aureus*, and/or to develop a combination monoclonal antibody product for use in the prevention of neonatal sepsis caused by *S. aureus* and/or other bacterial pathogens. We refer to each of these programs as a funded project. In each case, the Gates Foundation may elect to provide further funding and may request that the further development be co-funded by additional equity investments, subject to requisite approval by our board of directors and/or stockholders, or grants from the Gates Foundation pursuant to its standard grant making terms and processes. The specific level and allocation of any such funding responsibilities will be mutually agreed with the Gates Foundation to fairly allocate expected benefits between developing countries and developed countries in a manner that would not be reasonably likely to have a material adverse effect on our business or operations. Such funding will create an obligation for us, alone or through a third party, to conduct such research, development and launch activities. At the request of the Gates Foundation, we will grant the Gates Foundation a non-exclusive, sublicensable license to any candidates or products developed under any of these programs, and all related technology necessary for the development, production and/or distribution or sale of the relevant product(s), for use in the prevention of neonatal sepsis caused by *S. aureus* and/or other bacterial pathogens. The Gates Foundation would only be permitted to exercise any license to our background intellectual property under specified circumstances, which we collectively call a charitability default, or in the event of any other specified triggering event. A charitability default would occur in the event of our material breach of any of our global access commitments under the letter agreement (other than for regulatory, technical or scientific failure not within our reasonable control or knowledge prior to the letter agreement), our failure to comply with the restrictions on our use of the proceeds from the Gates Foundation investment, or our failure to comply with any related U.S. legal obligations set forth in the letter agreement. Other triggering events that would allow the Gates Foundation to exercise the license to our background intellectual property include if we commit an uncured material breach of any grant agreement for any applicable funded project; if we are unwilling or unable or cease to promptly conduct or complete any of the programs described above in this paragraph; if the Gates Foundation reasonably determines (after good faith discussions with us) that we do not have the ability to conduct or complete our global access commitments under the letter agreement in any material respect; or if we become insolvent or cease to conduct business in the ordinary course. Any exercise by the Gates Foundation of the license described in this paragraph will be subject to payment of applicable royalties under the Adimab Collaboration Agreement and, in certain circumstances, may involve payment of a reasonable royalty to us on sales of applicable products outside of the developing countries.

Under the letter agreement, we also agreed to conduct up to two additional projects proposed and funded by the Gates Foundation, or a Gates Foundation-supported entity, under the Gates Foundation's standard grant making terms and processes, to identify monoclonal antibody candidates against a target pathogen or antigens associated with a target pathogen, and potentially to further develop such candidates, each of which we refer to as an additional funded project. At the request of the Gates Foundation, such additional funded projects will include a non-exclusive, sublicensable license to the Gates Foundation to any product candidates and related technology resulting from the applicable program, to the extent necessary for the development, production or distribution or sale of the relevant product candidate within the field of use prescribed for such product candidate. The Gates Foundation will not practice any such license for sale or distribution of any product candidate outside of the developing countries unless we or one of our licensees commits a material breach of our global access commitments under the letter agreement. If the Gates Foundation requests that we continue the development of any candidate identified in one of these additional funded projects, the specific level and allocation of any funding responsibilities associated with such development will be mutually agreed with the Gates Foundation to fairly allocate expected benefits between developing countries and developed countries in a manner that would not be reasonably likely to have a material adverse effect on our business or operations.

In addition to the licenses described above, we granted to the Gates Foundation and/or Gates Foundation-supported entities, a non-exclusive, non-terminable, royalty-free (except as required under the Adimab Collaboration Agreement), sublicensable license to products, technologies, materials, processes and other intellectual property developed using funds provided by the Gates Foundation or a Gates Foundation-supported entity, or developed in connection with our conduct of any funded project or additional funded project, as well as all of our background intellectual property, to utilize and exploit products and services directed at pathogens or other targets subject to any funded project or additional funded project. As with the other license grants in the letter agreement, the Gates Foundation would only be able to exercise this license if there is a charitability default or other triggering event (as described above).

We are required to obtain and maintain all necessary rights and licenses needed to perform our global access commitments under the letter agreement, and we are required to use reasonable efforts to obtain all necessary licenses in order to enable completion of all applicable products in accordance with such global access commitments. The Gates Foundation will be responsible for costs payable to third parties for such licenses to the extent they are necessary for products in developing countries, provided that the Gates Foundation has consented to the terms of the applicable license and the applicable license agreements meet certain specified requirements.

Under the terms of the letter agreement, we are required to work with the Gates Foundation to develop and execute, prior to the completion of our Phase 2 clinical trials with respect to our ASN100 product candidate, a manufacturing and supply plan that will meet the reasonably expected demand in developing countries for any products developed under any funded project or any additional funded project. We agreed that the price of such products in developing countries will be such that the products are affordable to low income individuals, and in no case will the price charged by us with respect to such products in such countries exceed our actual production costs plus a specified percentage. The manufacturing and supply plan could involve the use of manufacturing partners and support from donors, and the specific level and allocation of funding responsibilities will be mutually agreed based on a fair allocation of the expected benefits between developing countries and developed countries.

If the Gates Foundation determines that it is reasonably necessary to work with a third-party manufacturer to achieve certain specified price and volume commitments, we agreed to license and transfer the necessary technology and intellectual property to such a manufacturer in order to allow the production of products for developing countries, and the Gates Foundation will pay all reasonable costs for any such transfer.

We are required to publish, in accordance with certain "open access" terms and conditions, results and information developed under any funded project or additional funded project within a reasonable period of time subject to delays and limitations necessary to protect our intellectual property and to third party confidentiality obligations, provide the Gates Foundation with access to data and information regarding such projects and the reasonably contemplated use of our platform technology for the programs under the letter agreement, and provide the Gates Foundation certain rights to share such data and information with third parties.

The term of the letter agreement continues in perpetuity. However, the Gates Foundation has a right to withdraw from its investment in us if there is a charitability default (as described above). If we do not cure the charitability default within a specified period of time, we have the obligation to redeem the Gates Foundation's stock, to the extent consistent with applicable law and so long as it does not render us insolvent, or to locate a purchaser of the Gates Foundation's stock. If we are not able to redeem or find a purchaser of the Gates Foundation's stock, we must use our best efforts to effect the Gates Foundation's withdrawal right as soon as practicable. During any period when we are unable to effect the withdrawal right, we may not pay dividends on any of our stock, redeem the capital stock of any other stockholder (other than certain circumstances for employees or contractors) or otherwise make any distribution to any other stockholder (other than as part of a stock option plan). For any redemption or purchase resulting from a charitability default, the Gates Foundation's stock will be valued at the greater of the original purchase price (plus specified interest) or the fair market value of such stock.

Government Regulation

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

Licensure and Regulation of Biologics in the United States

In the United States, mAb products are licensed by the FDA as biological products, or biologics, under the Public Health Service Act, or PHSA, and regulated under the Federal Food, Drug, and Cosmetic Act, or FDCA, and applicable implementing regulations and guidance. The failure of an applicant to comply with the applicable regulatory requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may result in delays to the conduct of a study, regulatory review and approval and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical trials, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or Department of Justice, or DOJ, or other government entities, including state agencies.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps before the product candidate will be licensed by the FDA:

- preclinical testing including laboratory tests, animal studies and formulation studies, which must be performed in accordance with the FDA's good laboratory practice, or GLP, regulations and standards;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with current good clinical practices, or GCP;
- preparation and submission to the FDA of a BLA for a biologic product which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labelling for one or more proposed indication(s);
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties, at which the product candidate or components thereof are manufactured to assess compliance with current good manufacturing practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with GCP and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA licensure of the BLA to allow marketing of the new biologic product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct any post-approval studies required by the FDA.

Preclinical Studies and Investigational New Drug Application. Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes. An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved BLA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing, and controls. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, on April 28, 2008, the FDA amended its regulations governing the acceptance of foreign clinical studies not conducted under an investigational new drug application as support for an IND or a new drug application. The final rule provides that such studies must be conducted in accordance with good clinical practice, or GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Expanded Access to an Investigational Drug for Treatment Use. Expanded access, sometimes called "compassionate use," is the use of investigational new products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency

settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational product for the requested treatment will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

On December 13, 2016, the 21st Century Cures Act established (and the 2017 Food and Drug Administration Reauthorization Act later amended) a requirement that sponsors of one or more investigational products for the treatment of a serious disease(s) or condition(s) make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug and biologic companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study; or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

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

Human Clinical Trials in Support of a BLA. Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of a qualified investigator in accordance with GCP requirements which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written clinical trial protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may also be required after approval.

Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients. During Phase 1 clinical trials, information about the investigational biological product's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. Phase 2 clinical trials are well controlled, closely monitored and conducted in a limited patient population, usually involving no more than several hundred participants.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 clinical trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic: such Phase 3 studies are referred to as "pivotal." Phase 3 clinical trials usually involve several hundred to several thousand participants.

In cases where two or more FDA-regulated products are combined to form a single product candidate, that product candidate is called a combination product and must be developed in compliance with regulations that apply to combination products. An example

of a combination product is two biologics combined as a fixed-dose combination product candidate, where the safety and efficacy of each component may need to be demonstrated in addition to the safety and efficacy of the combination product. Data to support combination product development and approval may include results from preclinical tests, clinical trials, and chemistry, manufacturing and controls.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further document a clinical benefit in the case of biologics approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Review and Approval of a BLA. In order to obtain approval to market a biological product in the United States, a marketing application must be submitted to the FDA that provides sufficient data establishing the safety, purity and potency of the proposed biological product for its intended indication. The application includes all relevant data available from pertinent preclinical 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 a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the biological product to the satisfaction of the FDA.

The BLA is, thus, a vehicle through which applicants formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new biologic product candidate must be the subject of an approved BLA before it may be commercialized in the United States. Under federal law, the submission of most BLAs is subject to an application user fee, which for federal fiscal year 2019 is $2,588,478 for an application requiring clinical data. The sponsor of an approved BLA is also subject to a program fee, which for fiscal year 2019 is $309,915. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

Following submission of a BLA, the FDA conducts a preliminary review of the application generally within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept the application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of BLAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within 10 months from the date on which the FDA accepts the application for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. For applications seeking approval of products that are not NMEs, the 10-month and six-month review periods run from the date that the FDA receives the application. The review process and the Prescription Drug User Fee Act goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Moreover, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with a BLA submission, including component manufacturing, finished product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Under the FDA Reauthorization Act of 2017, the FDA must implement a protocol to expedite review of

responses to inspection reports pertaining to certain applications, including applications for products in shortage or those for which approval is dependent on remediation of conditions identified in the inspection report.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity.

The FDA may refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy, Priority Review and Regenerative Advanced Therapy Designations. The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as Fast Track designation, Breakthrough Therapy designation, priority review designation and regenerative advanced therapy designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months.

With passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Accelerated Approval Pathway. The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and 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. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. Thus, the benefit of accelerated approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Limited Population Antibacterial Drug Pathway. With passage of the CURES Act in December 2016, Congress authorized FDA to approve an antibacterial or antifungal product, alone or in combination with one or more other products, as a "limited population drug." To qualify for this approval pathway, the product must be intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs; the standards for approval of drugs and biologics under the FDCA and PHSA must be satisfied; and FDA must receive a written request from the sponsor to approve the product as a limited population drug pursuant to this provision. The FDA's determination of safety and effectiveness for such a product must reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such a limited population.

Any drug or biologic approved under this pathway must be labeled with the statement "Limited Population" in a prominent manner and adjacent to the proprietary name of the drug or biological product. The prescribing information must also state that the product is indicated for use in a limited and specific population of patients and copies of all promotional materials relating to the product must be submitted to FDA at least 30 days prior to dissemination of the materials. If FDA subsequently approves the product for a broader indication, the agency may remove any post-marketing conditions, including requirements with respect to labeling and review of promotional materials applicable to the product. Nothing in this pathway to approval of a limited population drug prevents sponsors of such products from seeking designation or approval under other provisions of the FDCA, such as accelerated approval.

The FDA's Decision on a BLA. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities, 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 generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a new product, it may limit the approved indications for use of the product. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Regulation. If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA may have imposed as part of the approval process. The sponsor will be required to report, among other things, certain adverse reactions and manufacturing problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of 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 ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements 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 trials to assess safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant

commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, and its implementing regulations, as well as the Drug Supply Chain Security Act, or DSCA, which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Pediatric Studies and Exclusivity. Under the Pediatric Research Equity Act of 2003, or PREA, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

The FDA Reauthorization Act of 2017 established new requirements to govern certain molecularly targeted cancer indications. Any company that submits a BLA three years after the date of enactment of that statute must submit pediatric assessments with the BLA if the biologic is intended for the treatment of an adult cancer and is directed at a molecular target that FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The investigation must be designed to yield clinically meaningful pediatric study data regarding the dosing, safety and preliminary efficacy to inform pediatric labeling for the product.

Investigational products that have received orphan designation are exempt from the requirements of the PREA. Specifically, Section 505B(k) of the FDCA contains a statutory exemption from the requirement to conduct pediatric studies under PREA for certain products with orphan designation. Under this exemption, PREA does not apply to any application for an investigational product for an indication for which orphan designation has been granted when that application would otherwise trigger PREA because the application contains a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. In July 2018, the FDA issued draft guidance clarifying that it does not expect to grant any additional orphan-drug designation to investigational products for pediatric subpopulations of common diseases. Pediatric-subpopulation designations that have already been granted will not be affected by this change.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Drug Designation and Exclusivity. Under the Orphan Drug Act, the FDA may designate a biologic product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a product

available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must seek orphan drug designation before submitting a BLA for the candidate product. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not shorten the PDUFA goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the PDUFA application fee.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same condition for seven years, except in certain limited circumstances, including if a subsequent product with the same biologic for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

Orphan exclusivity also does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different conditions. If a biologic designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Biosimilars and Exclusivity. The 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 1, 2019, the FDA has approved 17 biosimilar products for use in the United States. No interchangeable biosimilars, however, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidances are expected to be finalized by FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their 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.

Patent Term Restoration and Extension. A patent claiming a new biologic product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of biologic products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to

broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other healthcare laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits 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;
- the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-government third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern 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.

Review and Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical Trial Approval. The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on Good Clinical Practice, or GCP, and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be

accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted. The Regulation is anticipated to enter into force in 2019. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

PRIME Designation in the EU. In March 2016, the European Medicines Agency, or EMA, launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises, or SMEs, may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated Agency contact and rapporteur from the Committee for Human Medicinal Products, or CHMP, or the Committee for Advanced Therapies, or CAT, are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Marketing Authorization. To obtain a marketing authorization for a product under European Union regulatory systems, an applicant must submit an MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States and three of the four European Free Trade Association, or EFTA, States, Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150

days but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 15 calendar days of receipt of a final opinion from the CHMP, the European Commission must prepare a draft decision concerning an application for marketing authorization. This draft decision must take the opinion and any relevant provisions of EU law into account. Before arriving at a final decision on an application for centralized authorization of a medicinal product the European Commission must consult the Standing Committee on Medicinal Products for Human Use. The Standing Committee is composed of representatives of the EU Member States and chaired by a non-voting European Commission representative. The European Parliament also has a related "droit de regard." The European Parliament's role is to ensure that the European Commission has not exceeded its powers in deciding to grant or refuse to grant a marketing authorization.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure similarly is based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

Regulatory Data Protection in the European Union. In the European Union, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During an additional two-year period of market exclusivity, a generic marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals. A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the European Union market (in case of centralized procedure) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity. Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a drug can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Once authorized, orphan medicinal products are entitled to 10 years of market exclusivity in all EU Member States and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, authorization through the centralized marketing authorization procedure covering all member countries and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

Regulatory Requirements after a Marketing Authorization has been Obtained. In case an authorization for a medicinal product in the European Union is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended, and EU Member State laws.

Brexit and the Regulatory Framework in the United Kingdom. On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provides a notice of withdrawal pursuant to the E.U. Treaty. Since the regulatory framework for pharmaceutical products in the United Kingdom. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement is reached between the United Kingdom and the European Union, then it is expected the United Kingdom's membership of the European Union will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the European Union. Discussions between the United Kingdom and the European Union focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the United Kingdom Government and Parliament sustains the possibility of the United Kingdom leaving the European Union on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

General Data Protection Regulation. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the

GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

Pharmaceutical Insurance Coverage and Healthcare Reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the insurance coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. 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 approved products for a particular indication.

In order to secure insurance coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide insurance coverage and reimbursement for the product, and the level of insurance coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable insurance coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting insurance coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the healthcare system in the United States. In March 2010, the United States Congress enacted the Affordable Care Act, or ACA, which, among other things, includes changes to the coverage and payment for products under government healthcare programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- 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;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed 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 the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, then-President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, 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. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress will likely consider other legislation to replace elements of the ACA during the next Congressional session.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently

proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, a company may be required to conduct a clinical trial that compares the cost effectiveness of its product candidates to other available therapies. If reimbursement of products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the ability of a company to generate revenues and become profitable could be impaired.

In addition, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improve the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs.

Outside the United States, ensuring adequate coverage and payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Employees

As of March 1, 2019, we had 15 full-time employees, including a total of six employees with M.D., Pharm.D. or Ph.D. degrees. Of these full-time employees, as of such date, eight employees were engaged in research and development and seven employees were engaged in general and administrative functions. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate Information

We were incorporated in the State of Delaware in 2010 under the name Arsanis, Inc. Our principal executive offices are located at 950 Winter Street, Suite 4500, Waltham, Massachusetts 02451 and our telephone number is (781) 819-5704. Our website address is www.arsanis.com. The information contained in, or accessible through, our website does not constitute a part of this Annual Report on Form 10-K.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. Such reports, proxy statements and other information can be read and copied at the public reference facilities maintained by the SEC at the Public Reference Room. The SEC maintains a web site (http://www.sec.gov) that contains material regarding issuers that file electronically, such as ourselves, with the SEC.

We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to the Proposed Merger with X4

If we do not successfully consummate the Merger with X4 or another strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, as to which we can give you no assurance.

There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of the company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while pursuing the Merger. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of the company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to stockholders. Our commitments and contingent liabilities may include (i) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of the company; (ii) litigation against us, and other various claims and legal actions arising in the ordinary course of business; (iii) debt obligations, such as the outstanding principal and interest due pursuant to our loans with Österreichische Forschungsförderungsgesellschaft mbH, or FFG; and (iv) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets would need to be reserved pending the resolution of such obligations.

In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of the company. If a dissolution and liquidation were to be pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company. A liquidation would be a lengthy and uncertain process with no assurance of any value ever being returned to our stockholders.

We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.

Our ability to successfully complete the Merger, or if the Merger is not completed, another potential strategic transaction, depends in large part on our ability to retain key management, finance and certain others of our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these key employees could potentially harm our ability to evaluate and pursue strategic alternatives, as well as fulfill our reporting obligations as a public company.

The issuance of shares of our common stock to current holders of X4 capital stock in the Merger will dilute substantially the voting power of our current stockholders.

If the Merger is completed, each outstanding share of X4 capital stock will be converted into the right to receive a number of shares of our common stock equal to the exchange ratios determined pursuant to the Merger Agreement. Immediately following the Merger, our securityholders (excluding for this purpose certain out-of-the-money options and warrants) are currently expected to own approximately 31.9% of the outstanding capital stock of the combined organization on a fully diluted basis, and X4 securityholders are currently expected to own approximately 68.1% of the outstanding capital stock of the combined organization on a fully diluted basis, assuming for this purpose a closing date of February 28, 2019. Accordingly, the issuance of shares of our common stock to X4 stockholders in the Merger will reduce significantly the relative voting power of each share of our common stock held by our current stockholders. Consequently, our stockholders as a group will have significantly less influence over the management and policies of the combined organization after the Merger than prior to the Merger.

If the combined organization after the Merger is unable to realize the strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving the expected commensurate benefit, or receiving only part of the commensurate benefit to the extent the combined organization is able to realize only part of the expected strategic and financial benefits currently anticipated from the Merger.

The pendency of the Merger could have an adverse effect on the trading price of our common stock and our business, financial condition, results of operations or business prospects.

While there have been no significant adverse effects to date, the pendency of the Merger could disrupt our businesses in the following ways, including:

- the attention of our management may be directed toward the closing of the Merger and related matters and may be diverted from the day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us or otherwise.

Should they occur, any of these matters could adversely affect the trading price of our common stock or harm our financial condition, results of operations or business prospects.

There is no assurance that the Merger will be completed in a timely manner or at all. If the Merger is not consummated, our business could suffer materially and our stock price could decline.

The closing of the Merger is subject to a number of closing conditions, including the approval by our stockholders of the issuance of shares of our common stock pursuant to the Merger Agreement and other customary closing conditions. If the conditions are not satisfied or waived, the Merger will not occur or will be delayed.

If the Merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

- we have incurred and expect to continue to incur significant expenses related to the Merger even if the Merger is not consummated;
- we could be obligated to pay X4 a termination fee of up to $600,000 under certain circumstances pursuant to the Merger Agreement;
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the Merger will be completed; and
- we may not be able to pursue an alternate merger or other strategic transaction if the Merger with X4 is not completed.

The combined organization may become involved in securities class action litigation that could divert management's attention and harm the combined organization's business and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action or shareholder derivative litigation often follows certain significant business transactions, such as the sale of a business division or announcement of a Merger. The combined organization may become involved in this type of litigation in the future. Litigation is often expensive and diverts management's attention and resources, which could adversely affect the combined organization's business.

Risks Related to our Financial Position and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant net losses. Our net loss was $43.0 million for the year ended December 31, 2018, $33.9 million for the year ended December 31, 2017 and $23.0 million for the year ended December 31, 2016. As of December 31, 2018, we had an accumulated deficit of $135.3 million. We have funded our operations to date primarily with proceeds from our initial public offering and concurrent private placement, the sale of preferred stock, convertible debt financings, borrowings under a loan agreement, proceeds received from governmental loans and grants and proceeds received under a non-governmental grant. To date, we have devoted substantially all of our resources to building our business to support discovery, research and development activities for our programs.

We have devoted a significant portion of our financial resources and efforts to the development of ASN100. On June 28, 2018, we announced that the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion. Based on the DRC recommendation, we decided to discontinue the Phase 2 clinical trial of ASN100 and have taken steps to notify health authorities and clinical investigators participating in the trial. We have ceased further clinical development of ASN100. Our determination as to our next steps will necessarily impact the amount of expenses we incur and the size of our operating losses for the foreseeable future.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter.

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

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been limited to organizing and staffing the company, business planning, raising capital, obtaining funding from government entities and non-government organizations, developing and securing our technology, identifying potential product candidates, undertaking preclinical studies and clinical trials of our most advanced product candidates and entering into licensing and funding agreements. We have not yet demonstrated the ability to initiate or complete later-stage clinical trials of any product candidates, obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any evaluation of our business to date or predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

The discontinuation of our clinical development of ASN100 has required us to reevaluate our future development plans for any product candidates and programs and has significantly decreased the likelihood that we will commercialize any product candidates in the near term. We may never be successful in developing or commercializing any product candidates.

We will need to raise substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, reduce or eliminate certain of our product development efforts or other operations.

Pending the planned consummation of the Merger, we plan to explore potential outlicensing opportunities for ASN100, continue the development of our ASN500 program as well as support our collaborators across our ongoing ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018. We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments through the fourth quarter of 2020 based on our current operating plans, which do not include material ASN100 expenses in 2019.

Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, our current changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate. Our future funding requirements, both short-term and long-term, will depend on many factors, including, but not limited to:

- our ability to successfully consummate the Merger or any other strategic transaction;
- the scope, progress, results and costs of researching and developing our ASN500 program and any product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of any product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any;
- costs associated with any litigation that might be brought against us in the future; and
- the absence of any breach, acceleration event or event of default under our funding agreements with FFG, including under our recently announced settlement agreement with FFG, or under any other agreements with third parties.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if any are approved, may not achieve commercial success. Our product revenue, if any, and any commercial milestones or royalty payments under our collaboration agreements will be derived from or based on sales of products that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government funding, grants, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. To the extent that we raise

additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our financing plans or the terms of such financings. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, additional debt financing would result in increased fixed payment obligations.

If we raise funds through government funding, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy, and we could be forced to delay, reduce or eliminate certain research and development programs or any future commercialization efforts.

Our existing and any future indebtedness, including our funding arrangements with FFG, could adversely affect our ability to operate our business.

Under our loans from FFG, principal amounts outstanding totaled $9.7 million as of December 31, 2018 and $10.2 million as of December 31, 2017. We are required to pay interest on our loans from FFG semi-annually, with payment of principal due at the maturity dates of the loans, which range from 2019 to 2021 (after giving effect to the settlement agreement with FFG described below).

Moreover, between 2011 and 2017, we recorded grants from FFG in the aggregate amount of approximately $9.2 million. We may be required to return all or a portion of the FFG loans and/or grants if we do not comply with the terms of the related FFG funding agreements and related guidelines, including specified requirements as to continued operations with respect to certain locations and funded projects, and or if we fail to comply with the terms of the settlement agreement with FFG described below.

On February 4, 2019, we and Arsanis Biosciences GmbH, or Arsanis GmbH, received letters from counsel to FFG alleging that we breached reporting, performance and other obligations in connection with the grants and loans made by FFG to Arsanis GmbH between September 2011 and March 2017 to fund qualifying research and development expenditures. The letters demanded the immediate repayment of all such subsidies. On March 8, 2019, we announced that we had entered into a settlement agreement with FFG in respect of these allegations and demands for repayment. Pursuant to the terms of the settlement agreement, in exchange for FFG's waiver of all claims against us and Arsanis GmbH except for its claims for repayment of the loans and regular interest, including its waiver of claims for repayment of grants and interest exceeding regular interest, subject to compliance by us and Arsanis GmbH with the terms of the settlement agreement, Arsanis GmbH has agreed to repay the outstanding loan principal (plus regular interest accrued thereon) on an accelerated payment schedule of three years instead of the original five years, with the final accelerated installment due and payable on June 30, 2021. The settlement agreement also contains certain other restrictive covenants, including a requirement to maintain a minimum cash balance equal to 70% of the then-outstanding principal amount of the loans at Arsanis GmbH in an account held with an Austrian bank, until all of the loans have been repaid and subject to other terms specified in the settlement agreement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations —Recent Developments—FFG Settlement" for further discussion of the terms of the settlement agreement.

We could in the future incur additional indebtedness beyond our borrowings from FFG.

Our outstanding indebtedness, combined with our other financial obligations and contractual commitments, including any additional future indebtedness beyond our borrowings from FFG, could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash and cash equivalents resources to the payment of interest and principal, prepayment and repayment fees and penalties, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- subjecting us to restrictive covenants (such as the minimum cash balance requirement under the FFG settlement agreement) that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete;

- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options; and
- increasing our vulnerability to adverse changes in general economic, industry and market conditions.

We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our existing debt. Failure to make payments or comply with other covenants under our existing debt instruments could result in an event of default and acceleration of amounts due. In particular, under the terms of the FFG settlement agreement, if we or Arsanis GmbH breach specified obligations under the settlement agreement (and fail to cure such breach during any applicable grace period), FFG is entitled to accelerate the repayment of any outstanding loans. If we are required to pay amounts due under our existing debt sooner than we expect, our available cash and cash equivalents may be insufficient to satisfy our liquidity requirements. In such an event, we may be forced to delay or reduce the scope of our planned operations, including our continued development of ASN500, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that the value of our securities will decline and/or become worthless and that investors will lose all or a part of their investment. Moreover, if we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern as a result of such lack of liquidity, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

Risks Related to the Development of Product Candidates

Our business to date has been almost entirely dependent on the success of ASN100, which was recently discontinued following failure to achieve the primary end-point in its Phase 2 clinical trial.

On June 28, 2018, we announced that the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion. Based on the DRC recommendation, we have discontinued the Phase 2 clinical trial of ASN100 and have taken steps to notify health authorities and clinical investigators participating in the trial. During the fourth quarter of 2018, we completed our analysis of the complete dataset from the trial and have ceased further clinical development of ASN100.

In light of the discontinuation of the Phase 2 clinical trial of ASN100, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by management. Because of the significant uncertainty regarding future plans, we are not able to accurately predict the impact of a potential change in our existing business strategy.

Our approach to the discovery and development of product candidates based on our targeted mAbs is unproven, and we do not know whether we will be able to successfully develop any products.

We are focused on the discovery, development and commercialization of monoclonal antibody, or mAb, immunotherapies to address serious infectious diseases. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates, including those that we are directly developing and those being developed under collaboration with subsidiaries of Bravos Bioscience, LLC, in future clinical trials or in obtaining marketing approval thereafter.

In addition, we have never had a product candidate receive approval from the FDA, the EMA, or other regulatory authority. The regulatory review process may be more expensive or take longer for our product candidates than we expect, and we may be required to conduct additional studies and/or trials beyond those we anticipate. If it takes us longer to develop and/or obtain regulatory approval for product candidates than we expect, such delays could materially and adversely affect our business, financial condition, results of operations and prospects.

Preclinical drug development is uncertain. Our preclinical programs, such as our ASN500 program, may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize any product candidates on a timely basis or at all, which would have an adverse effect on our business.

We are continuing to develop our ASN500 program, which is currently in preclinical development. We have outlicensed two preclinical product candidates, ASN200 and ASN300, to subsidiaries of Bravos Biosciences, LLC during the first half of 2018.

In order to obtain FDA approval to market a new biological product we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can

commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug application, or IND, in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per product candidate. Delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may continue to be affected by delays associated with the preclinical testing and studies of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

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

Moreover, even if clinical trials do begin for any product candidates, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety, purity and potency or efficacy to obtain the requisite regulatory approvals for any of our product candidates or product candidates employing our technology. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

Any future clinical trials of our product candidates may not be successful. If we or our collaborators are unable to commercialize any product candidates or if we experience significant delays in doing so, our business could be substantially harmed.

We currently have no products approved for sale and historically we have invested a significant portion of our efforts and financial resources in the development of ASN100, which we have ceased developing. We are continuing to develop our ASN500 program, which is currently in preclinical development. The success of any product candidates we may develop will depend on several factors, including the following:

- initiation and successful enrollment and completion of clinical trials;
- a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or other regulatory authorities for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment and maintenance of arrangements with third-party manufacturers for both clinical and any future commercial manufacturing;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by the patient community, the medical community and third-party payors;
- the performance of our future collaborators, if any; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including clinical development, the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize any product candidates, on our own or with any future collaborator, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of any product candidates are prolonged or delayed, we or our collaborators may be unable to obtain required regulatory approvals, and therefore will be unable to commercialize our product candidates on a timely basis or at all, which will adversely affect our business.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidates, we or our collaborators must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive, time-consuming, difficult to design and implement and uncertain as to outcome. We cannot guarantee that clinical trials will be conducted as planned, completed on schedule, if at all, or yield positive results.

A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities or collaborators on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board or independent ethics committee approval at each clinical trial site;
- delays in recruiting suitable subjects to participate in clinical trials;
- imposition of a clinical hold by regulatory authorities, including as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites;
- failure by us, any CROs we engage, clinical investigators, our collaborators or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with good clinical practices, or GCP, or applicable regulatory requirements in the European Union, the United States, or in other countries;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- delays or failures in demonstrating the comparability of product manufactured at one facility or with one process to product manufactured at another facility or with another process, including clinical trials to demonstrate such comparability;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or subjects dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from product sales, regulatory and commercialization milestones and royalties. In addition, if we or our collaborators make manufacturing or formulation changes to any product candidates, we may need to conduct additional trials to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

We could encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted or ethics committees, by the DRC or Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class of products to which our product candidate belongs. In June 2018, we discontinued our Phase 2 clinical trial of ASN100, based on the results of a planned interim analysis of unblinded trial data conducted by the DRC. The DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued. During the fourth quarter of 2018, we completed our analysis of the complete dataset from the trial and have ceased further clinical development of ASN100.

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

Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.

Results from preclinical studies or previous clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Any product candidates we develop may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials.

There can be no assurance that the success we achieved in preclinical studies and early clinical trials ultimately will result in success in potential future clinical trials of product candidates. For example, we have ceased clinical development of ASN100 after the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could materially and adversely affect our business, financial condition, results of operations and prospects.

We may find it difficult to enroll and dose patients in our clinical trials, which could delay or prevent us or our collaborators from proceeding with clinical trials of any product candidates.

Identifying and qualifying patients to participate in any future clinical trials of any product candidates is critical to our success. The timing of any future clinical trials will depend on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow-up periods. In addition, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements at certain clinical trial sites outside of the United States. These delays could be caused by regulatory reviews by non-U.S. regulatory authorities and contractual discussions with individual clinical trial sites, for example. Any delays in enrolling and/or dosing patients in any future clinical trials could result in increased costs, delays in advancing any product candidates, delays in testing the effectiveness of such product candidates or termination of the clinical trials altogether.

We may not be able to identify, recruit, enroll and dose a sufficient number of patients, or those with required or desired characteristics, to complete any future clinical trials in a timely manner. Subject enrollment and trial completion is affected by a number of factors, including:

- coordination between us, CROs and any future collaborators in our efforts to enroll and administer the clinical trial;
- size of the patient population and process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing commercially available therapies and other competing drug candidates' clinical trials;

- time of year in which the trial is initiated or conducted;
- variations in the seasonal incidence of the target indication;
- severity of the disease under investigation;
- ability to obtain and maintain subject consent;
- ability to enroll and treat patients in a timely manner;
- risk that enrolled subjects will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

We may conduct clinical trials for product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

We may in the future conduct one or more clinical trials with one or more trial sites that are located outside the United States.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of any future product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

We or our collaborators may fail to demonstrate safety and efficacy of any product candidates to the satisfaction of applicable regulatory authorities.

If the results of any clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with any product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be subject to the addition of labeling statements, such as contraindications or warnings, including a black box warning;

- be sued; or
- experience damage to our reputation.

If serious adverse or undesirable side effects are identified during the development of any product candidate, we or our collaborators may need to abandon or limit development of that product candidate.

If any product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or raise other safety issues that delayed or prevented further development of the compound.

If we or our collaborators elect or are forced to suspend or terminate any clinical trial of any product candidates, the commercial prospects of such product candidates will be harmed and our ability to generate product revenue from such product candidates will be delayed or eliminated. Any of these occurrences could materially harm our business, financial condition, results of operations and prospects.

The manufacture of biologic products is complex and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any loss of our master cell banks or if any of our third-party manufacturers encounter other difficulties, our ability to provide any product candidates for clinical trials or products, if approved, to patients could be delayed or halted.

The manufacture of biologic products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our collaborators and our third-party manufacturers must comply with current good manufacturing practices, or cGMP, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. Furthermore, if microbial, viral or other contaminations are discovered in any product candidates or in the manufacturing facilities in which such product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Delays in raw materials availability and supply may also extend the period of time required to develop any product candidates.

All of our mAbs are manufactured by starting with cells that are stored in a cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP and multiple working cell banks and believe we would have adequate backup should any cell bank be lost in a catastrophic event. However, it is possible that we or our third-party manufacturers could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks. We cannot assure you that any stability or other issues relating to the manufacture of any product candidates or products will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

If the market opportunities for any product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer.

Our projections of both the number of people who are affected by disease within our target indications, as well as the subset of these people who have the potential to benefit from treatment with any product candidates we may develop, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

If approved for the prevention of RSV infection, products from our ASN500 program would compete with palivizumab, which is marketed by MedImmune as Synagis, the only approved therapy in this indication. Any ASN500 products may also compete with other mAb product candidates currently in clinical development in this indication, including MedImmune's MEDI8897, which is in Phase 2 clinical development and Merck's MK-1654, which is in Phase 1 clinical development.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. In addition, the availability of our competitors' products could limit the demand and the prices we are able to charge for any products that we may develop and commercialize.

Risks Related to Dependence on Third Parties

We may enter into collaborations with third parties to develop product candidates. If these collaborations are not successful, our business could be adversely affected.

As part of our strategy, we intend to seek to enter into collaborations with third parties for one or more of our programs or product candidates. For example, we outlicensed our preclinical-stage ASN200 and ASN300 programs to subsidiaries of Bravos Biosciences, LLC during the first half of 2018. Our likely collaborators for any such collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Any collaborations we enter into in the future, may pose several risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of these collaborations may not be successful;
- collaborators may not pursue development and/or commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates developed in collaboration with us may be viewed by any collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates.

In addition, if any future collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of any future collaborators.

If we are not able to establish additional collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may seek additional collaborations to advance the development of product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate, document and execute. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

We expect to rely on third parties to conduct any future clinical trials and we currently rely on third parties for some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We do not expect to independently conduct any future clinical trials of any product candidates. We expect to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct any future clinical trials. In addition, we currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur in our product development activities. Although we seek to carefully manage our relationships with third parties, we could encounter similar challenges or delays in the future and these challenges or delays could have a material adverse impact on our business, financial condition and prospects.

Our reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our responsibility to comply with any such requirements and standards. We and these third parties are required to comply with GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA, or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, clinicaltrials.gov, within certain timeframes. Similar requirements are applicable outside the United States. Failure to comply can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, third parties on whom we rely may also have relationships with other entities, some of which may be our competitors. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical, non-clinical and preclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. As a result, our results of operations and the commercial prospects for our products would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Our reliance on third parties to manufacture product candidates will increase the risk that we will not have sufficient quantities of product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not, and do not plan to, own or operate manufacturing facilities for the production of clinical or commercial supplies of any product candidates. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any product candidates on a clinical or commercial scale. We currently rely on third parties for supply of product candidates, and our strategy is to outsource all manufacturing of any product candidates and products to third parties.

In order to conduct any future clinical trials of any product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of product candidates may shorten the expiry of such product candidates and lead to clinical trial material supply shortages in any future clinical trials, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of a product candidate in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of product candidates as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our product candidates.

Even after a third-party manufacturer has gained significant experience in manufacturing certain product candidates or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of such product candidates in a timely manner or continuously over time, or at all.

We do not currently have any agreements with third-party manufacturers for the long-term commercial supply of any product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of product candidates, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

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

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

Any product candidates and products that we develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements particularly for the development of mAbs, and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop such product candidates and compete effectively.

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

Our agreements with Adimab, LLC raise the potential for conflicts of interest.

We have entered into two agreements with Adimab, LLC, or Adimab, under which we were granted exclusive options to obtain ownership or exclusive worldwide licenses under specified patents relating to the development and commercialization of monoclonal antibodies. These agreements are important to our business and we have exercised certain of these options to a number of antibodies. Dr. Tillman U. Gerngross, the chairman of our board of directors, is the Chief Executive Officer of Adimab. If there is a dispute between us and Adimab, Dr. Gerngross would have a conflict of interest because he simultaneously has a financial interest in and owes a fiduciary duty to both Adimab and us.

Risks Related to the Commercialization of Product Candidates

If we or our collaborators are unable to establish sales, medical affairs and marketing capabilities or enter into agreements with third parties to market and sell product candidates, we may be unable to generate any product revenue.

We do not currently have a sales and marketing organization and have never commercialized a product. To successfully commercialize any products that may result from our development programs such as our ASN500 program, we will need to develop these capabilities, either on our own or with others. The establishment and development of our own commercial and medical science liaison teams or the engagement of a contract sales force to discuss any products we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with entities regarding product candidates to utilize their established marketing

and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many well-funded and profitable pharmaceutical and biotechnology companies that currently have extensive and experienced medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of product candidates. Without an internal team or the support of a third party to perform marketing, sales and medical affairs functions, we may be unable to compete successfully against these more established companies.

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

We expect that hospital formulary approval, insurance coverage and reimbursement of our products, if approved, by hospital, government and other third-party payors will be essential for most patients to be able to access these treatments. Accordingly, sales of any product candidates, if approved, will depend substantially on the extent to which the costs of such product candidates will be paid by hospitals, health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Hospital formulary approval, insurance coverage and reimbursement by other third-party payors may depend upon several factors, including the third-party payor's determination that use of a product is:

- a necessary and covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient population;
- cost-effective; and
- neither experimental nor investigational.

Obtaining hospital formulary approval, insurance coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that will require us to provide to the hospitals and payors supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to hospital formulary approval, insurance coverage and reimbursement. If hospital formulary approval, insurance coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates.

There is significant uncertainty related to hospital formulary approval, insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including government 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 and reimbursed. It is difficult to predict what third-party payors will decide with respect to the insurance coverage and reimbursement for product candidates.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations, and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries may use different methods to keep the cost of medical products artificially low. Foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenue.

Moreover, increasing efforts by hospital, government and other 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 new products approved and, as a result, they may not cover or provide adequate payment for product candidates. We expect to experience pricing pressures in connection with the sale of any product candidates due to the trend toward reducing hospital costs, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

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

Even with the requisite approvals from the FDA in the United States, EMA in the European Union and other regulatory authorities internationally, the commercial success of product candidates, if approved, will significantly depend on the acceptance of physicians, hospitals and healthcare payors of product candidates as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, hospitals, healthcare payors and others in the medical community. If these commercialized products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of our product candidates over other treatments;
- the cost effectiveness of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA or other regulatory body;
- the willingness of physicians to prescribe new therapies over the existing standard of care and future new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- relative convenience and ease of administration;
- our ability to educate the medical community and third-party payors about the benefit of our product candidates;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party payor insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

If we obtain approval to commercialize any product candidates outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We expect that we will be subject to additional risks in commercializing any product candidates outside the United States, including:

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations

We are substantially dependent on our remaining employees to facilitate the consummation of a strategic transaction.

Following our previously disclosed reduction in workforce, as of March 1, 2019, our workforce was comprised of 15 employees. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of any of these employees could potentially harm our ability to consummate the Merger, to run our day-to-day operations, as well as fulfill our reporting obligations as a public company.

We may experience difficulties in managing reductions in force.

Effecting our ongoing and planned reductions in workforce has, and is expected to continue to, place significant strains on management, our employees and our operational, financial and other resources. Furthermore, reductions in force involve certain additional costs, including severance and benefits payments to terminated employees, and we may also incur liabilities from early termination or assignment of contracts, potential litigation or other effects from such reduction in workforce. Such effects from the reduction in workforce could have a material adverse effect on our ability to execute on our business plan. There can be no assurance that we will be successful in implementing our reduction in workforce.

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

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

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

Our insurance coverage may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our internal computer systems, or those of any collaborators or contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of any collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to:

- comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions;
- provide accurate information to the FDA, the EMA and other regulatory authorities;
- comply with healthcare fraud and abuse laws and regulations in the United States and abroad;
- comply with the FCPA or other anti-corruption laws and regulations;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations regulate a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other forms of misconduct could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA, EMA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct and implemented other internal controls applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. 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, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

The United Kingdom's "Brexit" vote in favor of withdrawing from the European Union could adversely impact our operations, make it more difficult for us to do business in Europe and impose additional regulatory costs and challenges in securing approval of our candidate products.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as "Brexit." Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provided its notice of withdrawal.

It appears likely that this withdrawal will involve a process of lengthy negotiations between the United Kingdom and European Union member states to determine the future terms of the United Kingdom's relationship with the European Union. This could lead to a period of considerable uncertainty and volatility, particularly in relation to United Kingdom financial and banking markets. Weakening of economic conditions or economic uncertainties tend to harm our business, and if such conditions emerge in the U.K. or in the rest of Europe, it may have a material adverse effect on our operations and sales.

Currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit and that may continue to be the case. In addition, depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business in Europe more difficult.

We may also face new and additional regulatory costs and challenges from Brexit that could have a material adverse effect on our operations. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2018, we had U.S. federal and state net operating loss carryforwards of $38.8 million (of which $14.5 million was generated in 2018 and has an indefinite life) and $34.9 million respectively, which begin to expire in 2031 and 2036, respectively. In addition, as of December 31, 2018, we had foreign net operating loss carryforwards of $64.7 million, which do not expire. As of December 31, 2018, we also had U.S. federal and state research and development tax credit carryforwards of $0.4 million and $0.1 million, respectively, which begin to expire in 2032 and 2031, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Section 382. It is likely that the Merger will constitute an "ownership change" for purposes of Section 382 and that, therefore, our ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset our post-change income may be limited. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, reduction of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, the consummation of the Merger, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize products and technology may be adversely affected.

Our success depends, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to product candidates and technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to product candidates and technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the United States Patent and Trademark Office, or USPTO, itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

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

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

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

Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, there can be no assurance that our issued patents contain and pending applications will contain, if granted, claims of sufficient breadth to cover all antibodies alleged to be biosimilar versions of product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, and these decisions have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty

with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future decisions by the U.S. Congress, the federal courts and the USPTO, as well as similar bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or any collaborators may obtain in the future.

Patent reform legislation enacted in the United States in 2011 could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes 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 inventor to file" system. The USPTO has developed new 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 inventor to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

Our rights to develop and commercialize product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to several intellectual property license and option agreements, including agreements with the Gates Foundation, and Adimab, that are important to our business, and may need to obtain additional licenses from others to advance our research or allow commercialization of any product candidates that we may develop. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize technology and product candidates in the future. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, development and commercialization timelines, milestone payments, royalties and other obligations on us. See "Business – Collaboration and License Agreements." If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

For example, we have entered into two agreements with Adimab under which we were granted exclusive options to obtain ownership or exclusive worldwide licenses under specified patents relating to the development and commercialization of monoclonal antibodies, and we have exercised certain of those options to a number of antibodies. See "Business – Collaboration and License Agreements." Our agreements with Adimab impose specified diligence, milestone payment, royalty, asset transfer payment, acquisition payment, prosecution, insurance and other obligations on us. If we fail to comply with our obligations under the licenses, Adimab may have the right to terminate the license agreements, in which event we might not be able to market, and may be required to transfer to Adimab our rights in, any product that is covered by the Adimab agreements, including ASN100. Termination of the license agreements may also result in our having to negotiate a new or reinstated license with less favorable terms, which would have a material adverse impact on our business. Further, under our agreements with Adimab, under certain circumstances, Adimab is permitted to transfer to third parties antibody libraries that may include antibodies that we have licensed from Adimab, as well as certain information regarding certain attributes of such antibodies.

In our existing license agreements, and we expect in future agreements, patent prosecution of our licensed technology is in certain cases controlled solely by the licensor, and we are in certain cases required to reimburse the licensor for their costs of patent prosecution. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products covered by the intellectual property. Further, in each of our license agreements we are responsible for bringing any actions against any third party for infringing the patents we have licensed. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and

commercializing products and minimum yearly diligence obligations in developing and commercializing the product. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe the intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The exercise by the Gates Foundation of its licenses to certain of our intellectual property and its development and commercialization of products that we are also developing and commercializing could have an adverse impact on our market position.

In April 2017, we entered into a letter agreement with the Gates Foundation. In connection with the letter agreement, the Gates Foundation purchased $8.0 million of shares of our Series D convertible preferred stock, and we committed to use the proceeds from the investment by the Gates Foundation solely to advance the development of a specified antibody program, which involves the monoclonal antibodies ASN-1, ASN-2 and ASN-3 and our product candidate ASN100. We agreed to grant to the Gates Foundation three non-exclusive, sublicensable licenses to research, develop, manufacture, seek regulatory approval for and commercialize antibodies that we or our research contractors discover in specified areas of global health that the Gates Foundation has identified as underinvested or disproportionately impacting poor and vulnerable populations, including ASN100, for the treatment of neonatal sepsis caused by *S. aureus*. Two of these non-exclusive licenses will only be granted upon request from the Gates Foundation, and the third, although it has already been granted, would only be exercisable by the Gates Foundation upon certain "trigger events," as described further in the agreement.

In February 2017, we entered into a grant agreement with the Gates Foundation, which was amended and restated in August 2018. In connection with the grant agreement, the Gates Foundation granted us certain funds, which we are obligated to use to conduct preclinical development of monoclonal antibodies for the prevention of RSV infection in newborns, which we refer to as the RSV project.

In August 2018, we entered into a second grant agreement with the Gates Foundation pursuant to which the Gates Foundation granted us up to $1.1 million to conduct preclinical development activities for the RSV project that were not included in the February 2017 grant agreement, as amended and restated in August 2018. In connection with the grant agreements, we have granted the Gates Foundation a non-exclusive, sublicensable license to research and develop, manufacture, seek regulatory approval for and commercialize antibodies developed under the agreements for the benefit of people in developing countries.

The exercise by the Gates Foundation of any of its non-exclusive licenses to certain of our intellectual property (or its right to obtain such licenses), and its development and commercialization of product candidates and products that we are also developing and commercializing, could have an adverse impact on our market position.

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

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. To counter infringement or unauthorized use claims or to defend against claims of infringement can be expensive and

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

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

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

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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 trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

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

Our commercial success depends upon our ability and the ability of any collaborators to develop, manufacture, market and sell product candidates and use proprietary technologies without infringing the proprietary rights and intellectual property of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO. The risks of being involved in such litigation and proceedings may also increase as any product candidates that we develop approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

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

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

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

Trade secrets and know-how can be difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual

or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, there can be no assurance that such inventions will not be assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. For example, a public presentation in the scientific or popular press on the properties of our product candidates could motivate a third party, despite any perceived difficulty, to assemble a team of scientists having backgrounds similar to those of our employees to attempt to independently reverse engineer or otherwise duplicate our antibody technologies to replicate our success.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

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

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. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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.

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to product candidates we develop but that are not covered by the claims of the patents that we own or license or may own in the future;
- we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Any product candidates that we develop could fail to receive regulatory approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe, pure and potent or effective for its proposed indication;
- results of clinical trials may not meet the evidentiary standards required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of a biologics license application, or BLA, to the FDA or other submission or to obtain regulatory approval in the United States;
- FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

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

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for product candidates.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and to accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those 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, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because the FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another 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 shown to be safer, more effective or makes a major contribution to patient care.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A Fast Track designation by the FDA may not actually lead to a faster development, regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA Fast Track designation. Fast Track designation does not ensure that we will experience a faster development, regulatory review or approval process compared to conventional FDA procedures. Additionally, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Even if we complete the necessary preclinical and clinical studies, the marketing approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of drug products are subject to extensive regulation by the FDA, EMA and other regulatory authorities, and regulations may differ from country to country. We, and any future collaborators, are not permitted to market product candidates in the United States or in other countries until we, or they, receive approval of a BLA from the FDA, approval of a marketing authorization application, or MAA, from the EMA, or marketing approval from other applicable regulatory authorities. We are in the early stages of product candidate development and are subject to the risks of failure inherent in that process. We have not submitted an application for or received marketing approval for any product candidate in the United States, Europe or in any other jurisdiction. We have not yet been successful at conducting and managing the clinical trials necessary to obtain marketing approvals, including FDA approval of a BLA and EMA approval of an MAA.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical studies could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we develop from being marketed abroad.

In order to market and sell our products in the European Union 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 can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and our collaborators and could delay or prevent the introduction of product candidates in certain countries. In addition, if we or our collaborators fail to obtain the non-U.S. approvals required to market product candidates outside the United States or if we or our collaborators fail to comply with applicable non-U.S. regulatory requirements, our target market will be reduced and our ability to realize the full market potential of product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as "Brexit." On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of any product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement is reached between the United Kingdom and the European Union, then it is expected the United Kingdom's membership of the European Union will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the European Union. Discussions between the United Kingdom and the European Union focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the United Kingdom government and Parliament sustains the possibility of the United Kingdom leaving the European Union on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

Even if we, or any future collaborators, obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our third-party manufacturers, any future collaborators and their third-party manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or any future collaborators, receive marketing approval for any product candidates, we, and any future collaborators, and our and their third-party manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, we, and any future collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidates for which we, or any future collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial

penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any product candidates for which we, or any future collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to continual requirements of and review by the FDA, EMA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, or REMs.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown side effects or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals, including license revocation;
- refusal to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of product candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. 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, which would adversely affect our business, prospects, financial condition and results of operations.

We also 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. 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 regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements 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 constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any drugs for which we obtain marketing approval. Our future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. These include the following:

- *Anti-Kickback Statute*—the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- *False Claims Act*—the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- *HIPAA*—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information;
- *Transparency Requirements*—federal laws require applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals; and
- *Analogous State and Foreign Laws*—analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to sales or marketing arrangements and claims involving healthcare items or services and are generally broad and are enforced by many different federal and state agencies as well as through private actions.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010, or the Bribery Act. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Recently enacted and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, then-President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. Among the provisions of the ACA of importance to

our business, including, without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale, are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provision. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not

required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop and commercialize product candidates. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. 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.

Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, which we collectively refer to as Trade Control Laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control Laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control Laws by U.K., U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business.

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

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, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks Related to Ownership of Our Common Stock

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

Our stock price is volatile. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our product candidates or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;

- announcements regarding potential strategic transactions;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- significant litigation involving us;
- announcements of material developments in our business, financial condition and/or operations;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

If any of the foregoing matters were to occur, or if our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. For example, following our announcement of the discontinuation of our Phase 2 clinical trial of ASN100 as a result of the DRC’s futility determination, the price of our common stock substantially declined. In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

Our executive officers, directors and principal stockholders maintain the ability to control all matters submitted to stockholders for approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially own shares representing more than a majority of our outstanding common stock. In addition, three of our directors are affiliated with stockholders who each own more than 5% of our outstanding common stock. If these stockholders were to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of the company on terms that other stockholders may desire or result in management of the company that our public stockholders disagree with.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to compliance with applicable securities law. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one

or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on the Nasdaq Global Market on November 16, 2017. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price for our common stock and thereby affect the ability of our stockholders to sell their shares. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If we fail to continue to meet the requirements for continued listing on the Nasdaq Global Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is listed for quotation on the Nasdaq Global Market. We are required to meet specified financial requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a "public shell company." Additionally, if we conduct a reverse merger (including the Merger), the combined organization following such transaction will need to meet Nasdaq's initial listing standards. If we are unable to comply with Nasdaq's listing standards, Nasdaq may determine to delist our common stock from the Nasdaq Global Market or other of Nasdaq's trading markets. If our common stock is delisted for any reason, it could reduce the value of our common stock and liquidity.

If we commit certain material breaches under our agreement with the Gates Foundation, and fail to cure them, we may be required to redeem shares of our stock held by the Gates Foundation and its affiliates.

In the event the Gates Foundation terminates our agreement for certain specified uncured material breaches by us, we will be obligated, among other remedies, to redeem the then-held shares of our stock purchased by the Gates Foundation pursuant to the agreement or to facilitate the purchase of such stock by a third party. For any such redemption, the Gates Foundation stock will be valued at the greater of the original purchase price (plus specified interest) or the fair market value of such stock. If we are required to redeem such shares or to compensate the Gates Foundation, our financial condition could be materially and adversely affected.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, and particularly after we are no longer an EGC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and the Nasdaq Global Market have imposed various requirements on public companies, including establishment and

maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

Provisions in our corporate charter and our by-laws, each as amended and restated, may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a shareholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all 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, employees or stockholders.

Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by our directors, officers, other employees or stockholders to the company or our stockholders, any action asserting a claim against us arising pursuant to the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim arising pursuant to our restated certificate of incorporation or amended and restated by-laws, or governed by the internal affairs doctrine. This provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, other employees or other stockholders, which may discourage such lawsuits against us and our directors, officers, other employees or other stockholders. Alternatively, if a court were to find this provision in our restated certificate of incorporation 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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, our ability to pay cash dividends may be restricted by any future indebtedness. Our ability to pay cash dividends may also, under certain circumstances, be limited under the terms of a letter agreement we have entered into with the Gates Foundation. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future, and investors seeking cash dividends should not purchase shares of our common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our principal facilities consist of office and laboratory space. We currently occupy approximately 5,711 square feet of office space in Waltham, Massachusetts under a lease that currently expires in December 2023 and approximately 410 square meters of office and laboratory space in Vienna, Austria under a sublease that currently expires in February 2021. We believe that our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock commenced trading on the Nasdaq Global Market under the symbol "ASNS" on November 16, 2017. Prior to that date, there was no public trading market for our common stock.

Holders of Our Common Stock

As of March 1, 2019, there were 44 record holders of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Our ability to pay cash dividends may also, under certain circumstances, be limited under the terms of a letter agreement we have entered into with the Bill & Melinda Gates Foundation. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Use of Proceeds from Registered Securities

On November 20, 2017, we closed our initial public offering, in which we issued and sold 4,000,000 shares of common stock at a public offering price of $10.00 per share, and issued an additional 600,000 shares of common stock at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option. The aggregate gross proceeds to us from our initial public offering, inclusive of the over-allotment exercise, were $46.0 million.

All of the shares of common stock issued and sold in our initial public offering were registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to a registration statement on Form S-1 (Registration No. 333-221050), which was declared effective by the SEC on November 15, 2017.

The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise, were approximately $39.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us of approximately $6.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

As of December 31, 2018, we have used approximately $43.1 million of our existing cash and cash equivalents at the time of the initial public offering, together with the net proceeds from our initial public offering, to advance our product candidates through clinical trial programs and for working capital and general corporate purposes. There have been no material changes in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on November 17, 2017 pursuant to Rule 424(b).

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

We have derived the consolidated statement of operations data for the years ended December 31, 2018, 2017, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2018, 2017 and 2016 from our audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results that may be expected in any future period. You should read the selected financial data below in conjunction with the section of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,			
	2018	2017	2016	2015
	(in thousands)			
Revenue:				
License revenue	$ 3,500	$ —	$ —	$ —
Total revenue	3,500	—	—	—
Operating expenses:				
Research and development	30,979	28,128	17,831	12,706
General and administrative	18,406	8,005	6,515	2,119
Total operating expenses	49,385	36,133	24,346	14,825
Loss from operations	(45,885)	(36,133)	(24,346)	(14,825)
Other income (expense):				
Grant and incentive income	3,179	3,868	2,390	2,155
Interest expense	(1,039)	(2,079)	(2,515)	(472)
Interest income	809	214	—	—
Change in fair value of warrant liability	—	(31)	39	1
Change in fair value of derivative liability	—	762	1,388	—
Loss on extinguishment of debt	—	(462)	(35)	—
Other income (expense), net	(85)	(16)	104	(77)
Total other income (expense), net	2,864	2,256	1,371	1,607
Net loss	(43,021)	(33,877)	(22,975)	(13,218)
Accretion of redeemable convertible preferred stock to redemption value	—	(44)	(25)	(19)
Net loss attributable to common stockholders (1)	$ (43,021)	$ (33,921)	$ (23,000)	$ (13,237)
Net loss per share attributable to common stockholders—basic and diluted (1)	$ (3.01)	$ (16.45)	$ (44.79)	$ (26.02)
Weighted average common shares outstanding—basic and diluted (1)	14,308	2,062	514	509

(1) See Note 15 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

	As of December 31,		
	2018	2017	2016
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 30,754	$ 76,793	$ 3,035
Restricted cash (1)	640	355	394
Working capital (deficit) (2)	29,682	68,850	(6,344)
Total assets	36,004	81,254	7,604
Convertible promissory notes, net of discount	—	—	2,863
Loan payable, net of discount, including current portion	7,894	12,236	12,426
Warrant liability	—	—	47
Derivative liability	—	—	2,593
Redeemable convertible preferred stock (3)	—	—	39,838
Total stockholders' equity (deficit)	21,600	58,707	(56,562)

(1) Restricted cash as of December 31, 2018 consisted of amounts subject to letters of credit in connection with our office leases and corporate credit cards. Restricted cash as of December 31, 2017 consisted of amounts subject to letters of credit in connection with our office leases. Restricted cash as of December 31, 2016 consisted of amounts subject to letters of credit in connection with our office leases and corporate credit cards. See Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

(2) We define working capital (deficit) as current assets less current liabilities.

(3) Upon the closing of our initial public offering, 21,869,096 shares of preferred stock were converted into 7,180,483 shares of common stock.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and the other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, 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 Annual Report on Form 10-K, 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 that has historically focused on applying mAb immunotherapies to address serious infectious diseases. We possess a deep understanding of the pathogenesis of infection paired with access to what we believe to be some of the most advanced mAb discovery techniques and platforms available today. Our pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including *Staphylococcus aureus* (*S. aureus*) and RSV.

On June 28, 2018, we announced the discontinuation of our Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients following the completion of a planned interim analysis of unblinded trial data for 118 patients by an independent data review committee, or DRC. Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued. During the third quarter of 2018, we completed follow-up visits on patients dosed in the trial per the study protocol, and during the fourth quarter of 2018, we completed our analysis of the complete dataset from the 154 patients that were enrolled in the trial. We are currently exploring potential collaborations or out-licensing opportunities for the potential continued development of ASN100.

Following our discontinuation of ASN100 clinical development, in August 2018 we announced that we were considering strategic options that may potentially result in changes to our business strategy and future operations and our board of directors approved a reduction in workforce to reduce operating costs and better align our workforce with the needs of our business following our discontinuation of the clinical development of ASN100. As part of this planned reduction in workforce, we eliminated 28 positions across the company, representing approximately 65% of our workforce, through March 1, 2019.

Following an extensive process of evaluating strategic alternatives for the company and identifying and reviewing potential candidates for a strategic acquisition or other transaction, on November 26, 2018, we entered into the Merger Agreement with X4, pursuant to which a wholly owned subsidiary of the company will merge with and into X4, with X4 continuing as a wholly owned subsidiary of the company and the surviving corporation of the Merger. We and X4 believe that the Merger will result in a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for the treatment of rare diseases. We expect to devote significant time and resources to completion of the Merger. However, there can be no assurance that such activities will result in the completion of the Merger. Further, the completion of the Merger ultimately may not deliver the anticipated benefits or enhance shareholder value.

X4 has expressed interest in retaining certain members of our staff including our scientific team in Vienna, Austria, a team which has deep expertise in the research of virally-mediated infections.

Since our inception in 2010, we have devoted substantially all of our resources to building our business to support discovery, research and development activities for our programs. We do not have any products approved for sale and have not generated any revenue from product sales.

Since our inception, we have received significant proceeds from outside sources to fund our operations. We have funded our operations through December 31, 2018 primarily with proceeds from the following sources:

- net cash proceeds of $75.1 million from sales of our preferred stock;
- net cash proceeds of $39.5 million from sales of our common stock in our initial public offering;
- net cash proceeds of $18.6 million from sales of our common stock in our private placement to New Enterprise Associates 16, L.P., or NEA;
- gross proceeds of $14.4 million from borrowings under convertible promissory notes;

- proceeds of $9.5 million from borrowings under a loan and security agreement with Silicon Valley Bank, or SVB, which, as amended, we refer to as the 2012 Loan Agreement;
- proceeds of $9.2 million and $9.7 million of grant and loan proceeds, respectively, from our funding agreements with FFG;
- proceeds of $4.9 million of research and development incentive payments received from the Austrian government;
- proceeds of $2.7 million from grant agreements with the Bill & Melinda Gates Foundation, or the Gates Foundation; and
- proceeds of $3.5 million from a patent license and option agreement with Janssen Pharmaceuticals, Inc.

On November 20, 2017, we closed an initial public offering of our common shares, in which we issued and sold 4,000,000 common shares at a price to the public of $10.00 per share. Concurrent with the initial public offering, (i) we issued an additional 600,000 common shares at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option and (ii) NEA purchased 2,000,000 shares of our common stock at the initial per share public offering price of $10.00 in a private placement. The aggregate net proceeds to us from the initial public offering, inclusive of the over-allotment exercise, and the private placement were $58.1 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Since our inception, we have incurred significant operating losses. If we do not successfully consummate the Merger with X4 or another strategic transaction, our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net losses were $43.0 million, $33.9 million and $23.0 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $135.3 million.

Pending the planned closing of the Merger, we expect to continue the development of our ASN500 program. We also expect to continue to incur costs associated with operating as a public company. As a result, we will need substantial additional funding to support continuing operations and pursue our business strategy, until such time as we can generate significant revenue from product sales, if ever. We expect to finance operations with proceeds from outside sources, with a majority of such proceeds to be derived from the sale of equity. We may also pursue additional funding from outside sources, including proceeds from our existing grant and potential future grant agreements with the Gates Foundation; expansion of, or entry into, new borrowing arrangements; grants and loans under existing funding agreements with FFG; research and development incentive payments from the Austrian government; and entry into potential future collaboration agreements for one or more programs. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, as well as the risk that the Merger will not be consummated, as described elsewhere in this Annual Report on Form 10-K, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue operations at planned levels and be forced to reduce or terminate operations.

As of December 31, 2018, we had cash and cash equivalents of $30.8 million. We believe our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments through the fourth quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

Recent Developments

FFG Settlement

On February 4, 2019, we and Arsanis GmbH received letters from counsel to FFG alleging that we breached reporting, performance and other obligations in connection with the grants and loans made by FFG to Arsanis GmbH between September 2011 and March 2017 to fund qualifying research and development expenditures, which we collectively refer to as the subsidies. The letters demanded the immediate repayment of all subsidies, totaling approximately EUR 18.1 million ($20.4 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019), on or before February 19, 2019, which consisted of approximately EUR 7.2 million ($8.1 million) for the reimbursement of grants previously received by us, approximately EUR 8.5 million ($9.6 million) for the repayment of outstanding loan principal and approximately EUR 2.4 million ($2.7 million) for assessed interest, which we refer to, collectively, as the FFG Demands. FFG reserved all rights and remedies in connection with the subsidies.

On March 8, 2019, we entered into a settlement agreement, or the Settlement Agreement, with FFG, X4, Arsanis GmbH and Artemis AC Corp., our wholly owned subsidiary, in respect of the FFG Demands.

Pursuant to the terms of the Settlement Agreement, in exchange for FFG's waiver of all claims against us and Arsanis GmbH except for its claims for repayment of the loans and regular interest, including its waiver of claims for repayment of grants and interest exceeding regular interest, subject to compliance by us and Arsanis GmbH with the terms of the Settlement Agreement, Arsanis GmbH has agreed to repay the outstanding loan principal equal to EUR 8,505,204 ($9.5 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019) (plus regular interest accrued thereon) on an accelerated payment schedule of three years instead of five years, with the final accelerated installment due and payable on June 30, 2021. The parties have also agreed that (i) the portion of such loans to be repaid in 2019, or the 2019 Payment, is EUR 2,596,320 ($2.9 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019) and such payment will be made on March 31, 2019; (ii) until all of the loans have been repaid and subject to other terms specified in the Settlement Agreement, a minimum cash balance equal to 70% of the then-outstanding principal amount of the loans will be maintained at Arsanis GmbH in an account held with an Austrian bank, which we refer to as the minimum cash requirement; (iii) at least until December 31, 2021 and subject to other terms specified in the Settlement Agreement, Arsanis GmbH will maintain a physical premises in Austria with a minimum of eight full-time equivalent employees, retain ownership rights to intellectual property, or IP, which generated or may be generated (if any) from or in relation to the projects that are subject to the subsidy agreements with FFG in Austria, and to the extent that it licenses such IP to any third party it will receive arm's length compensation as consideration and (iv) Arsanis GmbH will comply with specified quarterly financial reporting obligations. We agreed (i) to procure the timely transfer of sufficient funds to Arsanis GmbH to ensure the minimum cash requirement is met, (ii) to use our best efforts to enable Arsanis GmbH to comply with specified obligations and (iii) to refrain from any instructions and measures that might endanger compliance with the specified obligations. X4 and Artemis AC Corp. agreed (i) to use commercially reasonable efforts to enable Arsanis GmbH and us to comply with their above-mentioned obligations and (ii) to refrain from any instructions and measures that might endanger compliance with such specified obligations. If we or Arsanis GmbH breach specified obligations under the Settlement Agreement (and fail to cure such breach during any applicable grace period), FFG is entitled to accelerate the repayment of any outstanding loans. In addition, subject to the fulfillment of Arsanis GmbH's obligations and commitments under the Settlement Agreement, FFG has agreed that effective as of December 31, 2021, it will release the parties, as applicable, from all obligations and claims arising in relation to the subsidies and their commitments provided under the Settlement Agreement and under other documents in favor of Arsanis GmbH, as in effect as of the date of the Settlement Agreement.

Merger Agreement Amendment

In connection with the Settlement Agreement, on March 8, 2019, we entered into a Second Amendment to Agreement and Plan of Merger, or the Merger Agreement Amendment, to the Merger Agreement with Artemis AC Corp. and X4.

Pursuant to the Merger Agreement Amendment, we and X4 have agreed to amend the terms of our previously announced Merger Agreement to reflect our agreement that 1/3rd of the 2019 Payment, which equals EUR 865,440 (approximately $968,600, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019) and is referred to as the Arsanis accelerated payment amount, would be deducted from our "net cash" at closing (as defined in the Merger Agreement) and as a result would increase the exchange ratios for the X4 common stock and X4 preferred stock in the merger. Specifically, the Merger Agreement currently excludes the approximately EUR 8.5 million principal amount of FFG loans to Arsanis GmbH from the deduction for unpaid indebtedness that otherwise reduces our "net cash" at closing. The Merger Agreement Amendment provides that this excluded amount (and thus "net cash") be reduced by the Arsanis accelerated payment amount, to approximately EUR 7.6 million.

Other than as expressly modified pursuant to (i) that certain First Amendment to Agreement and Plan of Merger, dated December 20, 2018, by and among us, Merger Sub and X4 and (ii) the Merger Agreement Amendment, the Merger Agreement remains in full force and effect as originally executed on November 26, 2018.

Lease Termination Agreement and Sublease Agreement

On February 26, 2019 Arsanis GmbH entered into a lease termination agreement, or the Termination Agreement, effective as of February 28, 2019, with Wüstenrot Marxbox GmbH & Co OG, or the Landlord, to terminate the lease dated November 26, 2010, by and between the Landlord (as successor-in-interest to Marxbox Bauprojekt GmbH & Co. OG) and Arsanis GmbH for its facility in Vienna, Austria, or the Lease. The Termination Agreement was conditioned upon a new tenant, Hookipa Biotech GmbH, or Hookipa, entering into a binding agreement to lease a portion of the premises subject to the Lease. Hookipa entered into its lease effective as of March 1, 2019.

In consideration for the termination of the Lease, Arsanis GmbH agreed to make a lump sum payment to the Landlord in the amount of EUR 45,000 (approximately $50,600, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019), plus 20% value-added tax, in full satisfaction of its obligations under the Lease.

In connection with the Lease Termination Agreement, Arsanis GmbH also entered into a sublease agreement with Hookipa, dated as of February 25, 2019, pursuant to which Arsanis GmbH agreed to sublease approximately 400 square meters of the premises subject to the original Lease from Hookipa with a term beginning on March 1, 2019, or the Sublease, to be used for laboratory and office space. The Sublease has a term of two years and is terminable by Arsanis GmbH upon three months' notice. The monthly rent for the Sublease is approximately EUR 11,400 ($12,800, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019). In addition, Arsanis GmbH agreed to sell certain laboratory equipment and office furniture to Hookipa.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales. License revenue is generated from our patent license and option agreement with Janssen. We recognize nonrefundable license fees as revenue upon delivery provided there are no undelivered elements in the arrangement. Under our patent license and option agreement with Janssen, we may also recognize revenue from potential future payments should Janssen exercise its option to acquire specified patents in our portfolio related to the ASN200 *E. coli* program. We recognize such revenue in the period the option exercise occurs, provided that specified conditions are met, Janssen's option to acquire such patents are considered probable of being achieved and we have no remaining performance obligations, assuming all other revenue recognition criteria are met.

We recognize proceeds received from grants under our funding agreements with FFG, our research and development incentives from the Austrian government and our grant agreements with the Gates Foundation as other income, rather than as revenue. See "—Critical Accounting Policies and Significant Judgments and Estimates—Government Contracts, Grant Agreements and Incentive Programs."

Operating Expenses

Research and Development Expenses. Research and development expenses consist primarily of costs incurred in connection with the discovery and development of product candidates. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, that are primarily engaged in the oversight and conduct of clinical trials, if any; contract manufacturing organizations, or CMOs, that are primarily engaged to provide preclinical and clinical drug substance and product for research and development programs, as well as investigative sites and consultants that conduct any clinical trials, preclinical studies and other scientific development services;
- the cost of acquiring and manufacturing preclinical and clinical trial materials, including manufacturing validation batches;
- employee-related expenses, including salaries, benefits and employee termination and severance expenses related to the reduction in workforce, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;
- facilities-related expenses, which include direct depreciation costs and allocated rent and maintenance of facilities and other operating costs; and
- payments made under third-party licensing or option agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to CROs, CMOs, laboratories, consultants and other external service providers in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under license or option agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because such costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as to manage our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
ASN100	$ 19,744	$ 19,037	$ 9,722
ASN200	26	47	138
ASN300	17	123	59
ASN400	3	50	166
ASN500	1,530	856	3
Unallocated research and development expenses	9,659	8,015	7,743
Total research and development expenses	$ 30,979	$ 28,128	$ 17,831

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of our ASN500 program or any potential future product candidates or when, if ever, material net cash inflows may commence from any potential future product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- successful enrollment and completion of clinical trials;
- a safety, tolerability and efficacy profile that is satisfactory to the FDA or any non-U.S. regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment and maintenance of arrangements with third-party manufacturers for both clinical and any future commercial manufacturing;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by the patient community, the medical community and third-party payors; and
- our ability to compete with other therapies.

We may never succeed in achieving regulatory approval for any product candidates. We may obtain unexpected results from clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of any product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay the planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. Drug commercialization will take several years and millions of dollars in development costs.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and benefits, stock-based compensation expense, directors and officers insurance and travel for personnel in executive, director, finance and administrative functions. General and administrative expenses also include professional fees for legal, audit, patent protection, and accounting services.

We anticipate that general and administrative expenses will decrease as a result of our reduction in workforce and reduction in legal fees following the closing of the planned merger with X4.

Other Income (Expense), Net

Grant and Incentive Income. Grant and incentive income consists of grant income recognized in connection with grants we receive under funding agreements with FFG, or the FFG Grants, including the imputed benefit of FFG loans at below-market interest rates; incentive income received in connection with the research and development incentive program provided by the Austrian government; and grant income received under our grant agreements with the Gates Foundation.

Interest Expense. Interest expense consists of interest on outstanding borrowings under the 2012 Loan Agreement, convertible promissory notes and loans from FFG as well as amortization of debt discount and debt issuance costs.

In April 2017, in connection with the sale of our Series D convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes that we issued in 2016 and 2017 was automatically converted into shares of Series D convertible preferred stock. As a result, in periods subsequent to this conversion, we incurred no interest expense related to convertible promissory notes.

Interest Income. Interest income primarily consists of interest earned on cash equivalents.

Change in Fair Value of Warrant Liability. In connection with the 2012 Loan Agreement, we issued to SVB warrants to purchase shares of our preferred stock. We recognized the non-cash changes in the fair value of the warrants as a component of other income (expense), net in our consolidated statement of operations. Upon the closing of our initial public offering, these warrants became exercisable for shares of common stock instead of convertible preferred stock. The warrants met the criteria to be classified in stockholders' equity and the fair value of the warrant liability as of the initial public offering date was reclassified to stockholders' equity (deficit). As a result, we no longer recognize any changes to the fair value of the warrants through other income (expense).

Change in Fair Value of Derivative Liability. We issued convertible promissory notes that contained a contingent put option and a conversion feature, each of which met the definition of a derivative instrument. We recognized the changes in the fair value of the derivative liability as a component of other income (expense), net in our consolidated statement of operations. The convertible promissory notes converted into shares of Series D convertible preferred stock in connection with the sale of our Series D convertible preferred stock in April 2017. As a result, no convertible promissory notes remained outstanding and we no longer recognize changes in the fair value of the derivative liability through other income (expense).

Loss on the Extinguishment of Debt. In April 2017, in connection with the sale of our Series D convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes that we issued in 2016 and 2017 was automatically converted into shares of Series D convertible preferred stock. We recorded a loss on extinguishment of debt related to this conversion.

Other Income (Expense). Other income (expense), net consists primarily of realized and unrealized foreign currency transaction gains and losses.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits or any foreign income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2018, we had U.S. federal and state net operating loss carryforwards of $38.8 million (of which $14.5 million was generated in 2018 and has an indefinite life) and $34.9 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2031 and 2036, respectively. In addition, as of December 31, 2018, we had foreign net operating loss carryforwards of $64.7 million, which do not expire. As of December 31, 2018, we also had U.S. federal and state research and development tax credit carryforwards of $0.4 million and $0.1 million, respectively, which begin to expire in 2032 and 2031, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017:

	Year Ended December 31,		
	2018	2017	Change
	(in thousands)		
Revenue:			
License revenue	$ 3,500	$ —	$ 3,500
Total revenue	3,500	—	3,500
Operating expenses:			
Research and development	30,979	28,128	2,851
General and administrative	18,406	8,005	10,401
Total operating expenses	49,385	36,133	13,252
Loss from operations	(45,885)	(36,133)	(9,752)
Other income (expense):			
Grant and incentive income	3,179	3,868	(689)
Interest expense	(1,039)	(2,079)	1,040
Interest income	809	214	595
Change in fair value of warrant liability	—	(31)	31
Change in fair value of derivative liability	—	762	(762)
Loss on extinguishment of debt	—	(462)	462
Other income (expense), net	(85)	(16)	(69)
Total other income (expense), net	2,864	2,256	608
Net loss	$ (43,021)	$ (33,877)	$ (9,144)

Revenue. Revenue was $3.5 million for the year ended December 31, 2018, compared to $0 for the year ended December 31, 2017. The increase of $3.5 million was due to license revenue recognized under the patent license and option agreement with Janssen during the year ended December 31, 2018.

Research and Development Expenses.

	Year Ended December 31,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
ASN100	$ 19,744	$ 19,037	$ 707
ASN200	26	47	(21)
ASN300	17	123	(106)
ASN400	3	50	(47)
ASN500	1,530	856	674
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	8,405	6,095	2,310
Other	1,254	1,920	(666)
Total research and development expenses	$ 30,979	$ 28,128	$ 2,851

Research and development expenses were $31.0 million for the year ended December 31, 2018, compared to $28.1 million for the year ended December 31, 2017. The increase of $2.9 million was primarily due to an increase of $0.7 million in direct costs for our ASN100 program, an increase of $0.7 million in direct costs for our ASN500 program, and an increase of $1.6 million in unallocated research and development expenses.

The increase in direct costs for our ASN100 program was primarily due to CMO and CRO fees for process development and establishment of manufacturing capabilities for the supply of our clinical materials, the oversight and conduct of our Phase 2 clinical trial and investigator fees for that same clinical trial. Based on our decision to discontinue the Phase 2 clinical trial of ASN100, we do not expect to incur material direct costs for ASN100 in 2019 as we and our CMO and CROs completed manufacturing and process development and clinical trial activities during the year ended December 31, 2018.

Our ASN500 program was initiated in March 2017. Direct costs for our ASN500 program during the year ended December 31, 2018 were primarily due to third-party fees for the oversight and conduct of preclinical research, facility costs and preclinical program expenses associated with internal lab consumables. We expect that our direct costs for our ASN500 program will increase as we advance our ASN500 program through preclinical development.

The increase in unallocated research and development expenses was due to an increase of $2.3 million in personnel-related costs (including increases in salaries and wages of $1.0 million, stock-based compensation of $0.8 million and personnel travel costs of $0.1 million) primarily due to the hiring of new personnel and increased employee compensation. The increase in unallocated research and development expenses also included severance and retention costs of $0.4 million related to the reduction in workforce.

General and Administrative Expenses. General and administrative expenses were $18.4 million for the year ended December 31, 2018, compared to $8.0 million for the year ended December 31, 2017. The increase of $10.4 million was primarily related to costs associated with operating as a public company, including increases of $6.1 million in personnel costs (which included increases in salaries and wages of $0.5 million, stock-based compensation of $4.0 million and personnel travel costs of $0.1 million) primarily due to an increase in headcount and employee compensation, $1.4 million in severance and retention costs related to the reduction in workforce, $0.4 million in board of directors fees, $0.6 million in insurance fees and $3.2 million in professional fees primarily due to legal and accounting costs associated with being a public company.

Other Income (Expense), Net. Other income, net was $2.9 million for the year ended December 31, 2018, compared to $2.3 million for the year ended December 31, 2017. The increase of $0.6 million in other income, net was primarily due to a decrease of $1.0 million in interest expense primarily associated with our convertible promissory notes, a decrease in loss on extinguishment of debt of $0.5 million in connection with the April 2017 conversion of our 2016 and 2017 convertible promissory notes into shares of our Series D convertible preferred stock, and an increase in interest income of $0.6 million, primarily from the bank interest earned on the cash received from the initial public offering and concurrent private placement of our common stock. These increases in other income, net were partially offset by a decrease of $0.8 million in gains recognized as a result of decreases in the fair value of the derivative liability associated with our convertible promissory notes, which were converted into shares of preferred stock in April 2017, and a decrease in grant and incentive income of $0.7 million primarily associated with our grant agreements with the Gates Foundation.

Comparison of the Years Ended December 31, 2017 and 2016

The following table summarizes our results of operations for the years ended December 31, 2017 and 2016:

	Year Ended December 31,		
	2017	2016	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 28,128	$ 17,831	$ 10,297
General and administrative	8,005	6,515	1,490
Total operating expenses	36,133	24,346	11,787
Loss from operations	(36,133)	(24,346)	(11,787)
Other income (expense):			
Grant and incentive income	3,868	2,390	1,478
Interest expense	(2,079)	(2,515)	436
Interest income	214	—	214
Change in fair value of warrant liability	(31)	39	(70)
Change in fair value of derivative liability	762	1,388	(626)
Loss on extinguishment of debt	(462)	(35)	(427)
Other income (expense), net	(16)	104	(120)
Total other income (expense), net	2,256	1,371	885
Net loss	$ (33,877)	$ (22,975)	$ (10,902)

Research and Development Expenses.

	Year Ended December 31,		
	2017	2016	Change
	(in thousands)		
Direct research and development expenses by program:			
ASN100	$ 19,037	$ 9,722	$ 9,315
ASN200	47	138	(91)
ASN300	123	59	64
ASN400	50	166	(116)
ASN500	856	3	853
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	6,095	5,451	644
Other	1,920	2,292	(372)
Total research and development expenses	$ 28,128	$ 17,831	$ 10,297

Research and development expenses were $28.1 million for the year ended December 31, 2017, compared to $17.8 million for the year ended December 31, 2016. The increase of $10.3 million was primarily due to an increase of $9.3 million in direct costs for our ASN100 program, an increase of $0.9 million in direct costs for our ASN500 program, and an increase of $0.3 million in unallocated research and development expenses.

The increase in direct costs for our ASN100 program was primarily due to CRO fees for the oversight and conduct of our Phase 2 clinical trial of ASN100 as well as investigator fees for that same clinical trial, which was initiated in January 2017.

Our ASN500 program was initiated in March 2017. Direct costs for our ASN500 program during the year ended December 31, 2017 were primarily due to preclinical program expenses associated with internal lab consumables, facility costs and third-party fees for the oversight and conduct of preclinical research of ASN500.

The increase in unallocated research and development expenses was due to an increase of $0.6 million in personnel-related costs (including an increase in stock-based compensation of less than $0.1 million) due to the hiring of our Senior Vice President of Clinical Operations and Clinical Trial Manager in May 2016 and Chief Medical Officer in June 2016, as well as an increase in our annual year-end performance bonuses. This increase was partially offset by a decrease in other costs of $0.4 million due to a decrease in general preclinical activities.

General and Administrative Expenses. General and administrative expenses were $8.0 million for the year ended December 31, 2017, compared to $6.5 million for the year ended December 31, 2016. The increase of $1.5 million was primarily due to an increase of $0.7 million in personnel-related costs (including an increase in stock-based compensation of $0.2 million) and an increase of $0.9 million in professional fees. The increase in personnel-related costs was due to an increase in the aggregate amounts related to annual year-end performance bonuses and the hiring of additional personnel in our general and administrative functions, including the hiring of our Chief Financial Officer and Chief Business Officer in March 2016, to support the build-out of our U.S. operations in anticipation of the initiation of our Phase 2 clinical trial of ASN100. The increase in professional fees was due to costs associated with the preparation, audit and review of our financial statements. These increases were partially offset by a decrease of $0.1 million in corporate communications and investor relations expenses incurred in the year ended December 31, 2016 related to redesigning our website and establishing our communications and marketing programs that were not similarly incurred in the year ended December 31, 2017.

Other Income (Expense), Net. Other income, net was $2.3 million for the year ended December 31, 2017, compared to $1.4 million for the year ended December 31, 2016. The increase of $0.9 million in other income, net was primarily due to an increase in grant and incentive income of $1.5 million, primarily from our February 2017 grant agreement with the Gates Foundation, a decrease in interest expense of $0.4 million primarily associated with our convertible promissory notes, and an increase in interest income of $0.2 million, primarily from the bank interest earned on the cash received from the initial public offering and concurrent private placement of our common stock. These increases were partially offset by a decrease of $0.6 million in gains recognized as a result of decreases in the fair value of the derivative liability associated with our convertible promissory notes, an increase in loss on extinguishment of debt of $0.4 million in connection with the conversion of our 2016 and 2017 convertible promissory notes into shares of our Series D convertible preferred stock, and a decrease of $0.1 million in other income, net, primarily related to foreign currency transaction losses.

Liquidity and Capital Resources

On November 20, 2017, we closed an initial public offering of our common shares, in which we issued and sold 4,000,000 common shares at a price to the public of $10.00 per share. Concurrent with the initial public offering, (i) we issued an additional 600,000 common shares at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option and (ii) NEA purchased 2,000,000 shares of our common stock at the initial per share public offering price of $10.00 in a private placement. The aggregate net proceeds to us from the initial public offering, inclusive of the over-allotment exercise, and the private placement were $58.1 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Since our inception, we have not generated any revenue from product sales, and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from our initial public offering and concurrent private placement, the sale of preferred stock, borrowings under convertible promissory notes, borrowings under the 2012 Loan Agreement, proceeds received from loans and grants under funding agreements with FFG, research and development incentive payments received from the Austrian government, proceeds from grant agreements with the Gates Foundation and proceeds from a patent license and option agreement with Janssen. Through December 31, 2018, we had received net cash proceeds of $75.1 million from sales of our preferred stock, net cash proceeds of $58.1 million from the sale of our common stock, gross proceeds of $14.4 million from borrowings under convertible promissory notes, proceeds of $9.5 million from borrowings under the 2012 Loan Agreement with SVB, $9.2 million and $9.7 million of grant and loan proceeds, respectively, from our funding agreements with FFG, $4.9 million of research and development incentive payments received from the Austrian government, $2.7 million of proceeds from grant agreements with the Gates Foundation and $3.5 million of proceeds from our patent license and option agreement with Janssen.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Net cash used in operating activities	$ (40,903)	$ (27,871)	$ (21,639)
Net cash used in investing activities	(34)	(42)	(73)
Net cash provided by (used in) financing activities	(4,531)	101,262	18,147
Effect of exchange rate changes on cash	(286)	370	(103)
Net increase (decrease) in cash and cash equivalents	$ (45,754)	$ 73,719	$ (3,668)

Operating Activities. During the year ended December 31, 2018, operating activities used $40.9 million of cash, resulting from our net loss of $43.0 million and changes in our operating assets and liabilities of $4.5 million, partially offset by net non-cash charges of $6.6 million. We expect the discontinuation of the clinical development of ASN100 to result in a decline in cash used in operating activities in 2019, as we expect our expenses associated with ASN100 to be substantially complete as of December 31, 2018.

Changes in our operating assets and liabilities for the year ended December 31, 2018 consisted primarily of a $3.0 million decrease in accounts payable and accrued expenses, a $0.6 million decrease in prepaid expenses and other assets, a $1.4 million increase in grant and incentive receivables and a $0.7 million decrease in unearned income. The decrease in accounts payable and accrued expenses was primarily due to the payment of the 2017 annual bonuses in March 2018 and the timing of vendor invoices and payments. The decreases in prepaid expenses and other assets were primarily due to the receipt of clinical materials during the year ended December 31, 2018. The increase in grant and incentive receivables was primarily due to income earned under the Austrian research and development incentive program during the year ended December 31, 2018. The decrease in unearned income was primarily due to the amortization of the discount associated with the FFG loans.

During the year ended December 31, 2017, operating activities used $27.9 million of cash, resulting from our net loss of $33.9 million, partially offset by cash provided by changes in our operating assets and liabilities of $3.4 million and net non-cash charges of $2.6 million. Cash provided by changes in our operating assets and liabilities for the year ended December 31, 2017 consisted primarily of a $3.3 million increase in accrued expenses, a $0.2 million increase in accounts payable, and a $0.3 million decrease in prepaid expenses and other assets, all partially offset by a $0.3 million decrease in unearned income. The increases in accounts payable and accrued expenses were primarily due to increases in clinical trial costs associated with our Phase 2 clinical trial of ASN100, an increase in professional fees incurred in connection with our initial public offering, and an increase in amounts related to our annual year-end performance bonuses, as well as the timing of vendor invoices and payments. The decrease in prepaid expenses and other assets was primarily due to our use in the period of prepaid clinical materials and process development services related to our Phase 2 clinical trial of ASN100, partially offset by an increase in prepaid directors' and officers' and other corporate insurance. The decrease in unearned income was primarily due to the recognition of unearned income recorded for the imputed benefit of FFG loans at below-market interest rates.

During the year ended December 31, 2016, operating activities used $21.6 million of cash, resulting from our net loss of $23.0 million and net cash used by changes in our operating assets and liabilities of $0.5 million, partially offset by net non-cash charges of $1.9 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2016 consisted primarily of a $1.3 million increase in prepaid expenses and other assets, a $0.9 million increase in other assets and a $0.2 million decrease in unearned income, all partially offset by a $1.3 million increase in accounts payable, a $0.5 million increase in accrued expenses and a $0.2 million decrease in grant and incentive receivables. The increase in prepaid expenses and other assets was primarily due to prepayments for clinical material associated with our Phase 2 clinical trial of ASN100 and payments for process development activities for clinical material. The increase in other assets was due to prepaid investigator fees for our Phase 2 clinical trial of ASN100. The decrease in unearned income was due to the timing of our recognition of grant income related to the imputed benefit of FFG loans at below-market rates of interest. The increase in accounts payable was primarily due to an increase in research, development and clinical trial activities performed by CROs. The increase in accrued expenses was primarily due to increased accrued CRO fees for our Phase 2 clinical trial of ASN100 and accrued bonuses due to an increase in headcount. The decrease in grant and incentive receivables was due to a decrease of $0.4 million in receivables from FFG Grants, partially offset by an increase of $0.2 million in research and development incentive receivables from the Austrian government.

Investing Activities. During each of the years ended December 31, 2018 and 2017, net cash used in investing activities was less than $0.1 million. During the year ended December 31, 2016, net cash used in investing activities was approximately $0.1 million. Net cash used in investing activities during the years ended December 31, 2018, 2017 and 2016 consisted of purchases of property and equipment.

Financing Activities. During the year ended December 31, 2018, net cash used in financing activities was $4.5 million, consisting primarily of the repayment of our obligations under the 2012 Loan Agreement.

During the year ended December 31, 2017, net cash provided by financing activities was $101.3 million, consisting primarily of net cash proceeds of $58.1 million from our issuance of common stock pursuant to our initial public offering and concurrent private placement, net cash proceeds of $39.9 million from our issuances of Series D convertible preferred stock, net proceeds of $4.9 million from our issuance of convertible promissory notes in January 2017 and proceeds of $0.7 million from loans under our funding agreements with FFG, partially offset by $2.3 million of principal repayments under the 2012 Loan Agreement.

During the year ended December 31, 2016, net cash provided by financing activities was $18.1 million, consisting primarily of net proceeds of $7.0 million from borrowings under the 2012 Loan Agreement, proceeds of $5.5 million from our issuance of convertible promissory notes in April 2016, net cash proceeds of $5.4 million from our issuance of Series C convertible preferred

stock in April 2016 and proceeds of $0.5 million from loans under our funding agreements with FFG, all partially offset by $0.3 million of principal repayments under the 2012 Loan Agreement.

2012 Loan Agreement

On December 7, 2012, we entered into the 2012 Loan Agreement with SVB, which, as amended, provided for aggregate borrowings of up to $7.0 million in the form of term loans. In February and August 2016, we borrowed the full $7.0 million available to us under the agreement. Following the August 2016 borrowing, no additional amounts remained available for borrowing under the 2012 Loan Agreement.

On October 31, 2018, we voluntarily remitted payment on our outstanding obligations under the 2012 Loan Agreement with SVB. Total outstanding obligations paid to SVB under the 2012 Loan Agreement on October 31, 2018 consisted of $2.7 million of principal, $0.4 million of final payment and less than $0.1 million of interest. All obligations under the 2012 Loan Agreement were satisfied by us on October 31, 2018.

Borrowings under the 2012 Loan Agreement bore interest at a rate per annum equal to the greater of 3.25% and The Wall Street Journal prime rate, in each case minus 0.25%; provided, however, that in an event of default, as defined in the 2012 Loan Agreement, the interest rate applicable to borrowings under the agreement would be increased by 4.0%. Under the agreement, we were required to make monthly interest-only payments through December 1, 2016 and were required to make 36 equal monthly payments of principal, plus accrued interest, from January 1, 2017 through December 1, 2019, when all unpaid principal and interest would become due and payable. We had the right to voluntarily prepay all, but not less than all, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee, which ranged from 1% to 2% of the outstanding principal if paid prior to February 19, 2018. The prepayment fee was 0% thereafter. A final payment of $0.4 million was due upon the earlier to occur of the maturity of the loan or the prepayment of all outstanding principal.

In connection with the 2012 Loan Agreement, between December 2012 and August 2016, we issued to SVB a warrant to purchase an aggregate of 11,013 shares of Series A-2 convertible preferred stock at an exercise price of $4.54 per share and a warrant to purchase an aggregate of 14,502 shares of Series B convertible preferred stock at an exercise price of $7.24 per share. The warrants became exercisable in connection with our borrowings under the 2012 Loan Agreement and are fully exercisable. The warrant to purchase shares of Series A-2 convertible preferred stock expires on December 6, 2022, and the warrant to purchase shares of Series B convertible preferred stock expires on February 18, 2026. In November 2017, in connection with the closing of the initial public offering, the warrants for the purchase of convertible preferred stock converted into warrants for the purchase of common stock. See Note 8 to our consolidated financial statements appearing in this Annual Report on Form 10-K for additional information on the conversion of the warrants.

Borrowings under the 2012 Loan Agreement were collateralized by a pledge of substantially all of our assets other than our intellectual property, including 65% of the outstanding capital stock of our subsidiary in Austria. The 2012 Loan Agreement contained customary affirmative and negative covenants, including restrictions on our ability to pay dividends and encumber our intellectual property, but did not contain any financial covenants.

FFG Loans

Between September 2011 and March 2017, we entered into a series of funding agreements with FFG that provided for loans and grants to fund qualifying research and development expenditures of Arsanis GmbH on a project-by-project basis, as approved by FFG. As of December 31, 2018 and 2017, the outstanding principal amount under loans from FFG was $9.7 million and $10.2 million, respectively, which loan amounts were based on our actual spending for qualified expenditures.

Amounts due under the FFG loans bear interest at varying fixed rates ranging from 0.75% to 2.0% per annum. Interest is payable semi-annually in arrears, with all accrued interest and principal due upon maturity. After giving effect to the Settlement Agreement, the FFG loans mature at varying dates between March 2019 and June 2021. The FFG loans are not secured by any of our assets. In connection with the Settlement Agreement, we agreed to certain restrictive covenants in connection with the FFG loans as further described under “—Recent Developments—FFG Settlement” above.

We may be required to return all or a portion of the FFG loans and/or grants if we do not comply with the terms of the related FFG funding agreements and related guidelines, including specified requirements as to continued operations with respect to certain locations and funded projects, or if we fail to comply with the terms of the Settlement Agreement.

See "—Recent Developments—FFG Settlement" above for further discussion of the recently announced Settlement Agreement with FFG.

Convertible Promissory Notes

Between December 2015 and January 2017, we issued an aggregate of $14.4 million of convertible promissory notes, all of which were subsequently converted into shares of our convertible preferred stock. A description of each issuance and conversion is provided below.

In December 2015, we issued an aggregate of $4.0 million of convertible promissory notes, or the 2015 Notes. The 2015 Notes accrued interest at a rate of 0.56% per annum, with a maturity date of December 16, 2016, unless earlier converted under the terms of the 2015 Notes. All principal and interest accrued under the 2015 Notes was converted into shares of Series C convertible preferred stock in connection with our sale of Series C convertible preferred stock in April 2016.

In April 2016, we issued an aggregate of $5.5 million of convertible promissory notes, or the 2016 Notes, which accrued interest at a rate of 0.7% per annum and had a maturity date of October 12, 2017, unless earlier converted under the terms of the 2016 Notes. All principal and interest accrued under the 2016 Notes was converted into shares of Series D convertible preferred stock in connection with our sale of Series D convertible preferred stock in April 2017.

In January 2017, we issued an aggregate of $4.9 million of convertible promissory notes, or the 2017 Notes. The 2017 Notes accrued interest at a rate of 0.96% per annum, with a maturity date of October 12, 2017, unless earlier converted under the terms of the 2017 Notes. All principal and interest accrued under the 2017 Notes was converted into shares of Series D convertible preferred stock in connection with our sale of Series D convertible preferred stock in April 2017.

Funding Requirements

Pending the planned closing of the Merger, our current operating plan provides for the continued development of our ASN500 program as well as the continued support of our collaborators across our ongoing ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018. We have ceased further clinical development of ASN100 and do not expect to incur material costs for this program in 2019.

We expect to continue to incur significant expenses for at least the next several years as we advance our ASN500 program through preclinical development and clinical trials and seek regulatory approval of any product candidates. In addition, we expect to continue to incur costs associated with operating as a public company. Our expenses could increase over the long-term as we:

- advance our ASN500 program;
- advance potential future product candidates into preclinical and clinical development;
- conclude our ongoing review of strategic options for our business that may potentially result in changes to our current business strategy and future operations, which in turn may result in significant future research and development and general and administrative expenses based on the outcome of our strategic review;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

Based on our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments through the fourth quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional funding to complete the clinical development of any successful product candidate from our ASN500 program, commercialize any product candidate, if we receive regulatory approval, and pursue in-licenses or acquisitions of

other product candidates. If we receive regulatory approval for any potential future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize such product candidate itself. Also, in light of the discontinuation of the Phase 2 clinical trial of our lead product candidate ASN100, we are considering strategic options for the business that may potentially result in changes to our current business strategy and future operations.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- our ability to successfully consummate the Merger or any other strategic transaction;
- the scope, progress, results and costs of researching and developing our ASN500 program and any product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of any product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-licenses other product candidates and technologies;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any;
- costs associated with any litigation that might be brought against us in the future; and
- the absence of any breach, acceleration event or event of default under our funding agreements with FFG, including the Settlement Agreement, or under any other agreements with third parties.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government funding, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. We filed a universal shelf registration statement on Form S-3 (File No. 333-229377) with the SEC to register for sale up to $150.0 million of any combination of our common stock, preferred stock, debt securities, warrants and/or units from time to time and at prices and on terms that we may determine, which was declared effective by the SEC on February 14, 2019. Under SEC rules and regulations, we must meet certain requirements to use our Form S-3 registration statement to sell up to the full amount of $150.0 million of securities to be registered for sale under the Form S-3 registration statement, including that the market value of our outstanding common stock held by non-affiliates, or public float, be at least $75.0 million as of a date within 60 days prior to the date on which the Form S-3 is filed (and within 60 days prior to the date of any Form 10-K filing by us thereafter, which is deemed a re-evaluation date). If we do not meet that requirement, then the aggregate market value of securities sold by us in a primary offering under our Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. During the 60-day period prior to the date the Form S-3 was filed, which is our most recent re-evaluation date, our public float was less than $75.0 million, and we will therefore be subject to the one-third of public float limitation, at least until our public float equals or exceeds $75.0 million subsequent to the effective date of the Form S-3. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, additional debt financing would result in increased fixed payment obligations.

If we raise funds through governmental funding, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, reduce or eliminate our product development or future

commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
	(in thousands)				
Debt obligations (1)	$ 9,939	$ 84	$ 5,045	$ 4,810	$ —
Operating lease commitments (2)	2,637	884	1,227	526	—
Total	$ 12,576	$ 968	$ 6,272	$ 5,336	$ —

(1) On March 8, 2019, we entered into the Settlement Agreement with FFG, pursuant to which we agreed, among other things, to repay the outstanding loans on an accelerated payment schedule of three years instead of five years. See "—Recent Developments—FFG Settlement" for more information. Amounts in the table reflect the contractually required principal and interest payable as of December 31, 2018 pursuant to the loans from FFG before giving effect to the Settlement Agreement with FFG. The loans from FFG bear interest at fixed rates. The table reflects interest payments due under the FFG loans at the contractually required rates of interest before giving effect to the Settlement Agreement with FFG.

(2) Amounts in the table reflect minimum payments due for our leases of office, laboratory and other space under operating leases that expire between January 2019 and December 2023.

During the year ended December 31, 2018, we entered into an amendment to our lease agreement with BP Bay Colony LLC, referred to as the Amended Lease Agreement, with respect to our new corporate headquarters in Waltham, MA.

The term of the Amended Lease Agreement commences on January 1, 2019 and expires December 31, 2023. We have the option to extend the term for one additional five-year period upon written notice to the lessor at least nine months and no more than 12 months in advance of the extension. The Amended Lease Agreement terminates our one-time right of first offer, subject to certain terms and conditions, for additional space containing approximately 4,000 square feet specified in the original lease agreement.

The annual base rent obligation is approximately $0.3 million, with a total cash obligation for the base rent over the initial five-year term of the Amended Lease Agreement of approximately $1.3 million. In addition to the base rent, we are also responsible for our share of operating expenses, electricity and real estate taxes, in accordance with the terms of the Amended Lease Agreement. We provided a security deposit in the amount of $0.3 million as well as a relocation payment of $0.1 million to the lessor during the year ended December 31, 2018.

Collaboration, License and Funding Arrangements

In February 2017, we entered into a collaboration agreement with Adimab, pursuant to which we have agreed to pay royalties of a mid single-digit percentage based on net sales by us or our affiliates of products that use or are based on any antibody discovered or optimized under the agreement, any derivative or modified version of any such antibody, or any sequence information as to any such antibody. In addition, if we sell or license to any third party, or otherwise grant rights to any third party to, any of the products for which we are obligated to pay Adimab royalties, either alone or as part of a package including specified patents not directed to these antibodies, we are obligated to pay Adimab either the same royalties on net sales of such products by such third party, or a percentage, ranging from the low double digits to a maximum of less than 30%, of the payments we receive from such third parties that are attributable to such grant of rights.

If we (or one of our affiliates with rights under the agreement) undergo a change in control and, at the time of such change in control, we have not sold or licensed to third parties all of our rights in antibodies for which we are obligated to pay Adimab royalties under the agreement, then we are obligated to either pay Adimab a percentage, in the mid double digits, of the payments we receive from that change in control that are reasonably attributable to those rights and certain patents arising from the collaboration, or require our acquirer and all of its future third-party collaborators to pay to Adimab royalties at a mid single-digit percentage of net sales based on those rights. If we grant rights to a third party under certain patents that are not directed to the antibodies for which we are

obligated to pay Adimab royalties, we are also obligated to pay Adimab, in place of royalties or a percentage of payments received from the third party, a lump sum in the high six digits.

Under our option and license agreement with Adimab, if we exercise our option to obtain rights to certain RSV antibodies, we are obligated to pay Adimab an option fee of $0.3 million and make clinical and regulatory milestone payments of up to $24.4 million as well as royalty payments on a product-by-product and country-by-country basis of a mid single-digit percentage based on net sales by us, our affiliates, licensees or sublicensees of products based on certain RSV antibodies during the applicable term for such product in that country.

In February 2017, we entered into a grant agreement with the Gates Foundation, under which the Gates Foundation agreed to provide us up to $9.3 million to conduct preclinical development of mAbs for the prevention of RSV infection in newborns, which we refer to as the RSV project. In August 2018, we entered into an amended and restated grant agreement which replaces the February 2017 grant agreement in its entirety, and includes amendments to conform to current Gates Foundation audit, reporting, and other administrative requirements as well as to make the perpetual license that is granted to the Gates Foundation with respect to any funded developments resulting from the grant agreement irrevocable. In August 2018, we entered into an additional grant agreement with the Gates Foundation pursuant to which the Gates Foundation granted us up to $1.1 million to conduct preclinical development activities for the RSV project that were not included in the February 2017 grant agreement, as amended and restated in August 2018. The company recognized grant income of $1.1 million during the year ended December 31, 2018, under the August 2018 grant agreement with the Gates Foundation upon incurring qualifying expenses. Pursuant to both grant agreements, as amended, we have no payment obligations under the Adimab option and license agreement with respect to sales of products based on licensed RSV antibodies to the extent they are sold at cost in developing countries. However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess will be subject to the royalty payment obligations described in the preceding paragraph.

In April 2017, we entered into a letter agreement with the Gates Foundation pursuant to which we licensed to the Gates Foundation certain rights under our ASN100 program. We have no payment obligations under the Adimab collaboration agreement with respect to sales of certain antibody products if they are sold at cost in developing countries under our letter agreement with the Gates Foundation. However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess over cost will be subject to the royalty payment obligations described above. In addition, if the Gates Foundation terminates the agreement for certain specified uncured material breaches by us, we will be required, among other remedies, to redeem the then-held shares of our stock purchased by the Gates Foundation pursuant to the agreement or to facilitate the purchase of such stock by a third party. For any such redemption, the Gates Foundation stock will be valued at the greater of the original purchase price (plus specified interest) or the fair market value of such stock.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

To date, we have not generated any revenue from product sales. License revenue is generated from our patent license and option agreement with Janssen, which was entered into in December 2018. Pursuant to the terms of our patent license and option agreement with Janssen, or the Janssen License and Option Agreement, we granted to Janssen (i) a non-exclusive license to specified patents in our portfolio related to the ASN200 E. coli program, and (ii) an option for Janssen to acquire these patents in the future if specified conditions are met. Janssen agreed to pay us $3.5 million within 15 business days after the December 12, 2018 effective date of the Janssen License and Option Agreement, in addition to a future $0.5 million payment in the event Janssen exercises its option to acquire the relevant patents.

We recognize revenue in accordance with Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers ("Topic 606"). Nonrefundable up-front license fees are recognized as revenue at a point in time when the licensed intellectual property is made available for the customer's use and benefit, which is generally at the inception of the arrangement. Exclusivity fees are recognized as revenue when the performance obligation to which the customer option has been allocated has been satisfied.

Government Contracts, Grant Agreements and Incentive Programs

We recognize proceeds received from grants under our funding agreements with FFG, research and development incentives from the Austrian government and our grant agreements with the Gates Foundation as other income, rather than as revenue, because the corresponding agreements contain no specified performance obligations other than to conduct research on a particular program or in a particular field and contain no obligations to deliver specified products or technology.

Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under the funding agreements with FFG and for proceeds under the research and development incentive program from the Austrian government, we recognize grant and incentive income in an amount equal to the qualifying expenses we incur in each period multiplied by the applicable reimbursement percentage. For grants received under our grant agreements with the Gates Foundation, we recognize grant income in an amount equal to the qualifying expenses incurred in each period, up to the amount previously funded by the Gates Foundation.

Grant funding that has been received by us in advance of incurring qualifying expenses is recorded in our consolidated balance sheet as unearned income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in our consolidated balance sheet as grant and incentive receivables.

The loans we have received under the funding agreements with FFG bear interest at rates that are below market rates of interest. We account for the imputed benefit arising from the difference between a market rate of interest and the rate of interest charged by FFG as additional grant funding from FFG, and we record interest expense for the FFG loans at a market rate of interest. On the date that FFG loan proceeds are received, we recognize the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is subsequently recognized as additional grant income over the term of the funding agreement.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including central laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical and clinical studies; and
- CMOs in connection with drug substance and drug product formulation of preclinical and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too

high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Emerging Growth Company Status

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

As of December 31, 2018, we had $29.8 million of cash equivalents consisting of money market funds held in our sweep account. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because of the short-term nature of the instruments in our portfolio, we would not expect an immediate 10% change in market interest rates to have a material impact on our financial position or results of operations.

Foreign Currency Exchange Risk

We are also exposed to foreign exchange rate risk. Our headquarters are located in the United States, where the majority of our general and administrative expenses are incurred in U.S. dollars. Research and development costs are incurred by our subsidiary in Austria, whose functional currency is the Euro. During the year ended December 31, 2018, we recognized a foreign currency transaction loss of less than $0.1 million. This loss primarily related to unrealized and realized foreign currency losses as a result of transactions entered into by our U.S. entity in currencies other than the U.S. dollar. These foreign currency transaction losses were recorded as a component of other income (expense), net in our consolidated statements of operations. We believe that a 10% change in the exchange rate between the U.S. dollar and the Euro would not have a material impact on our financial position or results of operations.

As we continue to grow our business, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports we file and submit under the Exchange Act is recorded,

processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer, who serve as our principal executive and principal financial officer, respectively, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. Based on such evaluation, our Chief Executive Officer and Chief Operating Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Management's Report on Internal Control Over Financial Reporting

The management of the company is responsible for establishing and maintaining adequate internal control over financial reporting for the company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The company's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2018. In making this assessment, the company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of December 31, 2018, the company's internal control over financial reporting is effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for "emerging growth companies."

Changes in Internal Control over Financial Reporting

There has been no significant change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Board of Directors

Set forth below are the names of and certain information for each member of our board of directors as of March 1, 2019. The information presented includes each director's and nominee's principal occupation and business experience for the past five years, and the names of other public companies of which he or she has served as a director during the past five years. The information presented below regarding the specific experience, qualifications, attributes and skills of each director led our nominating and corporate governance committee and our board of directors to conclude that he or she should serve as a director. There are no family relationships among any of our directors, nominees for director, or executive officers.

Name	Age	Position(s)
William Clark, M.B.A.(1)	50	Director
Tillman U. Gerngross, Ph.D.	55	Chairman of the Board of Directors
Carl Gordon, Ph.D., C.F.A.(1)	54	Director
Michael Gray, M.B.A., C.P.A.	48	President and Chief Executive Officer, Chief Financial Officer, Director
David McGirr, M.B.A.(1)	64	Director
Terrance McGuire(3)	62	Director
Claudio Nessi, Ph.D., M.B.A.	50	Director
Michael Ross, Ph.D.(2)	69	Director
René Russo, Pharm.D., BCPS	43	Director
Amy Schulman, J.D.(2)(3)(4)	58	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

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

(4) Lead independent director.

William Clark, M.B.A. Mr. Clark has served as a member of our board of directors since September 2017. Mr. Clark is currently the President and Chief Executive Officer of Genocea Biosciences, Inc., or Genocea, a publicly traded biopharmaceutical company, a position he has held since February 2011. He also served as Genocea's Chief Business Officer from August 2010 to February 2011. Prior to joining Genocea, Mr. Clark served as Chief Business Officer at Vanda Pharmaceuticals, Inc., or Vanda, a biopharmaceutical company he co-founded in 2004. Prior to Vanda, Mr. Clark was a principal at Care Capital, LLC, a venture capital firm investing in biopharmaceutical companies, after serving in a variety of commercial and strategic roles at SmithKline Beecham (now GlaxoSmithKline). Mr. Clark currently serves on the board of directors of Genocea, where he has served since February 2011. Mr. Clark holds a B.A. from Harvard University and an M.B.A. from The Wharton School at the University of Pennsylvania. Our board of directors believes that Mr. Clark's experience as a founder and senior executive officer of other biopharmaceutical companies, as well as his prior public company board service, provide him with the qualifications and skills to serve on our board of directors.

Tillman U. Gerngross, Ph.D., Chairman. Dr. Gerngross co-founded Arsanis in 2010, served as our President from August 2010 to August 2013 and from December 2015 to April 2016. He has served as chairman of the board of directors since August 2010. Prior to joining us, Dr. Gerngross co-founded Adimab, LLC and has served as its Chief Executive Officer and chairman of its board of directors since 2007. Dr. Gerngross has co-founded a number of other biotechnology companies including Alector, LLC and Avitide, Inc., where he has served as chairman of their boards of directors since 2014 and 2013, respectively. Dr. Gerngross is currently a Venture Partner at SV Health Investors, LLC, which he joined in 2006. Dr. Gerngross co-founded GlycoFi, Inc. and served as its Chief Scientific Officer from 2000 to 2006 until it was acquired by Merck. Dr. Gerngross currently teaches in the departments of Biology and Chemistry, as well as at the School of Engineering at Dartmouth College, where he has taught since 1998. Dr. Gerngross attended the Technical University of Vienna, Austria, where he received a B.S./M.S. in Chemical Engineering and later received a Ph.D. in Molecular Biology. Our board of directors believes Dr. Gerngross' expertise and experience in antibody drug discovery and development, his experience as a founder and director of other companies and his educational background provide him with the qualifications and skills to serve on our board of directors.

Carl Gordon, Ph.D., C.F.A. Dr. Gordon has served as a member of our board of directors since September 2010. In addition, Dr. Gordon is a Founding Partner and Co-Head of Global Private Equity at OrbiMed, a position in which he has served since January 1997. In addition to Arsanis, Dr. Gordon also currently serves on the board of directors of Armo Biosciences, a publicly traded immune-oncology company. Dr. Gordon served on the boards of directors of Acceleron Pharma, Inc., a publicly traded biopharmaceutical company, from 2006 to 2013; Amarin Corporation plc, a publicly traded biotechnology company, from May 2008 to July 2013; Selecta Biosciences, Inc., a publicly traded biopharmaceutical company, from 2010 to June 2017; and Intellia Therapeutics, Inc., a publicly traded biotechnology company, from August 2015 to July 2017. From 1995 to 1997, Dr. Gordon served as a senior biotechnology analyst at Mehta & Isaly. Dr. Gordon was a Fellow at the Rockefeller University from 1993 to 1995. Dr. Gordon received his B.S. from Harvard College in 1987 and later received a Ph.D. in Molecular Biology from the Massachusetts Institute of Technology in 1993. Our board of directors believes Dr. Gordon's expertise and experience in the biotechnology industry through his role as Founding Partner and Co-Head of Global Private Equity at OrbiMed over a 20-year period, in which he has been involved in the evaluation, investment and oversight of several biotechnology companies, as well as his scientific educational background, provide him with the qualifications and skills to serve on our board of directors.

Michael Gray, M.B.A., C.P.A. Mr. Gray has served as our President and Chief Executive Officer since November 2018, and as our Chief Financial Officer since March 2016. Previously, Mr. Gray served as our Chief Operating Officer from September 2017 to November 2018, and as our Chief Business Officer from March 2016 to September 2017. Prior to joining us, Mr. Gray served in various leadership positions from August 2000 through February 2016 at Curis, Inc., a publicly held oncology drug development company. He served as Curis' Chief Financial Officer and Chief Business Officer from February 2014 to February 2016 and as its Chief Financial Officer and Chief Operating Officer from December 2006 to February 2014. From December 2003 until December 2006, Mr. Gray served as Curis' Vice President of Finance and Chief Financial Officer and from August 2000 until December 2003, served as its Senior Director of Finance and Controller. Previously, Mr. Gray held positions including Controller and de facto Chief Financial Officer at Reprogenesis, a biotechnology company focused on the development of cell therapy drug candidates, and as an audit professional for the accounting and consulting firm of Ernst & Young, LLP. Mr. Gray received his M.B.A. in corporate finance and entrepreneurial management from the F.W. Olin Graduate School of Business at Babson College and a B.S. in accounting from Bryant College. Our board of directors believes that Mr. Gray's expertise and experience as our President and Chief Executive Officer, as well as his experience as an executive officer of several other biotechnology companies, provide him with the qualifications and skills to serve on our board of directors.

David McGirr, M.B.A. Mr. McGirr has served as a member of our board of directors since September 2017. From March 2013 until June 2014, Mr. McGirr was Senior Advisor to the chief executive officer of Cubist Pharmaceuticals, Inc., or Cubist, a biopharmaceutical company where he also served as Senior Vice President and Chief Financial Officer from November 2002 to March 2013. Prior to joining Cubist in 2002, Mr. McGirr was the President and Chief Operating Officer of hippo inc, an internet technology, venture-financed company. From 1996 to 1999, he was the President of GAB Robins North America, Inc., a risk management company, serving also as Chief Executive Officer from 1997 to 1999. Mr. McGirr was a private equity investor from 1995 to 1996. From 1978 to 1995, Mr. McGirr served in various positions within the S.G. Warburg Group, ultimately as Chief Financial Officer, Chief Administrative Officer and Managing Director of S.G. Warburg & Co., Inc., a position held from 1992 to 1995. Mr. McGirr is currently a member of the board of directors of Insmed Incorporated, a publicly traded biopharmaceutical company where he has served since October 2013; Rhythm Pharmaceuticals, Inc., a publicly traded biopharmaceutical company where he has served since November 2015; and Menlo Therapeutics, Inc., a publicly traded biopharmaceutical company where he has served since November 2017. Mr. McGirr also served on the board of directors of Roka Bioscience, Inc., a molecular diagnostics company, from December 2013 to January 2018. Mr. McGirr received a B.Sc. in Civil Engineering from the University of Glasgow and received an M.B.A. from The Wharton School at the University of Pennsylvania. Our board of directors believes that Mr. McGirr's experience as an executive officer or director of a number of public and private pharmaceutical companies provide him with the qualifications and skills to serve on our board of directors.

Terrance McGuire. Mr. McGuire has served as a member of our board of directors since February 2011. Additionally, Mr. McGuire is a Founding Partner of Polaris Partners, a venture capital firm investing in technology and healthcare companies across all stages of development, where he has worked since 1996. Prior to starting Polaris in 1996, he spent seven years at Burr, Egan, Deleage & Co. investing in early stage medical and information technology companies. Mr. McGuire serves as chairman of the board of directors of Ironwood Pharmaceuticals, Inc., a publicly traded drug manufacturer, and has served as a director since 1998. Mr. McGuire also currently serves on the board of directors of Pulmatrix, Inc., a publicly traded biopharmaceutical company, where he has served since May 2006. From January 2008 to July 2014, Mr. McGuire served on the board of directors of Trevena, Inc., and from 2005 to November 2017, Mr. McGuire served on the board of directors of Acceleron Pharma, Inc., both publicly traded biopharmaceutical companies. Mr. McGuire is emeritus chairman of the National Venture Capital Association, chairman of the Global Ventures Capital Congress and chairs the board of the Thayer School of Engineering at Dartmouth College. He also sits on the boards of MIT's The David H. Koch Institute for Integrative Cancer Research, The Arthur Rock Center for Entrepreneurship at Harvard Business School and The Healthcare Initiative Advisory Board. Mr. McGuire holds an M.B.A. from Harvard Business School, and M.S. in engineering from the Thayer School at Dartmouth College, and a B.S. in physics and economics from Hobart College. Our board of directors believes Mr. McGuire's expertise and experience in the biotechnology industry through his role as a Founding Partner of Polaris Partners and his cumulative career in venture capital over a period spanning over 30 years, in which he has been involved in the evaluation, investment and oversight of numerous biotechnology companies, as well as his experience as a director of several biotechnology companies, including other public companies, provide him with the qualifications and skills to serve on our board of directors.

Claudio Nessi, Ph.D., M.B.A. Dr. Nessi has served as a member of our board of directors since August 2013. Dr. Nessi has served as Managing Partner at NeoMed Management, a venture capital firm, since 2016, where he has served as a Partner since 2005 and served as an Investment Director from 2001 until 2005. Also, Dr. Nessi has served as Managing Director of Omega Funds, an investment advisory firm, since November 2016. Dr. Nessi held other board positions at Endosense SA from October 2005 to August 2013, Kuros BioSurgery AG from October 2002 to February 2013, PregLem SA from June 2007 to October 2010 and Creabilis Ltd. from February 2008 to December 2016. Dr. Nessi also currently serves on the board of directors of the private biotechnology companies Avitide, Inc. and Anaconda Biomed and is the Chairman of the board of directors of the public biotechnology company GenKyoTex SA. Dr. Nessi received his M.B.A. from Erasmus University in the Netherlands, and received his Ph.D. in Genetics from the University of Pavia, Italy. Our board of directors believes Dr. Nessi's expertise and experience in the biotechnology industry through his roles of increasing responsibility at NeoMed Management spanning a period of over 15 years, in which he has been involved in the evaluation, investment and oversight of several biotechnology companies; his scientific and business-focused educational background, as well as his experience as a director of other companies provide him with the qualifications and skills to serve on our board of directors.

Michael Ross, Ph.D. Dr. Ross has served as a member of our board of directors since February 2011. Additionally, he has served as a Managing Partner at SV Health Investors, LLC, a venture capital investment advisory firm, since 2002 where he also served as a Venture Partner from 2001 until 2002. Prior to joining SV Health Investors, Dr. Ross served at Genentech for 13 years in roles of increasing responsibility, including as its Vice President of Drug Development. Dr. Ross was also the founder and served as Chief Executive Officer of numerous biotechnology companies such as Arris Pharmaceutical, MetaXen, ExSAR and CyThera (now Viacyte). Additionally, Dr. Ross served as a Managing Partner for Didyma, LLC, a biotechnology management consulting firm, and served on the boards of directors of Cartar Proteomics, Epimmune, Genencor, MetaXen and Xenova. Dr. Ross currently serves on the boards of directors of Catabasis Pharmaceuticals, Inc., a publicly traded pharmaceutical company, where he has served since April 2010, and Ophthotech Corporation, a publicly traded biopharmaceutical company, where he has served since April 2013. Dr. Ross earned his B.A. in Chemistry from Dartmouth College and his Ph.D. in Chemistry from the California Institute of Technology. He later held an NIH Postdoctoral Fellowship in Molecular Biology at Harvard. Our board of directors believes Dr. Ross' expertise and experience in the biotechnology industry through his role as Managing Partner at SV Health Investors, in which he has been involved in the evaluation, investment and oversight of numerous biotechnology companies; his industry experience, including his service as a Chief Executive Officer and in various drug development leadership roles at biotechnology companies; as well as his experience as a director of several biotechnology companies, provide him with the qualifications and skills to serve on our board of directors.

René Russo, Pharm.D., BCPS. Dr. Russo has served as a member of our board of directors since April 2016. Dr. Russo served as our President and Chief Executive Officer from April 2016 until November 2018, and as our Chief Development Officer from July 2015 until April 2016. Previously, Dr. Russo served in various roles over an 11-year period at Cubist Pharmaceuticals, Inc., a public pharmaceutical development company, focused on the development and commercialization of infectious disease therapeutics, from 2003 until its acquisition by Merck in May 2015, most recently as its Vice President, Global Medical Affairs. From 1999 to 2004, she held roles of increasing responsibility at Bristol-Myers Squibb where she started her industry career as a Postdoctoral Fellow in Industrial Pharmacy Infectious Diseases. Prior to joining the biotechnology industry, Dr. Russo held clinical positions at Robert Wood Johnson University Hospital and Princeton Hospital. Dr. Russo received her Pharm.D. and B.S. from Rutgers University. Our board of directors believes that Dr. Russo's expertise and experience as our former President and Chief Executive Officer, her perspective and experience as an executive at public and private pharmaceutical companies and her expertise in clinical development and commercialization of therapeutics targeting infectious diseases, provide her with the qualifications and skills to serve on our board of directors.

Amy Schulman, J.D. Ms. Schulman has served as a member of our board of directors since February 2015. She joined in July 2014 as an Entrepreneur Partner at Polaris Partners, a venture capital firm, and she served as CEO of Arsia Therapeutics, a Polaris-backed company, from July 2014 until its acquisition by Eagle Pharmaceuticals in November 2016. She served as director of Bind Therapeutics from September 2014 to June 2016. In July 2015, Ms. Schulman co-founded Lyndra, where she currently serves as CEO, and since January 2017 she has served as CEO of Olivo Laboratories, which sold its cosmetic assets to Shiseido in January 2018. She serves as the Executive Chair of SQZ Biotech and Suono Bio. Ms. Schulman currently serves on the boards of directors of Alnylam Pharmaceuticals, a publicly traded biopharmaceutical company, where she has served since July 2014; Ironwood Pharmaceuticals, Inc., a publicly traded drug manufacturer, where she has served since January 2017; and Blue Buffalo Pet Products, Inc., a publicly traded pet food company, where she has served since 2014. In addition, she serves as a director of the Whitehead Institute. She is a member of Harvard Business School's Faculty where she serves as a Senior Lecturer and teaches legal and corporate accountability. A Phi Beta Kappa graduate of Wesleyan University, Ms. Schulman earned her J.D. from Yale Law School in 1989. Our board of directors believes that Ms. Schulman's qualifications to serve on our board include her years of experience serving as President and Chief Executive Officer of a number of biotech companies, her educational background and experience as attorney, including her service as general counsel of Pfizer, Inc., as well as her experience as a director of several biotechnology companies, including other public companies.

Board Committees

We have established an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees operates under a charter that has been approved by our board of directors. A copy of each committee's charter can be found under the "Investors & Media—Corporate Governance" section of our website, which is located at www.arsanis.com.

Audit Committee

Our audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our risk assessment and risk management policies;
- establishing policies and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

The current members of our audit committee are William Clark, Carl Gordon and David McGirr. Mr. McGirr chairs the audit committee. Our board of directors has determined that Mr. McGirr qualifies as an "audit committee financial expert" within the meaning of applicable SEC rules, and also satisfies the independence standards for the audit committee established by the SEC and the Nasdaq Listing Rules, including the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

Compensation Committee

Our compensation committee's responsibilities include:

- reviewing and approving, or making recommendations to our board with respect to, the compensation of our chief executive officer and other executive officers;
- overseeing the evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent such disclosure is then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

The processes and procedures followed by our compensation committee in considering and determining executive and director compensation are described below under the heading "Narrative Disclosure to Summary Compensation Table".

The current members of our compensation committee are Michael Ross and Amy Schulman. Ms. Schulman chairs the compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee's responsibilities include:

- recommending to our board the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board of directors with respect to our board leadership structure and board committee structure;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- developing and recommending to our board corporate governance principles; and
- overseeing an annual evaluation of our board.

The current members of our nominating and corporate governance committee are Terrance McGuire and Amy Schulman. Mr. McGuire chairs the nominating and corporate governance committee.

Executive Officers

Certain information regarding our executive officer who is not also a director is set forth below, as of March 1, 2019.

Name	Age	Position(s)
David Mantus, Ph.D.	55	Chief Development Officer

David Mantus, Ph.D. Dr. Mantus has served as our Chief Development Officer since April 2016, and as our Executive Vice President, Regulatory, Clinical Operations and Manufacturing from October 2015 until April 2016. From December 2014 until October 2015, Dr. Mantus served as the Vice President, Regulatory Affairs & Quality Assurance at BIND Therapeutics, Inc., a biotechnology company. From May 2004 until May 2011 he held various leadership roles in development at Cubist Pharmaceuticals, Inc., including Vice President, Regulatory Affairs. Prior to Cubist, Dr. Mantus served as the Vice President of Sention, Inc., a biotechnology company. Previously, he served as the Director of Regulatory Affairs at Shire Biologics as well as various leadership positions at PAREXEL, Inc. and Procter & Gamble, Inc. Dr. Mantus was previously a Postdoctoral Research Fellow in Biomedical Engineering at the University of Washington and Associate Professor of Pharmaceutical Science at MCPHS University. He received his M.S. and Ph.D. in Chemistry from Cornell University.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers and holders of more than 10% of our common stock to file with the SEC initial reports of ownership of our common stock and other equity securities on a Form 3 and reports of changes in such ownership on a Form 4 or Form 5. Directors and officers and holders of 10% of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. To our knowledge, based solely on a review of our records and representations made by our directors and officers regarding their filing obligations, we believe all Section 16(a) filing requirements were satisfied with respect to fiscal 2018.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, including our principal executive, financial and accounting officers, and our directors and employees. We have posted the text of our Code of Business Conduct and Ethics under the "Investors & Media — Corporate Governance" section of our website, www.arsanis.com. We intend to disclose on our website any amendments to, or waivers from, the Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

Item 11. Executive Compensation

Executive Compensation

This section discusses the material elements of our executive compensation policies for our "named executive officers" and the most important factors relevant to an analysis of these policies. For 2018, our "named executive officers" are Michael Gray, our President and Chief Executive Officer and Chief Financial Officer, David Mantus, our Chief Development Officer, René Russo, our former President and Chief Executive Officer and Christopher Stevens, our former Chief Medical Officer. In addition, this section provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers and is intended to place in perspective the data presented in the following tables and the corresponding narrative.

Summary Compensation Table

The following table sets forth information regarding compensation earned by our named executive officers during the years indicated.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Michael Gray, M.B.A., C.P.A.	2018	405,193	181,136	1,030,000	1,310,947	—	2,927,276
President and Chief Executive Officer, Chief Financial Officer	2017	363,077	231,525	—	262,090	—	856,692
David Mantus, Ph.D.	2018	358,750	—	—	595,885	120,250	1,074,885
Chief Development Officer	2017	363,077	231,525	—	262,090	—	856,692
René Russo, Pharm.D., BCPS	2018	405,866	—	—	1,906,833	1,046,250	3,358,949
Former President and Chief Executive Officer	2017	388,750	254,100	—	524,182	—	1,167,032
Christopher Stevens, M.D.	2018	380,000	—	—	595,885	329,333	1,305,218
Former Chief Medical Officer	2017	380,000	159,600	—	117,937	—	657,537

(1) Except where noted otherwise, the amounts reported in the "Bonus" column reflect discretionary annual cash bonuses paid to our executive officers for their performance.

(2) The amounts reported in the "Option Awards" column reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board, Accounting Standards Codification Topic 718, or ASC 718. See Note 2 to our consolidated financial statements in our Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

(3) The amounts reported in the "All Other Compensation" column reflects severance paid to René Russo in connection with her separation as the Company's President and CEO; Retention Bonus amounts accrued as of December 31, 2018 for David Mantus, Ph.D. and Christopher Stevens, M.D.

Narrative Disclosure to Summary Compensation Table

We review compensation for our executive officers annually. The material terms of the elements of our executive compensation program for 2018 are described below.

Our compensation committee sets base salaries and bonuses and grants equity incentive awards to our executive officers. In setting base salaries and bonuses and granting equity incentive awards, our compensation committee considers compensation for comparable positions in the market, the historical compensation levels of our executives, individual and corporate performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. As part of this process, Mr. Gray, as our president and chief executive officer, prepares performance evaluations for the other executive officers and recommends annual salary increases, annual stock option awards and cash bonuses to the compensation committee. The compensation committee conducts a performance evaluation of Mr. Gray. The compensation committee consults with the board of directors as to the achievement of corporate objectives that drive contingent compensation awards.

Our compensation committee has the authority to retain compensation consultants and other outside advisors to assist in the evaluation of executive officer compensation.

Base Salary. For 2017, the annualized base salary of each of our named executive officers was initially $350,000 for Mr. Gray, $310,000 for Dr. Mantus, $380,000 for Dr. Russo and $380,000 for Dr. Stevens. In September and October 2017, our board of directors and the compensation committee of our board of directors approved increases in the annualized base salaries of Dr. Russo, Mr. Gray and Mr. Mantus to $450,000, $400,000 and $340,000, respectively, in each case subject to and effective upon the closing of our initial public offering and, in the case of Mr. Gray's increase, to be retroactive to September 27, 2017, which was the effective date of Mr. Gray's promotion to the role of Chief Operating Officer and Chief Financial Officer. Mr. Gray previously served as our Chief Financial Officer and Chief Business Officer. In June 2018, our compensation committee approved an increase to the annualized base salary of Dr. Mantus to $370,000. In November 2018, our compensation committee approved an increase in the annualized base salary of Mr. Gray to $450,000 effective as of November 27, 2018, which was the effective date of Mr. Gray's promotion to the role of President and Chief Executive Officer.

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Annual Bonus. Our board of directors may, in its discretion, award bonuses to our named executive officers from time to time. We typically establish annual bonus targets based around a set of specified corporate goals for our named executive officers and conduct an annual performance review to determine the attainment of such goals. Our management may propose bonus awards to our board of directors primarily based on such review process. Our board of directors makes the final determination of the eligibility requirements for and the amount of such bonus awards.

Equity Incentives. Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options. In 2017, based upon our overall performance, we granted to Mr. Gray an option to purchase 97,665 shares of our common stock, to Dr. Mantus an option to purchase 43,949 shares of our common stock, to Dr. Russo an option to purchase 195,331 shares of our common stock, and to Dr. Stevens an option to purchase 43,948 shares of our common stock. In 2018, based upon our overall performance, we granted to Mr. Gray an option to purchase 110,000 shares of our common stock, to Dr. Mantus an option to purchase 50,000 shares of our common stock, to Dr. Russo an option to purchase 160,000 shares of our common stock, and to Dr. Stevens an option to purchase 50,000 shares of our common stock.

We use stock options to compensate our executive officers in the form of initial grants in connection with the commencement of employment and also at various times, often but not necessarily annually, if we have performed as expected or better than expected. Prior to our initial public offering, the award of stock options to our executive officers was made by our board of directors or compensation committee. None of our executive officers is currently party to an employment agreement that provides for automatic award of stock options. We have granted stock options to our executive officers with time-based vesting. The options that we have granted to our executive officers typically become exercisable as to 25% of the shares underlying the option on the first anniversary of the grant date, and as to an additional 1/48th of the original number of shares underlying the option monthly thereafter. Vesting rights cease upon termination of employment and exercise rights cease shortly after termination, except that vesting is fully accelerated upon certain terminations in connection with a change of control (including the Merger) and exercisability is extended in the case of death or disability. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including no voting rights and no right to receive dividends or dividend equivalents.

Prior to our initial public offering, we have historically granted stock options with exercise prices that are equal to the fair market value of our common stock on the date of grant as determined by our board of directors or compensation committee, based on a number of objective and subjective factors. The exercise price of all stock options granted after the closing of our initial public offering is equal to the fair market value of shares of our common stock on the date of grant, which is determined by reference to the closing market price of our common stock on the date of grant.

In addition, in connection with his promotion to the role of President and Chief Executive Officer in November 2018, we granted to Mr. Gray a restricted stock award with respect to 250,000 shares of our common stock. The restricted stock award will vest as to 25% of the shares subject to the award on the one-year anniversary of the date of grant, with the remainder vesting in equal monthly installments until the fourth anniversary of the date of grant, subject to Mr. Gray’s continued service with the company. The restricted stock award will vest in full upon a change of control of the company, which includes the closing of the Merger.

Outstanding Equity Awards at Fiscal Year End 2018

The following table sets forth information regarding outstanding equity awards, which consist of stock options and restricted stock, held by our named executive officers as of December 31, 2018.

	Option Awards				Restricted Stock Awards	
Name	Number of Shares of Arsanis Common Stock Underlying Unexercised Options (#) Exercisable	Number of Shares of Arsanis Common Stock Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Restricted Arsanis Common Stock	
Michael P. Gray, M.B.A., C.P.A.	—	—	—	—	250,000	(10)
	35,258	16,016 (1)	$ 9.39	7/20/2026	—	
	36,628	61,037 (2)	$ 4.00	6/18/2027	—	
	—	110,000 (3)	$ 17.34	3/7/2028	—	
David Mantus, Ph.D.	11,599	3,050 (4)	$ 8.33	2/3/2026	—	
	7,327	4,392 (5)	$ 9.39	7/20/2026	—	
	16,481	27,468 (6)	$ 4.00	6/18/2027	—	
	—	50,000 (7)	$ 17.34	3/7/2028	—	
René Russo, Pharm.D., BCPS	80,889	— (8)	$ 8.20	7/21/2025	—	
	47,757	— (8)	$ 9.39	7/20/2026	—	
	195,331	— (8)	$ 4.00	6/18/2027	—	
	160,000	— (8)	$ 17.34	3/7/2028	—	
Christopher Stevens, M.D.	16,487	9,882 (9)	$ 9.39	7/20/2026	—	
	16,482	27,466 (9)	$ 4.00	6/18/2027	—	
	—	50,000 (9)	$ 17.34	3/7/2028	—	

(1) This option award vests over four years, with 25% of the shares underlying the option vested on March 1, 2017 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(2) This option award vests over four years, with 25% of the shares underlying the option vested on June 19, 2018 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(3) This option award vests over four years, with 25% of the shares underlying the option vested on March 7, 2019 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(4) This option award vests over four years, with 25% of the shares underlying the option vested on October 12, 2016 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(5) This option award vests over four years, with 25% of the shares underlying the option vested on June 1, 2017 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(6) This option award vests over four years, with 25% of the shares underlying the option vested on June 19, 2018 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(7) This option award vests over four years, with 25% of the shares underlying the option vested on March 7, 2019 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

(8) In connection with Dr. Russo's stepping down from her position as President and Chief Executive Officer of Arsanis, all unvested stock options held by Dr. Russo vested in full upon her letter agreement with the company, dated as of November 26, 2018, becoming effective and irrevocable as of December 3, 2018. See " — Employment and Change in Control Arrangements—Letter Agreement for Dr. René Russo" below for more information.

(9) In connection with Dr. Stevens's stepping down from his position as Chief Medical Officer of Arsanis, all unvested stock options held by Dr. Stevens vested in full upon his letter agreement with the company, dated as of January 15, 2019, and becoming effective and irrevocable as of January 22, 2019. See " — Employment and Change in Control Arrangements—Letter Agreement for Dr. Christopher Stevens" below for more information.

(10) This restricted stock award vests over four years, with 25% of the shares underlying the option vesting on November 27, 2019 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

Employment and Change in Control Arrangements

We have entered into written offer letters with each of our named executive officers. These agreements set forth the terms of the named executive officer's compensation, including his or her initial base salary, severance and annual cash bonus opportunity. In addition, the agreements provide that the named executive officers are eligible to participate in company-sponsored benefit programs that are available generally to all of our employees.

We have also entered into written bonus retention agreements and/or letter agreements with certain of our named executive officers which replace such named executive officers' existing severance benefits as set forth in their written offer letters, as described below.

2018 Amended and Restated Employment Agreement for Michael P. Gray

In connection with the appointment of Michael P. Gray as President and Chief Executive Officer of Arsanis, on November 26, 2018, we entered into an amended and restated employment agreement with Mr. Gray, which agreement became effective as of November 27, 2018 and replaced his October 10, 2017 amended and restated letter agreement. We refer to such amended and restated employment agreement as the Gray 2018 agreement. Under the Gray 2018 agreement, Mr. Gray's base salary is $450,000 per annum and he is entitled to participate in our medical and other benefits programs, and may be entitled to receive an annual bonus based on his individual performance and the company's performance during the applicable year, all as determined by the our board of directors in its sole discretion, at a target bonus rate of 55% of his annualized base salary.

The Gray 2018 agreement provides that the vesting of all equity awards granted to Mr. Gray before the closing of our initial public offering on November 20, 2017 will accelerate in full upon a "change of control" of the company (as defined in the Gray 2018 agreement and including the Merger). Specifically, on July 20, 2016, Mr. Gray received a grant of options to purchase 51,274 shares of our common stock with an exercise price of $9.39 per share, which will vest in full upon the closing of the Merger. On June 19, 2017, Mr. Gray received a grant of options to purchase 97,665 shares of our common stock with an exercise price of $4.00 per share, which will vest in full upon the closing of the Merger. The Gray 2018 agreement also provides that, subject to approval of our board of directors, we will grant Mr. Gray a restricted stock award with respect to 250,000 shares of our common stock, which grant our board of directors did approve and which grant became effective on November 27, 2018. Pursuant to the terms of the Gray 2018 agreement, Mr. Gray's employment with the company may be terminated at any time, with or without "cause" (as defined in the Gray 2018 agreement and set forth below) by either Mr. Gray or us. If we terminate Mr. Gray's employment without cause or Mr. Gray terminates his employment for "good reason" (as defined in the Gray 2018 agreement and set forth below) he will be entitled to (i) 12 months' pay at his then-current base salary, (ii) a portion of the same year's target bonus, pro-rated to reflect the portion of the year elapsed, and (iii) COBRA premium benefits for up to 12 months. If we terminate Mr. Gray's employment without cause or Mr. Gray terminates his employment for good reason within 18 months following a change of control of the company, Mr. Gray will be entitled to (i) an amount equal to the sum of (x) 1.5 times his then-current base salary and (y) 1.5 times his target bonus for the year of termination, and (ii) COBRA premium benefits for up to 12 months. In addition, on March 7, 2018, Mr. Gray received a grant of options to purchase 110,000 shares of our common stock with an exercise price of $17.34 per share. If we terminate Mr. Gray's employment without cause or Mr. Gray terminates his employment for good reason, each within 18 months following a change of control, this option will vest in full, and the period during which Mr. Gray may exercise certain stock options granted to him in June 2017 would be extended for up to two years following his separation date. The Gray 2018 agreement also provides for a limitation on payments under the Gray 2018 agreement if limiting the payments would leave Mr. Gray in a better net position than bearing the tax penalties under Section 280G of the Code. If we terminate Mr. Gray's employment without cause or Mr. Gray terminates his employment for good reason, each within 18 months following a change of control (including the Merger), Mr. Gray will have the right to exercise the June 2017 option for a two-year period after such termination. The restricted stock award vests in full upon a change of control.

Pursuant to the Gray 2018 agreement:

The following, as determined by our board of directors in its reasonable judgment, constitutes "cause" for termination: (i) the commission of, or indictment or conviction for, any felony, or any other crime involving dishonesty; (ii) participation in any fraud, deliberate and substantial misconduct, breach of duty of loyalty or breach of fiduciary duty against the company; (iii) intentional and substantial damage to any property of the company; (iv) failure of performance of Mr. Gray's duties under the Gray 2018 agreement (not attributable to sickness, disability or death) after reasonable written notice no later than 30 days following the occurrence of the failure and a 30-day opportunity to cure, provided, however, that such opportunity to cure shall only apply to any failure that our board of directors, in its reasonable discretion, deems susceptible to cure; or (v) Mr. Gray's breach of any material provision of the Gray 2018 agreement, his Invention, Non-Competition, Non-Solicitation and Non-Disclosure Agreement, or any other agreement to which he and the company are both parties, after reasonable written notice no later than 30 days following the occurrence of the breach and a 30-day opportunity to cure, provided, however, that such opportunity to cure shall only apply to any breach that our board of directors, in its reasonable discretion, deems susceptible to cure, and that any breach by Mr. Gray of his obligations of confidentiality or non-competition under his non-disclosure agreement shall be deemed not susceptible to cure.

The following, if occurring without Mr. Gray's consent, constitutes "good reason" for termination: (i) a material and adverse diminution of Mr. Gray's duties and responsibilities with the company, provided that such change is not in connection with a termination of his employment relationship with the company; (ii) a material diminution of Mr. Gray's then base salary, provided that such change is not in connection with a termination of his employment relationship with the company; (iii) relocation of Mr. Gray's principal place of employment outside a 30 mile radius from Boston, Massachusetts, if such relocation increases his daily commuting distance; or (iv) a material breach by us of the Gray 2018 agreement.

"Change of control" means the first to occur of any of the following: (i) a merger or consolidation, business combination, acquisition or similar transaction (a "Transaction") in which (A) the company is a constituent party, or (B) a subsidiary of the company is a constituent party and the company issues shares of its capital stock pursuant to such Transaction, except in the case of either clause (A) or (B) any such Transaction involving the company or a subsidiary of the company in which the beneficial owners of the shares of our capital stock outstanding immediately prior to such Transaction continue beneficially to own, immediately following such Transaction, at least a majority by voting power of our capital stock of (x) the surviving or resulting corporation or (y) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such Transaction, the parent corporation of such surviving or resulting corporation; (ii) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the company or a subsidiary of the company of all or substantially all the assets of the company and the company's subsidiaries taken as a whole (except in connection with a Transaction not constituting a change of control under clause (i) or where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the company); or (iii) the sale or transfer, in a single transaction or series of related transactions, by our stockholders of more than 50% by voting power of our then-outstanding capital stock to any person or entity or group of affiliated persons or entities.

Amended and Restated Letter Agreement and Retention Bonus Agreement for Dr. David Mantus

On November 26, 2018, we entered into a retention bonus agreement with Dr. David Mantus, our Chief Development Officer, which replaced Dr. Mantus's existing severance benefits as set forth in the amended and restated letter agreement, dated October 10, 2017, between Dr. Mantus and us. Dr. Mantus remains eligible to receive payment from us for benefits continuation and any equity acceleration provided by his amended and restated letter agreement. Under his retention bonus agreement, Dr. Mantus is eligible for a retention bonus payment of $481,000 upon the earliest to occur of the following, subject to Dr. Mantus's continued service with the company on such date: (i) March 31, 2019, (ii) the closing of a "change of control" of the company (as defined in the retention bonus agreement and including the Merger), (iii) the termination of Dr. Mantus's employment by us without "cause" (as defined in the retention bonus agreement and set forth below), or (iv) Dr. Mantus's death. Dr. Mantus's receipt of the retention bonus payment is conditioned upon his entering into a release of claims agreement in favor of the company.

Except as expressly modified by the retention bonus agreement, Dr. Mantus's amended and restated letter agreement remains in full force and effect. Dr. Mantus's amended and restated letter agreement provides that the vesting of all equity awards granted to Dr. Mantus before the closing of our initial public offering on November 20, 2017 will accelerate in full upon a "change of control" of the company (as defined in the amended and restated employment agreement and including the Merger). The amended and restated letter agreement also provides Dr. Mantus's employment with us may be terminated at any time, with or without "cause" (as defined in the amended and restated letter agreement and set forth below) by either Dr. Mantus or us. If we terminate Dr. Mantus's employment without cause or Dr. Mantus terminates his employment for "good reason" (as defined in the amended and restated letter agreement and set forth below), he will be entitled to COBRA premium benefits for up to 12 months. If we terminate Dr. Mantus's employment without cause or Dr. Mantus terminates his employment for good reason within 12 months following a change of control of the company, Dr. Mantus will be entitled to (i) COBRA premium benefits for up to 12 months; and (ii) vesting in full of all unvested stock options and other equity awards then held by him. The amended and restated letter agreement also provides for a limitation on payments under the agreement if limiting the payments would leave Dr. Mantus in a better net position than bearing the tax penalties under Section 280G of the Code.

On February 26, 2016, Dr. Mantus received a grant of options to purchase 14,649 shares of our common stock with an exercise price of $8.33 per share. On July 20, 2016, Dr. Mantus received a grant of options to purchase 11,719 shares of our common stock with an exercise price of $9.39 per share. On June 19, 2017, Dr. Mantus received a grant of options to purchase 43,949 shares of our common stock with an exercise price of $4.00 per share. Each of these option grants will vest in full upon the closing of the Merger.

On March 7, 2018, Dr. Mantus received a grant of options to purchase 50,000 shares of our common stock with an exercise price of $17.34 per share. If we terminate Dr. Mantus's employment without cause or Dr. Mantus terminates his employment for good reason, each within 12 months following a change of control, these options will vest in full.

Pursuant to Dr. Mantus's amended and restated letter agreement and retention bonus agreement:

The following, as determined by our board of directors in its reasonable judgment, constitutes "cause" for termination: (i) the commission of, or indictment or conviction for, any felony, or any other crime involving dishonesty; (ii) participation in any fraud, deliberate and substantial misconduct, breach of duty of loyalty or breach of fiduciary duty against the company; (iii) intentional and substantial damage to any property of the company; (iv) failure of performance of Dr. Mantus's duties (not attributable to sickness, disability or death) after reasonable written notice no later than 30 days following the occurrence of the failure and a 30-day opportunity to cure, provided, however, that such opportunity to cure shall only apply to any failure that the our board of directors, in its reasonable discretion, deems susceptible to cure; or (v) Dr. Mantus's breach of any material provision of his amended and restated letter agreement, his Invention, Non-Competition, Non-Solicitation and Non-Disclosure Agreement, or any other agreement to which he and the company are both parties, after reasonable written notice no later than 30 days following the occurrence of the breach and a 30-day opportunity to cure, provided, however, that such opportunity to cure shall only apply to any breach that our board of directors, in its reasonable discretion, deems susceptible to cure, and that any breach by Dr. Mantus of his obligations of confidentiality or non-competition under his non-disclosure agreement shall be deemed not susceptible to cure.

"Change of control" means the first to occur of any of the following: (i) a merger or consolidation, business combination, acquisition or similar transaction (a "Transaction") in which (A) the company is a constituent party, or (B) a subsidiary of the company is a constituent party and the company issues shares of our capital stock pursuant to such Transaction, except in the case of either clause (A) or (B) any such Transaction involving the company or a subsidiary of the company in which the beneficial owners of the shares of our capital stock outstanding immediately prior to such Transaction continue beneficially to own, immediately following such Transaction, at least a majority by voting power of the capital stock of (x) the surviving or resulting corporation or (y) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such Transaction, the parent corporation of such surviving or resulting corporation; (ii) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the company or a subsidiary of the company of all or substantially all the assets of the company and the company's subsidiaries taken as a whole (except in connection with a Transaction not constituting a change of control under clause (i) or where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the company); or (iii) the sale or transfer, in a single transaction or series of related transactions, by our stockholders of more than 50% by voting power of our then-outstanding capital stock to any person or entity or group of affiliated persons or entities.

Pursuant to Dr. Mantus's amended and restated letter agreement:

The following, if occurring without Dr. Mantus's consent, constitutes "good reason" for termination: (i) a material and adverse diminution of Dr. Mantus's duties and responsibilities with the company, provided that such change is not in connection with a termination of his employment relationship with the company; (ii) a material diminution of Dr. Mantus's then base salary, provided that such change is not in connection with a termination of his employment relationship with the company; (iii) relocation of Dr. Mantus's principal place of employment outside a 30 mile radius from Boston, Massachusetts, if such relocation increases his daily commuting distance; or (iv) a material breach by us of Dr. Mantus's amended and restated letter agreement.

Letter Agreement for Dr. René Russo

In connection with Dr. Russo stepping down from her position as President and Chief Executive Officer of Arsanis, on November 26, 2018, Dr. Russo signed a letter agreement, which upon expiration of a release revocation period replaces Dr. Russo's existing severance benefits as set forth in the amended and restated letter agreement, dated October 10, 2017, between Dr. Russo and us. Under the November 2018 letter agreement, in exchange for, among other things, her general release of claims in favor of the company, Dr. Russo is entitled to severance benefits comprised of (i) a lump-sum payment of $1,046,250; (ii) COBRA premium benefits for up to 18 months; and (iii) the vesting in full of all unvested stock options then held by Dr. Russo. In addition, we agreed to extend the period during which Dr. Russo may exercise the stock options granted to her in June 2017 for up to two years following her separation date, and also agreed to waive Dr. Russo's post-employment non-competition obligations.

On July 22, 2015, Dr. Russo received a grant of options to purchase 80,889 shares of our common stock with an exercise price of $8.20 per share. On July 20, 2016, Dr. Russo received a grant of options to purchase 47,757 shares of our common stock with an exercise price of $9.39 per share. On June 19, 2017, Dr. Russo received a grant of options to purchase 195,331 shares of our common stock with an exercise price of $4.00 per share. As described above, Dr. Russo will have the right to exercise this June 2017 option for a period of up to two-years following her separation date. On March 7, 2018, Dr. Russo received a grant of options to purchase 160,000 shares of our common stock with an exercise price of $17.34 per share. All unvested stock options held by Dr. Russo vested in full upon her letter agreement becoming effective and irrevocable.

Notwithstanding her stepping down as President and Chief Executive Officer of the company, Dr. Russo's equity awards will remain outstanding in accordance with their terms (subject to the provisions of her letter agreement described above) for so long as

she continues to serve as a director of the company and, following the consummation of the Merger, as a director of the combined organization.

Letter Agreement for Dr. Christopher Stevens

Effective January 15, 2019, Dr. Stevens stepped down from his position as Chief Medical Officer of Arsanis. In connection with the termination of his employment, Dr. Stevens signed a letter agreement, dated January 15, 2019, which upon expiration of a revocation period replaces Dr. Stevens's existing severance benefits as set forth in the retention bonus agreement, dated November 26, 2018, between Dr. Stevens and us and the amended and restated letter agreement, dated October 10, 2017, between Dr. Stevens and us. Under the January 2019 letter agreement, in exchange for, among other things, his general release of claims in favor of the company, Dr. Stevens is entitled to severance benefits comprised of (i) a lump-sum payment of $494,000; (ii) COBRA premium benefits for up to 12 months; and (iii) the vesting in full of all unvested stock options then held by Dr. Stevens, which will remain exercisable for the period of time set forth in the applicable grant agreement. In addition, we agreed to waive Dr. Stevens's post-employment non-competition obligations.

On July 20, 2016, Dr. Stevens received a grant of options to purchase 26,369 shares of our common stock with an exercise price of $9.39 per share. On June 19, 2017, Dr. Stevens received a grant of options to purchase 43,948 shares of our common stock with an exercise price of $4.00 per share. On March 7, 2018, Dr. Stevens received a grant of options to purchase 50,000 shares of our common stock with an exercise price of $17.34 per share. All unvested stock options held by Dr. Stevens vested in full upon his letter agreement becoming effective and irrevocable as of January 22, 2019.

Other Agreements

Each of our named executive officers has entered into a standard form agreement with respect to non-competition, non-solicitation, confidential information and assignment of inventions. Under this agreement, each named executive officer has agreed not to compete with us during his or her employment and for a period of one year after the termination of his or her employment, not to solicit our employees, consultants, clients or customers during his or her employment and for a period of one year after the termination of his or her employment, and to protect our confidential and proprietary information indefinitely. In addition, under this agreement, each named executive officer has agreed that we own all inventions that are developed by such executive officer during his or her employment with us that are within the field of monoclonal antibody-based therapeutic treatments for infectious diseases. Each named executive officer also agreed to provide us with a non-exclusive, royalty-free, perpetual license to use any prior inventions that such executive officer incorporates into inventions assigned to us under this agreement.

401(k) Retirement Plan

We maintain a defined contribution employee retirement plan for our employees, including our named executive officers. The plan is intended to qualify as a tax-qualified 401(k) plan so that contributions to the 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan (except in the case of contributions under the 401(k) plan designated as Roth contributions). Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee as directed by participants. The 401(k) plan provides us with the discretion to match employee contributions, but to date we have not provided any employer matching contributions.

Indemnification

For a summary of certain indemnification arrangements with our named executive officers, see "—Limitation of Liability and Indemnification" below.

Tax Considerations

The compensation committee of our board of directors considers the potential future effects of Section 162(m) of the Code on compensation paid to our named executive officers. Section 162(m) of the Code generally disallows a tax deduction to public companies for compensation in excess of $1 million paid to each of the company's chief executive officer and the three most highly compensated executive officers (other than the chief executive officer and chief financial officer). Pursuant to tax legislation signed into law on December 22, 2017 (the "Tax Act"), for taxable years beginning after December 31, 2017, the Section 162(m) deduction limitation is expanded so that it also applies to compensation in excess of $1 million paid to a public company's chief financial officer. Historically, compensation that qualified under Section 162(m) as performance-based compensation was exempt from the deduction limitation. However, subject to certain transition rules, the Tax Act eliminated the qualified performance-based compensation

exception. As a result, for taxable years beginning after December 31, 2017, all compensation in excess of $1 million paid to each of the executives described above (other than certain grandfathered compensation or compensation paid pursuant to certain equity awards granted before or during a transition period following our initial public offering) will not be deductible by us.

Director Compensation

Under our director compensation program, we pay our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairman of the board, the lead independent director and the chair of each committee receive higher retainers for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors, on such committee or in such position. The fees paid to non-employee directors for service on the board of directors, for service as a lead independent director and for service on each committee of the board of directors on which the director is a member are as follows:

	Member Annual Fee	Chairman Annual Fee	Lead Independent Director Annual Fee
Board of Directors	$ 35,000	$ 75,000	$ 50,000
Audit Committee	$ 7,500	$ 15,000	—
Compensation Committee	$ 5,000	$ 10,000	—
Nominating and Corporate Governance Committee	$ 4,000	$ 8,000	—

We also reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which they serve.

In addition, under our director compensation program, we granted the directors who were in office at the time of the closing of our initial public offering, and will grant to new non-employee directors upon their initial election to our board of directors, an option to purchase 25,000 shares of our common stock. Each of these options will vest as to 33.3333% of the shares of our common stock underlying such option on the first anniversary of the date of grant, with the remainder vesting in equal monthly installments until the third anniversary of the date of grant, subject to the non-employee director's continued service as a director. Further, on the dates of each of our annual meetings of stockholders, each non-employee director that has served on our board of directors for at least six months will automatically receive, under our 2017 Equity Incentive Plan, or the 2017 Plan, an option to purchase 10,000 shares of our common stock. Each of these options will vest in equal monthly installments until the first anniversary of the date of grant (or, if earlier, the date of our next annual meeting of stockholders following the date of grant) unless otherwise provided at the time of grant, subject to the non-employee director's continued service as a director, with full acceleration of vesting upon a change in control of our company. All options issued to our non-employee directors under our director compensation program will be issued at exercise prices equal to the closing price of our common stock on the date of grant.

Mr. Gray, our director who also serves as President and Chief Executive Officer and Chief Financial Officer, does not receive any additional compensation for his service as a director. Dr. Russo also served as President and Chief Executive Officer during 2018, until she stepped down from such positions on November 26, 2018. Dr. Russo did not receive any additional compensation for her service as a director. Mr. Gray and Dr. Russo are two of our named executive officers and, accordingly, the compensation that we pay to Mr. Gray and Dr. Russo is discussed under "—Summary Compensation Table" and "—Narrative to Summary Compensation Table."

The following table sets forth information regarding compensation earned by our non-employee directors during fiscal 2018.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Tillman U. Gerngross, Ph.D.	94,615	111,785	206,400
William Clark, M.B.A.	47,871	111,785	159,656
Carl Gordon, Ph.D., C.F.A.	47,871	111,785	159,656
David McGirr, M.B.A.	56,319	111,785	168,104
Terrance McGuire	48,434	111,785	160,219
Claudio Nessi, Ph.D., M.B.A.	39,423	111,785	151,208
Michael Ross, Ph.D.	45,055	111,785	156,840
Amy Schulman, J.D.	72,088	111,785	183,873

(1) The amounts reported in the "Option Awards" column reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of ASC 718. See Note 2 to our consolidated financial statements appearing in our Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

As of December 31, 2018, our non-employee directors held the following stock options, all of which were granted under our 2010 Special Stock Incentive Plan, as amended, or the 2010 Plan, our 2011 Stock Incentive Plan, or 2011 Plan, and our 2017 Plan:

Name	Option Awards
Tillman U. Gerngross, Ph.D.	100,484
William Clark, M.B.A.	35,000
Carl Gordon, Ph.D., C.F.A.	35,000
David McGirr, M.B.A.	35,000
Terrance McGuire	35,000
Claudio Nessi, Ph.D., M.B.A.	35,000
Michael Ross, Ph.D.	35,000
Amy Schulman, J.D.	41,482
René Russo	483,977

Limitation of Liability and Indemnification

Our Restated Certificate of Incorporation limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our Restated Certificate of Incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with our directors and executive officers. These indemnification agreements may require us, among other things, to indemnify each such executive officer or director for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our executive officers or directors.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

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

Compensation Committee Interlocks and Insider Participation

During the year ended December 31, 2018, the members of our compensation committee were Michael Ross and Amy Schulman, as well as Tillman U. Gerngross prior to his stepping down from the committee in November 2018.

Dr. Gerngross is a former officer of our company, having served as our president from August 2010 to August 2013 and from December 2015 to April 2016. In addition, Dr. Gerngross is a co-founder and the current Chief Executive Officer of Adimab, LLC, a company with which we have a commercial relationship, as described further under the heading "Related Person Transactions" below.

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of Arsanis Common Stock as of January 31, 2019 (except where otherwise indicated) for:

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

The number of shares beneficially owned by each entity, person, director or executive officer is determined under the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has the sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days of January 31, 2019, through the exercise of any stock option or other right. Unless otherwise indicated, each person has sole investment and voting power, or shares such powers with his or her spouse, with respect to the shares set forth in the following table.

The percentage of ownership is based on 14,572,246 shares of common stock outstanding on January 31, 2019, adjusted as required by the rules promulgated by the SEC to determine beneficial ownership. Except for the Merger and the related support agreements, we do not know of any arrangements, including any pledge by any person of our securities, the operation of which may at a subsequent date result in a change of control of the company.

Unless otherwise indicated, the address of all listed stockholders is c/o Arsanis, Inc., 950 Winter Street, Suite 4500, Waltham, Massachusetts 02451.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders:		
Entities affiliated with Polaris Ventures(1)	1,868,957	12.8%
Entities affiliated with SV Health Investors, LLC(2)	1,868,961	12.8%
OrbiMed Private Investments IV LP(3)	1,868,966	12.8%
New Enterprise Associates 16, L.P.(4)	2,000,000	13.7%
Bill & Melinda Gates Foundation(5)	722,179	5.0%
NeoMed Innovation V LP(6)	867,639	6.0%
Directors and Named Executive Officers:		
Michael Gray, M.B.A., C.P.A.(7)	359,763	2.5%
David Mantus, Ph.D.(8)	52,546	*
Tillman U. Gerngross, Ph.D.(9)	473,696	3.2%
William Clark, M.B.A.(10)	18,611	*
Carl Gordon, Ph.D., C.F.A.(11)	1,887,577	12.9%
David McGirr, M.B.A.(12)	18,611	*
Terrance McGuire(13)	1,887,568	12.9%
Claudio Nessi, Ph.D., M.B.A.(14)	886,250	6.1%
Michael Ross, Ph.D.(15)	1,887,572	12.9%
René Russo, Pharm.D., BCPS(16)	483,977	3.2%
Amy Schulman, J.D.(17)	25,093	*
Christopher Stevens, M.D.(18)	120,317	*
All current executive officers and directors as a group (11 persons)(19)	7,981,264	51.7%

* Less than one percent

(1) Based on information provided in a Schedule 13D filed on November 29, 2017. Consists of (a) 1,803,429 shares of common stock held by Polaris Venture Partners V, L.P., (b) 35,146 shares of common stock held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., (c) 12,351 shares of common stock held by Polaris Venture Partners Founders' Fund V, L.P. and (d) 18,031 shares of common stock held by Polaris Venture Partners Special Founders' Fund V, L.P. Each of Polaris Venture Partners V, L.P., Polaris Venture Partners Entrepreneurs' Fund V, L.P., Polaris Venture Partners Founders' Fund V, L.P. and Polaris Venture Partners Special Founders' Fund V, L.P. (collectively, the "Polaris Funds") has the sole voting and investment power with respect to the shares directly held by it. Polaris Venture Management Co. V, L.L.C. ("PVM V") is the general partner of each the Polaris Funds. PVM V may be deemed to have sole power to vote and dispose of the shares held by the Polaris Funds. Terrance McGuire, a member of our board of directors, and Jonathan Flint (collectively, the "Managing Members") are the managing members of PVM V and each may be deemed to share voting and dispositive power with respect to the shares held by the Polaris Funds. Each of PVM V and the Managing Members disclaim beneficial ownership of all of the shares owned by the Polaris Funds, except to the extent of their respective and proportionate pecuniary interests therein. The address of the Polaris Funds is One Marina Park Drive, 10th Floor, Boston, Massachusetts 02210.

(2) Based on information provided in a Schedule 13D filed on February 14, 2018. Consists of (a) 903,110 shares of common stock held by SV Life Sciences Fund V, L.P. ("SVLS V LP"), (b) 19,082 shares of common stock held by SV Life Sciences Fund V Strategic Partners, L.P. ("SVLS V SPP"), (c) 915,428 shares of common stock held by SV Life Sciences Fund VI, L.P. ("SVLS VI LP") and (d) 31,341 shares of common stock held by SV Life Sciences Fund VI Strategic Partners, L.P. ("SVLS VI SPP"). SV Life Sciences Fund V (GP), LP ("SVLS V GP") is the general partner of SVLS V LP and SVLS V SPP (collectively, the "SV V Funds"). The general partner of SVLS V GP is SVLSF V, LLC. SVLS V GP and SVLSF V, LLC may each be deemed to share voting, dispositive and investment power over the shares held of record by the SV V Funds. Each of SVLS V GP and SVLSF V, LLC disclaims beneficial ownership of the shares owned directly by the SV V Funds except to the extent of any pecuniary interest therein. The members of the investment committee of SVLSF V, LLC are Kate Bingham, James Garvey, Eugene D. Hill, III and Michael Ross, a member of our board of directors. The investment committee of SVLSF V, LLC controls voting and investment decisions over the shares held by the SV V Funds by a majority vote. As such, no member of the investment committee of SVLSF V, LLC may be deemed to have any beneficial ownership of the shares held of record by the SV V Funds. SV Life Sciences Fund VI (GP), LP ("SVLS VI GP") is the general partner of SVLS VI LP and SVLS VI SPP (collectively, the "SV VI Funds"). The general partner of SVLS VI GP is SVLSF VI, LLC. SVLS VI GP and SVLSF VI, LLC may each be deemed to share voting, dispositive and investment power over the shares held of record by the SV VI Funds. Each of SVLS VI GP and SVLSF VI, LLC disclaims beneficial ownership of the shares owned directly by the SV VI Funds except to the extent of any pecuniary interest therein. The members of the investment committee of SVLSF VI, LLC are Kate Bingham, James Garvey, Eugene D. Hill, III, Paul LaViolette, Thomas Flynn and Michael Ross, a member of our board of directors. The investment committee of SVLSF VI, LLC controls voting and investment decisions over the shares held by the SV VI Funds by a majority vote. As such, no member of the investment committee of SVLSF VI, LLC may be deemed to have any beneficial ownership of the shares held of record by the SV VI Funds. The address for the entities is One Boston Place, Suite 3900, 201 Washington Street, Boston, Massachusetts 02108.

(3) Based on information provided in a Schedule 13D/A filed on January 26, 2018. Consists of 1,868,966 shares of common stock held by OrbiMed Private Investments IV, LP ("OPI IV"). OrbiMed Capital GP VI LLC ("GP IV") is the general partner of OPI IV. OrbiMed Advisors LLC ("OrbiMed Advisors") is the managing member of GP IV. By virtue of such relationships, GP IV and OrbiMed Advisors may be deemed

to have voting and investment power with respect to the shares held by OPI IV and as a result may be deemed to have beneficial ownership of such shares. Dr. Carl L. Gordon, a member of OrbiMed Advisors, is a member of our board of directors. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein. Each of GP IV, OrbiMed Advisors, Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein disclaims beneficial ownership of the shares held by OPI IV. The address of OPI VI is 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(4) Based on information provided in a Schedule 13D filed on November 29, 2017. Consists of 2,000,000 shares of common stock held by New Enterprise Associates 16, L.P. ("NEA 16"). NEA Partners 16, L.P. ("NEA Partners 16") is the sole general partner of NEA 16, and NEA 16 GP, LLC ("NEA 16 LLC") is the sole general partner of NEA Partners 16. Peter J. Barris, Forest Baskett, Anthony A. Florence, Jr., Mohamad H. Makhzoumi, Joshua Makower, David M. Mott, Chetan Puttagunta, Jon M. Sakoda, Scott D. Sandell, Peter W. Sonsini and Ravi Viswanathan are the managers of NEA 16 LLC (collectively, the "Managers"). By virtue of such relationships, NEA Partners 16, NEA 16 LLC and each of the Managers may be deemed to have voting and investment power with respect to the shares held by NEA 16. NEA Partners 16, NEA 16 LLC and each of the Managers disclaims beneficial ownership of the shares owned of record by NEA 16. The address of the principal business office of NEA 16 is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.

(5) Based on information provided in a Schedule 13G filed on February 13, 2018. Consists of 722,179 shares of common stock held by the Bill & Melinda Gates Foundation (the "Foundation"). For purposes of Rule 13d-3 under the Exchange Act, all shares beneficially owned by the Foundation may be deemed to be beneficially owned by William H. Gates III and Melinda French Gates as Co-Trustees of the Foundation. The address for the Foundation is 500 Fifth Avenue North, Seattle, Washington 98109.

(6) Consists of 867,639 shares of common stock held by NeoMed Innovation V L.P. Claudio Nessi, a member of our board of directors, is the Managing Partner of NeoMed Management (Jersey) Limited, which is the Investment Manager to NeoMed Innovation V L.P. By virtue of such relationships, NeoMed Management (Jersey) Limited and Dr. Nessi may be deemed to have voting and investment power with respect to the shares held by NeoMed Innovation V L.P. Each of NeoMed Management (Jersey) Limited and Dr. Nessi disclaims beneficial ownership of the shares held by NeoMed Innovation V L.P., except to the extent of its or his pecuniary interest therein, if any. The business address for NeoMed Innovation V L.P. is 13 Castle Street, St. Helier, Jersey, JE4 5UT.

(7) Consists of (a) 250,000 shares of common stock owned by Mr. Gray and (b) 109,763 shares of common stock underlying options held by Mr. Gray that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(8) Consists of shares of common stock underlying options held by Dr. Mantus that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(9) Consists of (a) 392,821 shares of common stock owned by Dr. Gerngross, and (b) 80,875 shares of common stock underlying options held by Dr. Gerngross that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(10) Consists of shares of common stock underlying options held by Mr. Clark that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(11) Consists of (a) the shares described in note 3 above, and (b) 18,611 shares of common stock underlying options held by Dr. Gordon that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(12) Consists of shares of common stock underlying options held by Mr. McGirr that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(13) Consists of (a) the shares described in note 1 above, and (b) 18,611 shares of common stock underlying options held by Mr. McGuire that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(14) Consists of (a) the shares described in note 6 above, and (b) 18,611 shares of common stock underlying options held by Dr. Nessi that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(15) Consists of (a) the shares described in note 2 above, and (b) 18,611 shares of common stock underlying options held by Dr. Ross that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(16) Consists of shares of common stock underlying options held by Dr. Russo that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(17) Consists of shares of common stock underlying options held by Ms. Schulman that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date. Although Ms. Schulman is affiliated with certain affiliates of the Polaris Funds, she does not have voting or dispositive power with respect to the shares owned by the Polaris Funds and referenced in note 1 above.

(18) Consists of shares of common stock underlying options held by Dr. Stevens that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

(19) Includes 863,920 shares of common stock underlying options that are exercisable as of January 31, 2019 or will become exercisable within 60 days after such date.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights		Weighted average exercise price of outstanding options, warrants and rights		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
	(a)		(b)		(c)	
Equity compensation plans approved by security holders	1,953,804	(1)	$ 10.16	(2)	308,288	(3)
Equity compensation plans not approved by security holders	—		—		—	
Total	1,953,804		$ 10.16		308,288	(4)

(1) Consists of (i) 103,100 shares to be issued upon exercise of outstanding options under our 2010 Plan as of December 31, 2018, (ii) 967,404 shares to be issued upon exercise of outstanding options under our 2011 Plan as of December 31, 2018 and (iii) 883,300 shares to be issued upon exercise of outstanding options under our 2017 Plan as of December 31, 2018.

(2) Consists of the weighted average exercise price of the 1,953,804 stock options outstanding on December 31, 2018.

(3) Consists of (i) 308,288 shares that remained available for future issuance under our 2017 Plan as of December 31, 2018, and (ii) 219,111 shares that remained available for future issuance under our 2017 Employee Stock Purchase Plan, or 2017 ESPP, as of December 31, 2018. No shares remained available for future issuance under the 2010 Plan or 2011 Plan as of December 31, 2018.

(4) Our 2017 Plan has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2017 Plan to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2027, equal to the least of 1,025,490 shares of our common stock, 4% of the number of shares of our common stock outstanding on the first day of the applicable fiscal year and an amount determined by our board of directors. On January 1, 2019, 582,889 additional shares were reserved for issuance under the 2017 Plan pursuant to this provision. Our 2017 ESPP has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2017 ESPP to be added on the first day of each fiscal year, beginning on January 1, 2019 and ending on December 31, 2029, in an amount equal to the least of 512,745 shares of our common stock, 2% of the total number of shares of our common stock outstanding on the first day of the applicable fiscal year and an amount determined by our board of directors. On January 1, 2019, 291,444 additional shares were reserved for issuance under the 2017 ESPP pursuant to this provision.

Item 13. Certain Relationships and Related Transactions and Director Independence

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy to set forth policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds $120,000, and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related party transaction," the related person must report the proposed related person transaction to our chief financial officer. The policy calls for the proposed related person transaction to be reviewed and approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under this policy will be considered approved or ratified if it is authorized by the audit committee in accordance with the standards set forth in the policy after full disclosure of the related person's interests in the transaction. As appropriate for the circumstances, the policy provides that the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than the terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The audit committee may approve or ratify the related person transaction only if the audit committee determines that, under all of the circumstances, the transaction is in our best interests. The audit committee may impose any conditions on the related person transaction as it deems appropriate. The policy also provides that transactions involving compensation of executive officers will be reviewed and approved by our compensation committee in the manner specified in its charter.

Related Person Transactions

In addition to the compensation arrangements with directors and executive officers described elsewhere in this Annual Report on Form 10-K, since January 1, 2018, we have engaged in, or currently propose to engage in, the following transactions in which the amount involved exceeds $120,000 and any of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, or any person who was in any of those categories at the time of such transaction, had or has a direct or indirect material interest. We believe that all of these transactions were on terms comparable to terms that could have been obtained from unrelated third parties.

Services and Facilities Agreement with EveliQure Biotechnologies GmbH

Our subsidiary, Arsanis Biosciences GmbH, leases approximately 1,500 square meters of office and lab space from Marxbox Bauprojekt GmbH & Co. OG. In February 2015, Arsanis Biosciences GmbH entered into a services and facilities agreement with EveliQure Biotechnologies GmbH, or EveliQure, under which we provided certain laboratory services and sublet approximately 150 square meters of office and lab space. Tamás Henics, the husband of Eszter Nagy, our former Chief Scientific Officer and director, serves as Chief Scientific Officer at EveliQure.

Since January 1, 2018, payments due to us from EveliQure under the agreement were approximately $0.2 million. These amounts included rental charges as well as amounts attributable to facilities and laboratory services. The agreement with EveliQure was terminated by Arsanis Biosciences GmbH effective as of December 31, 2018.

Agreements with Adimab, LLC

We have entered into two agreements with Adimab—the Adimab Collaboration Agreement and the Adimab Option Agreement—under which we were granted exclusive options to obtain ownership or exclusive worldwide licenses under specified patents relating to the development and commercialization of monoclonal antibodies. See "Item 1. Business—Collaboration and License Agreements—Adimab, LLC" for more information. Tillman U. Gerngross, Ph.D., the chairman of our board of directors, is a co-founder of Adimab and currently serves as its Chief Executive Officer.

Under the Adimab Collaboration Agreement, as of December 31, 2018, we had paid Adimab approximately $4.3 million in the aggregate, consisting of upfront payments and reimbursement for research conducted by Adimab. Under the Adimab Option Agreement, as of December 31, 2018, we had incurred costs paid to Adimab of approximately $0.2 million in the aggregate, consisting of reimbursement for affinity maturation work performed by Adimab and for certain patent prosecution costs incurred by Adimab. Since January 1, 2018, payments due to Adimab pursuant to the Adimab Option Agreement were approximately $0.1 million.

Agreements with Bill & Melinda Gates Foundation

We are party to grant agreements with the Gates Foundation, a 5% stockholder, pursuant to which the Gates Foundation has agreed to grant us up to an aggregate of $10.4 million to conduct preclinical development of monoclonal antibodies for the prevention of RSV infection in newborns. See "Item 1. Business—Collaboration and License Agreements—The Bill & Melinda Gates Foundation" for more information. Since January 1, 2018, we have received $1.1 million under the grant agreements with the Gates Foundation.

Board Determination of Independence

Rule 5605 of the Nasdaq Listing Rules requires a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Rule 5605(a)(2) of the Nasdaq Listing Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In February 2019, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors other than Mr. Gray and Drs. Russo and Gerngross is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Listing Rules. Mr. Gray is not an independent director under Rule 5605(a)(2) because he is our President and Chief Executive Officer and Chief Financial Officer. Dr. Russo is not an independent director under Rule 5605(a)(2) because she was employed by our company, as President and Chief Executive Officer, within the past three years. Dr. Gerngross is not an independent director under Rule 5605(a)(2) because he was employed by our company, as President, within the past three years, and because of his service as Chief Executive Officer of Adimab, LLC, a company with which we have a commercial relationship. Our board of directors also determined that William Clark, Carl Gordon and David McGirr, who currently comprise our audit committee satisfy the independence standards for the audit committee established by the SEC and the Nasdaq Listing Rules, including the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our board of directors further determined that Michael Ross and Amy Schulman, members of our compensation committee are independent within the meaning of Rule 10C-1 under the Exchange Act. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Item 14. Principal Accountant Fees and Services

Audit Fees and Services

The following table sets forth fees billed for professional audit services and other services rendered to us by PwC for the fiscal years ended December 31, 2018 and 2017. All such services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below.

Fee Category	2018	2017
Audit Fees(1)	$ 731,372	$ 1,437,218
Audit-Related Fees(2)	—	—
Tax Fees(3)	—	—
All Other Fees(4)	1,800	—
Total Fees	$ 733,172	$ 1,437,218

(1) "Audit Fees" consist of fees billed for professional services performed by PwC for the audit of our annual financial statements, the review of interim financial statements, and related services that are normally provided in connection with registration statements. Included in the 2017 Audit Fees is $926,309 of fees billed in connection with our initial public offering, which closed in November 2017, and fees billed in connection with the filing of registration statements. Included in the 2018 Audit Fees is $188,372 of fees billed in connection with the filing of registration statements.

(2) "Audit-Related Fees" may consist of fees billed by an independent registered public accounting firm for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements. There were no such fees incurred in 2018 or 2017.

(3) "Tax Fees" may consist of fees for professional services, including tax consulting and compliance performed by an independent registered public accounting firm. There were no such fees incurred in 2018 or 2017.

(4) All other fees represent payment for access to the PricewaterhouseCoopers LLP online accounting research and financial disclosure databases.

Pre-Approval Policies and Procedures

Our audit committee has adopted procedures requiring the pre-approval of all non-audit services performed by our independent registered public accounting firm in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is to be reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the audit committee for each engagement of the independent registered public accounting firm to perform other audit-related or other non-audit services. The audit committee does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management.

The standard applied by the audit committee, or the chair of the audit committee, in determining whether to grant approval of any type of non-audit service, or of any specific engagement to perform a non-audit service, is whether the services to be performed, the compensation to be paid therefore and other related factors are consistent with the independent registered public accounting firm's independence under guidelines of the SEC and applicable professional standards. Relevant considerations include whether the work product is likely to be subject to, or implicated in, audit procedures during the audit of our financial statements, whether the independent registered public accounting firm would be functioning in the role of management or in an advocacy role, whether the independent registered public accounting firm's performance of the service would enhance our ability to manage or control risk or improve audit quality, whether such performance would increase efficiency because of the independent registered public accounting firm's familiarity with our business, personnel, culture, systems, risk profile and other factors, and whether the amount of fees involved, or the non-audit services portion of the total fees payable to the independent registered public accounting firm in the period would tend to reduce the independent registered public accounting firm's ability to exercise independent judgment in performing the audit.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(1) Financial Statements

The following documents are included on pages F-1 through F-40 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

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

(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit No.	Description	Incorporation by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
Agreement and Plan of Merger Documents					
2.1+	Agreement and Plan of Merger, dated November 26, 2018, by and among the Company, Artemis AC Corp. and X4 Pharmaceuticals, Inc.	8-K	11/27/2018	2.1	
2.2	First Amendment to Agreement and Plan of Merger, dated December 20, 2018, by and among the Company, Artemis AC Corp. and X4 Pharmaceuticals, Inc.	8-K	12/20/2018	2.1	
Organizational Documents and Documents Related to Common Stock					
3.1	Restated Certificate of Incorporation of the Company	8-K	11/20/2017	3.1	
3.2	Amended and Restated By-laws of the Company	8-K	11/20/2017	3.2	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1	10/20/2017	4.1	
10.1	Second Amended and Restated Investors' Rights Agreement, as amended	S-1/A	11/6/2017	10.1	
10.2	Second Amended and Restated Stockholders' Agreement, dated as of April 12, 2016, among the Company and the other parties thereto, as amended	S-1/A	11/6/2017	10.37	
10.3	Warrant to purchase shares of Series A-2 Convertible Preferred Stock issued by the Company to Silicon Valley Bank	S-1	10/20/2017	10.23	
10.4	Warrant to purchase shares of Series B Convertible Preferred Stock issued by the Company to Silicon Valley Bank	S-1	10/20/2017	10.24	
Equity Plan Documents					
10.5*	2010 Special Stock Incentive Plan, as amended	S-1	10/20/2017	10.2	
10.6*	Form of Non-Statutory Stock Option Agreement under the 2010 Special Stock Incentive Plan	S-1	10/20/2017	10.3	
10.7*	2011 Stock Incentive Plan, as amended	S-1	10/20/2017	10.4	
10.8*	Form of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan	S-1	10/20/2017	10.5	
10.9*	Form of Non-Statutory Stock Option Agreement under the 2011 Stock Incentive Plan	S-1	10/20/2017	10.6	
10.10*	2017 Equity Incentive Plan	S-1	10/20/2017	10.7	
10.11*	Form of Incentive Stock Option Agreement under the 2017 Equity Incentive Plan	S-1	10/20/2017	10.8	

Exhibit No.	Description	Incorporation by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
10.12*	Form of Nonstatutory Stock Option Agreement under the 2017 Equity Incentive Plan	S-1	10/20/2017	10.9	
10.13*	2017 Employee Stock Purchase Plan	S-1	10/20/2017	10.10	
10.14*	Form of Restricted Stock Agreement under the 2017 Equity Incentive Plan	8-K	11/27/2018	10.6	
Agreements with Directors and Executive Officers					
10.15*	Form of Indemnification Agreement (for directors and executive officers)	S-1/A	11/6/2017	10.36	
10.16*	2018 Amended and Restated Employment Agreement, dated November 26, 2018, by and between the Company and Michael Gray	8-K	11/27/2018	10.3	
10.17*	Letter Agreement, dated November 26, 2018, by and between the Company and René Russo	8-K	11/27/2018	10.4	
10.18*	Retention Bonus Agreement, dated November 26, 2018, by and between the Company and Christopher Stevens	8-K	11/27/2018	10.5	
10.19*	Letter Agreement, dated January 15, 2019, by and between the Company and Christopher Stevens	S-4/A	2/13/2019	10.19	
10.20*	Amended and Restated Letter Agreement, dated October 10, 2017, by and between the Company and David Mantus	S-4/A	2/13/2019	10.20	
10.21*	Retention Bonus Agreement, dated November 26, 2018, by and between the Company and David Mantus	S-4/A	2/13/2019	10.21	
Leases					
10.22	Lease, dated October 30, 2015, by and between the Company and Waltham Winter Street 890 LP	S-1	10/20/2017	10.16	
10.23	Lease Agreement, dated November 26, 2010, by and between Arsanis Biosciences GmbH and Wüstenrot Marxbox GmbH & Co. OG (as successor-in-interest to Marxbox Bauprojekt GmbH & Co. OG), as amended (English translation)	S-1	10/20/2017	10.17	
10.24	Indenture of Lease, dated June 6, 2018, by and between the Company and BP Bay Colony LLC	8-K	6/12/2018	10.1	
10.25	First Amendment to Lease, dated August 10, 2018, by and between the Company and BP Bay Colony LLC	10-Q	8/13/2018	10.2	
Licenses and Collaboration Agreements					
10.26†	Collaboration Agreement, dated as of May 1, 2011, by and between the Company and Adimab, LLC, as amended	S-1	10/20/2017	10.18	
10.27†	Option and License Agreement, dated as of February 27, 2017, by and between the Company and Adimab, LLC	S-1	10/20/2017	10.19	
10.28†	Amendment No. 1 to the Option and License Agreement, dated as of February 27, 2017, by and between the Company and Adimab, LLC, dated as of October 13, 2017	S-1	10/20/2017	10.41	
Financing Agreements					
10.29†	Grant Agreement, dated February 20, 2017, by and between the Company and Bill & Melinda Gates Foundation, as amended	S-1	10/20/2017	10.20	
10.30†	Letter agreement, dated as of April 24, 2017, by and between the Company and Bill & Melinda Gates Foundation	S-1	10/20/2017	10.21	
10.31	Loan and Security Agreement, dated as of December 7, 2012, by and between the Company and Silicon Valley Bank, as amended	S-1	10/20/2017	10.22	
10.32	Funding contract, dated September 20, 2011, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.25	
10.33	Funding contract, dated July 2, 2012, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.26	
10.34	Funding contract, dated December 5, 2012, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.27	
10.35	Funding contract, dated March 29, 2013, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.28	

Exhibit No.	Description	Incorporation by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit Number	
10.36	Funding contract, dated August 6, 2013, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.29	
10.37	Funding contract, dated April 3, 2014, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.30	
10.38	Funding contract, dated June 9, 2014, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.31	
10.39	Funding contract, dated July 20, 2015, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.32	
10.40	Funding contract, dated July 20, 2015, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.33	
10.41	Funding contract, dated July 14, 2016, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.34	
10.42	Funding contract, dated March 23, 2017, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)	S-1	10/20/2017	10.35	
10.43	Share Purchase Agreement, dated as of November 15, 2017, by and between the Company and New Enterprise Associates 16, L.P.	10-K	3/9/2018	10.37	
10.44†	Amended and Restated Agreement, dated August 8, 2018, by and between the Company and the Bill & Melinda Gates Foundation	10-Q	8/13/2018	10.3	
10.45†	Grant Agreement, dated August 8, 2018, by and between the Company and the Bill & Melinda Gates Foundation	10-Q	8/13/2018	10.4	
10.46	Forbearance Agreement, dated August 8, 2018, by and between the Company and Silicon Valley Bank	10-Q	8/13/2018	10.5	
Support Agreements					
10.47	Form of Support Agreement, dated November 26, 2018, by and among the Company, X4 Pharmaceuticals, Inc. and certain stockholders of the Company	8-K	11/27/2018	10.1	
10.48	Form of Support Agreement, dated November 26, 2018, by and among the Company, X4 Pharmaceuticals, Inc. and certain officers, directors and stockholders of X4 Pharmaceuticals, Inc.	8-K	11/27/2018	10.2	
Subsidiaries, Consents and Certifications					
21.1	List of Subsidiaries	S-1	10/20/2017	21.1	
23.1	Consent of PricewaterhouseCoopers LLC, independent registered public accounting firm				X
31.1	Certification of the Principal Executive Officer and Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of the Principal Executive Officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

* Denotes a management contract or compensatory plan or arrangement

+ All schedules (or similar attachments) have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any schedules to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ARSANIS, INC.

Date: March 11, 2019

By: /s/ Michael Gray
Michael Gray
President and Chief Executive Officer, Chief Financial Officer

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

Signature	Title	Date
/s/ Michael Gray Michael Gray	President and Chief Executive Officer, Chief Financial Officer, Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 11, 2019
/s/ Tillman U. Gerngross Tillman U. Gerngross	Chairman of the Board	March 11, 2019
/s/ William Clark William Clark	Director	March 11, 2019
/s/ Carl Gordon Carl Gordon	Director	March 11, 2019
/s/ David McGirr David McGirr	Director	March 11, 2019
/s/ Terrance McGuire Terrance McGuire	Director	March 11, 2019
/s/ Claudio Nessi Claudio Nessi	Director	March 11, 2019
/s/ Michael Ross Michael Ross	Director	March 11, 2019
/s/ René Russo René Russo	Director	March 11, 2019
/s/ Amy Schulman Amy Schulman	Director	March 11, 2019

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Arsanis, Inc. and its subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit), and consolidated statements of cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company will require additional financing to fund planned future operations. Management's plans in regard to this matter are described in Note 1.

PricewaterhouseCoopers LLP

Boston, MA
March 11, 2019

We have served as the Company's auditor since 2017.

ARSANIS, INC.

CONSOLIDATED BALANCE SHEETS

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 30,754	$ 76,793
Grant and incentive receivables	2,859	1,608
Restricted cash	101	—
Prepaid expenses and other current assets	1,366	1,129
Total current assets	35,080	79,530
Property and equipment, net	285	421
Restricted cash	539	355
Other assets	100	948
Total assets	$ 36,004	$ 81,254
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 545	$ 1,893
Accrued expenses	4,116	5,779
Unearned income	737	694
Loans payable, net of discount	—	2,314
Total current liabilities	5,398	10,680
Loan payable, net of discount and current portion	7,894	9,922
Unearned income	1,107	1,936
Other long-term liabilities	5	9
Total liabilities	14,404	22,547
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized as of December 31, 2018 and 2017, respectively; 14,572,246 and 14,294,383 shares issued and outstanding as of December 31, 2018 and 2017, respectively	15	15
Additional paid-in capital	156,630	150,830
Accumulated other comprehensive income	241	127
Accumulated deficit	(135,286)	(92,265)
Total stockholders' equity	21,600	58,707
Total liabilities and stockholders' equity	$ 36,004	$ 81,254

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

ARSANIS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year Ended December 31,		
	2018	**2017**	**2016**
Revenue:			
License revenue	$ 3,500	$ —	$ —
Total revenue	3,500	—	—
Operating expenses:			
Research and development	30,979	28,128	17,831
General and administrative	18,406	8,005	6,515
Total operating expenses	49,385	36,133	24,346
Loss from operations	(45,885)	(36,133)	(24,346)
Other income (expense):			
Grant and incentive income	3,179	3,868	2,390
Interest expense	(1,039)	(2,079)	(2,515)
Interest income	809	214	—
Change in fair value of warrant liability	—	(31)	39
Change in fair value of derivative liability	—	762	1,388
Loss on extinguishment of debt	—	(462)	(35)
Other income (expense), net	(85)	(16)	104
Total other income (expense), net	2,864	2,256	1,371
Net loss	(43,021)	(33,877)	(22,975)
Accretion of redeemable convertible preferred stock to redemption value	—	(44)	(25)
Net loss attributable to common stockholders	$ (43,021)	$ (33,921)	$ (23,000)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.01)	$ (16.45)	$ (44.79)
Weighted average common shares outstanding—basic and diluted	14,307,934	2,061,845	513,527

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

ARSANIS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Amounts in thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Net loss	$ (43,021)	$ (33,877)	$ (22,975)
Other comprehensive loss:			
Foreign currency translation gain (loss)	114	(707)	116
Comprehensive loss	$ (42,907)	$ (34,584)	$ (22,859)

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

ARSANIS, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(Amounts in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of December 31, 2015	5,076,970	$ 29,948	513,900	$ 1	$ 372	$ 718	$ (35,413)	$ (34,322)
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of $87	569,946	5,413	—	—	—	—	—	—
Issuance of Series C redeemable convertible preferred stock in connection with the extinguishment of convertible promissory note	461,396	4,452	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	25	—	—	(25)	—	—	(25)
Stock-based compensation expense	—	—	—	—	644	—	—	644
Foreign currency translation adjustment	—	—	—	—	—	116	—	116
Net loss	—	—	—	—	—	—	(22,975)	(22,975)
Balances as of December 31, 2016	6,108,312	$ 39,838	513,900	$ 1	$ 991	$ 834	$ (58,388)	$ (56,562)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of $208	12,340,380	39,845	—	—	—	—	—	—
Issuance of Series D redeemable convertible preferred stock in connection with the extinguishment of convertible promissory note	3,420,404	11,102	—	—	—	—	—	—
Issuance of common stock upon closing of initial public offering, net of issuance costs of $6,516	—	—	4,600,000	5	39,479	—	—	39,484
Issuance of common stock upon closing of private placement, net of issuance costs of $1,400	—	—	2,000,000	2	18,598	—	—	18,600
Accretion of redeemable convertible preferred stock to redemption value	—	44	—	—	(44)	—	—	(44)
Conversion of convertible preferred stock into common stock upon closing of initial public offering	(21,869,096)	(90,829)	7,180,483	7	90,822	—	—	90,829
Conversion of convertible preferred stock warrants into common stock warrants	—	—	—	—	78	—	—	78
Stock-based compensation expense	—	—	—	—	906	—	—	906
Foreign currency translation adjustment	—	—	—	—	—	(707)	—	(707)
Net loss	—	—	—	—	—	—	(33,877)	(33,877)
Balances as of December 31, 2017	—	$ —	14,294,383	$ 15	$ 150,830	$ 127	$ (92,265)	$ 58,707
Exercise of common stock options	—	—	27,226	—	177	—	—	177
Issuance of common stock under employee stock purchase plan	—	—	637	—	3	—	—	3
Issuance of restricted common stock	—	—	250,000	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5,620	—	—	5,620
Foreign currency translation adjustment	—	—	—	—	—	114	—	114
Net loss	—	—	—	—	—	—	(43,021)	(43,021)
Balances as of December 31, 2018	—	$ —	14,572,246	$ 15	$ 156,630	$ 241	$ (135,286)	$ 21,600

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

ARSANIS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net loss	$ (43,021)	$ (33,877)	$ (22,975)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	5,620	906	644
Depreciation and amortization expense	155	195	285
Non-cash interest expense	804	1,773	2,307
Non-cash rent expense	—	(23)	9
Loss on extinguishment of debt	—	462	35
Change in fair value of warrant liability	—	31	(39)
Change in fair value of derivative liability	—	(762)	(1,388)
Changes in operating assets and liabilities:			
Grant and incentive receivables	(1,374)	(64)	152
Prepaid expenses and other assets	612	284	(2,219)
Accounts payable	(1,339)	182	1,264
Accrued expenses	(1,677)	3,290	521
Unearned income	(683)	(268)	(235)
Net cash used in operating activities	(40,903)	(27,871)	(21,639)
Cash flows from investing activities:			
Purchases of property and equipment	(34)	(42)	(73)
Net cash used in investing activities	(34)	(42)	(73)
Cash flows from financing activities:			
Proceeds from issuance of redeemable convertible preferred stock	—	40,053	5,500
Proceeds from issuance of loans payable	—	—	7,000
Proceeds from issuance of convertible promissory notes	—	4,935	5,500
Proceeds from issuance of loans under funding agreements	—	694	514
Proceeds from issuance of common stock in initial public offering	—	46,000	—
Proceeds from issuance of common stock in private placement	—	20,000	—
Proceeds from exercise of stock options	179	—	—
Repayments of loans payable	(4,667)	(2,333)	(250)
Payments of issuance costs of convertible promissory notes	—	(17)	—
Payments of issuance costs of redeemable convertible preferred stock	—	(197)	(87)
Payments of issuance costs of loans payable	—	—	(30)
Payments of initial public offering costs	(43)	(6,473)	—
Payments of private placement costs	—	(1,400)	—
Net cash provided by (used in) financing activities	(4,531)	101,262	18,147
Effect of exchange rate changes on cash	(286)	370	(103)
Net increase (decrease) in cash, cash equivalents and restricted cash	(45,754)	73,719	(3,668)
Cash, cash equivalents and restricted cash at beginning of period	77,148	3,429	7,097
Cash, cash equivalents and restricted cash at end of period	$ 31,394	$ 77,148	$ 3,429
Supplemental disclosure of non-cash investing and financing activities:			
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ —	$ 2
Initial public offering costs included in accounts payable and accrued expenses	$ —	$ 43	$ —
Issuance of redeemable convertible preferred stock upon extinguishment of convertible promissory notes	$ —	$ 11,102	$ 4,452
Derivative liability in connection with issuance of convertible promissory notes	$ —	$ 403	$ 3,929
Extinguishment of convertible promissory notes	$ —	$ 8,405	$ 2,677
Extinguishment of derivative liability in connection with extinguishment of convertible promissory notes	$ —	$ 2,234	$ 1,741
Issuance of warrants in connection with issuance of loans payable	$ —	$ —	$ 60
Conversion of redeemable convertible preferred stock warrants into common stock warrants	$ —	$ 78	$ —
Conversion of redeemable convertible preferred stock into common stock	$ —	$ 90,829	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 44	$ 25

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

1. Nature of the Business

Arsanis, Inc. (the "Company") was incorporated under the laws of the State of Delaware on August 2, 2010, and is headquartered in Waltham, Massachusetts. The Company is a clinical-stage biopharmaceutical company that has historically focused on applying monoclonal antibody, or mAb, immunotherapies to address serious infectious diseases. The Company possesses a deep understanding of the pathogenesis of infection, paired with access to what the Company believes to be some of the most advanced mAb discovery techniques and platforms available today. The Company's pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including *Staphylococcus aureus* ("*S. aureus*") and respiratory syncytial virus ("RSV").

On June 28, 2018, the Company announced the discontinuation of its Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients following the completion of a planned interim analysis of unblinded trial data for 118 patients by an independent data review committee, or DRC. Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued. During the third quarter of 2018, the Company completed follow-up visits on patients dosed in the trial per the study protocol, and during the fourth quarter of 2018, the Company completed its analysis of the complete dataset from the 154 patients that were enrolled in the trial. The Company is currently exploring potential collaborations or out-licensing opportunities for the potential continued development of ASN100.

Following its discontinuation of ASN100 clinical development, in August 2018 the Company announced that it was considering strategic options that may potentially result in changes to its business strategy and future operations and the Company's board of directors approved a reduction in workforce to reduce operating costs and better align its workforce with the needs of its business following its discontinuation of the clinical development of ASN100. As part of the planned reduction in workforce, the Company eliminated 28 positions across the company, representing approximately 65% of its workforce, through March 1, 2019.

On November 26, 2018, the Company and X4 Pharmaceuticals, Inc. ("X4") have entered into an Agreement and Plan of Merger, as amended (the "Merger Agreement"), pursuant to which a wholly owned subsidiary of the Company will merge with and into X4, with X4 continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the "Merger"). The Company expects to devote significant time and resources to completion of the Merger. However, there can be no assurance that such activities will result in the completion of the Merger. Further, the completion of the Merger ultimately may not deliver the anticipated benefits or enhance shareholder value.

The Company has devoted substantially all of its resources to building its business to support discovery, research and development activities for its programs. The Company does not have any products approved for sale and has not generated any revenue from product sales.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Reverse Stock Split

On November 3, 2017, the Company effected a one-for-3.4130 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

Initial Public Offering

On November 20, 2017, the Company completed an initial public offering ("IPO") of its common stock, and issued and sold 4,000,000 common shares at a price to the public of $10.00 per share. Concurrent to the IPO, (i) the Company issued an additional 600,000 common shares at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option and (ii) New Enterprise Associates 16, L.P., or NEA, purchased 2,000,000 shares of the Company's common stock at the initial per share public offering price of $10.00 in a private placement. The aggregate net proceeds to the Company from the IPO, inclusive of the over-allotment exercise, and the private placement were $58.1 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the outstanding redeemable convertible preferred stock of the Company automatically converted into 7,180,483 shares of the Company's common stock.

Going Concern

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of December 31, 2018, the Company had an accumulated deficit of $135.3 million. During the year ended December 31, 2018, the Company incurred a net loss of $43.0 million and used $40.9 million of cash in operations. The Company expects to continue to generate operating losses for the foreseeable future. Based on its current operating plan, the Company expects that its cash and cash equivalents of $30.8 million as of December 31, 2018, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months from the issuance date of these financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations. The Company will seek additional funding through public or private financings, debt financing, license agreements or government grants. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of common stock and stock options. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of Arsanis, Inc. and its wholly owned subsidiary, Arsanis Biosciences GmbH, which was incorporated in Vienna, Austria. All significant intercompany accounts and transactions have been eliminated.

Foreign Currency and Currency Translation

The functional currency for Arsanis Biosciences GmbH, is the Euro. Assets and liabilities of Arsanis Biosciences GmbH are translated into United States dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative

translation adjustment, which is included in the consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) as a component of accumulated other comprehensive income. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income (expense), net in the consolidated statements of operations as incurred.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original final maturities of 90 days or less from the date of purchase to be cash equivalents. The Company's cash equivalents consist of money market funds. Cash equivalents are reported at fair value.

Restricted Cash

The Company maintains letters of credit for the benefit of the landlords in connection with the Company's office, laboratory, parking and storage space leases in Waltham, MA and Vienna, Austria and another letter of credit in connection with the Company's corporate credit cards. As of December 31, 2018, short term restricted cash consisted of a letter of credit related to the Company's lease of its corporate facility at 890 Winter Street, Waltham, MA and a letter of credit related to the Company's corporate credit cards of approximately $51,000 and $50,000, respectively. The Company had no short term restricted cash as of December 31, 2017.

As of December 31, 2018, long term restricted cash consisted of letters of credit related to the Company's leases of office, laboratory, parking and storage space lease in Vienna, Austria, which expires on April 30, 2021, and its new corporate headquarters at 950 Winter Street, Waltham, MA, which expires on December 31, 2023, of approximately $0.3 million and $0.3 million, respectively. As of December 31, 2017, long term restricted cash consisted of a letter of credit related to the Company's lease on prior corporate headquarters, which expired on January 31, 2019, of approximately $0.4 million.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the assets. As of December 31, 2018 and 2017, the Company's property and equipment consisted of laboratory and office equipment, computer equipment and software, furniture and fixtures and leasehold improvements. Property and equipment are recorded at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the assets as follows:

	Estimated Useful Life
Laboratory and office equipment	3 to 10 years
Furniture and fixtures	3 to 10 years
Computer equipment and software	1 to 5 years
Leasehold improvements	Shorter of lease term or 10 years

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its

carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recognized any impairment losses on long-lived assets.

Fair Value Measurements

Certain assets of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of cash equivalents, other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's loans received under the funding agreements with Österreichische Forschungsförderungsgesellschaft mbH ("FFG") approximates their fair value because the Company records imputed interest expense based on rates that approximate market rates of interest as of the issuance date of each FFG loan.

Segment Information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular current focus is on applying mAb therapies to address serious infectious diseases.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC"), Topic 606, Revenue from Contracts with Customers ("Topic 606"), using the modified retrospective transition method. The modified retrospective method requires that the cumulative effect of initially applying ASC 606 be recognized as an adjustment to the opening balance of retained earnings or accumulated deficit of the annual period that includes the date of initial application. The Company did not have any arrangements that were in the scope of ASC 606 on January 1, 2018 and thus there was no impact to the consolidated financial statements as a result of the adoption. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as collaboration arrangements and leases.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised

goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue generating arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method.

License Revenue

The Company enters into out-licensing agreements that are within the scope of Topic 606. The terms of such out-license agreements include the license of functional intellectual property, given the functionality of the intellectual property is not expected to change substantially as a result of the licensor's ongoing activities, and typically include payment of one or more of the following: non-refundable up-front license fees and exclusivity fees related to customer options. Nonrefundable up-front license fees are recognized as revenue at a point in time when the licensed intellectual property is made available for the customer's use and benefit, which is generally at the inception of the arrangement. Exclusivity fees are recognized as revenue when the performance obligation to which the customer option has been allocated has been satisfied.

Government Contracts, Grant Agreements and Incentive Programs

The Company recognizes proceeds received from the FFG grants, research and development incentives from the Austrian government and the grant agreements with the Bill & Melinda Gates Foundation (the "Gates Foundation") as other income, rather than as revenue, in the consolidated statements of operations because the corresponding agreements contain no specified performance obligations other than to conduct research on a particular program or in a particular field and contain no obligations to deliver specified products or technology.

Income from grants and incentives is recognized in the period during which the related qualifying expenses are incurred, provided that the conditions under which the grants or incentives were provided have been met. For grants under the funding agreements with FFG and for proceeds under the research and development incentive program from the Austrian government, the Company recognizes grant and incentive income in an amount equal to the qualifying expenses incurred in each period multiplied by the applicable reimbursement percentage. For grants received under the grant agreements with the Gates Foundation, the Company recognizes grant income in an amount equal to the qualifying expenses incurred in each period, up to the amount previously funded by the Gates Foundation.

Grant funding that has been received by the Company in advance of incurring qualifying expenses is recorded in the consolidated balance sheet as unearned income. Grant and incentive income recognized upon incurring qualifying expenses in advance of receipt of grant funding or proceeds from research and development incentives is recorded in the consolidated balance sheet as grant and incentive receivables.

Loans the Company has received under the funding agreements with FFG bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between a market rate of interest and the rate of interest charged by FFG as additional grant funding from FFG, and records interest expense for the FFG loans at a market rate of interest. On the date that FFG loan proceeds are received, the Company recognizes the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is subsequently recognized as additional grant income over the term of the funding agreement.

Research and Development Costs

The Company expenses all costs incurred in performing research and development activities. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, third-party license fees, and external costs of outside vendors engaged to conduct clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Research Contract Costs and Accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. These agreements are cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company’s estimates. The Company’s historical accrual estimates have not been materially different from the actual costs.

Patent Costs

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

Stock-Based Compensation

The Company measures stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance-based vesting conditions.

For stock-based awards granted to consultants and non-employees, compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company’s common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statement of operations in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. Prior to November 20, 2017, the Company had been a private company and lacked company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the year ended December 31, 2018, comprehensive loss included $0.1 million of foreign currency translation gain adjustments. For the years ended December 31, 2017 and 2016, comprehensive loss included $0.7 million of foreign currency translation loss adjustments and $0.1 million of foreign currency translation gain adjustments, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares during the years ended December 31, 2017 and 2016 that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, options to purchase common stock, unvested restricted stock, redeemable convertible preferred stock, warrants to purchase common stock and warrants to purchase redeemable convertible preferred stock are considered potential dilutive common shares.

The Company's redeemable convertible preferred stock contractually entitled the holders of such shares to participate in dividends but contractually did not require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes most existing revenue recognition guidance under GAAP. The FASB also issued several amendments and updates to the new revenue standard (collectively, "Topic 606"). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle, and will require companies to use more judgment and make more estimates than under the current guidance. These judgments and estimates include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* ("ASU 2016-08"), which further clarifies the implementation guidance on principal versus agent considerations in ASU 2014-09. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensin*g, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments in this update reduce the cost and complexity of identifying promised goods or services and improve the guidance for determining whether promises are separately identifiable. The amendments in this update also provide implementation guidance on determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), which clarifies the objective of the collectability criterion, presentation of taxes collected from customers, non-cash consideration, contract modifications at transition, completed contracts at transition and how guidance in ASU 2014-09 is retrospectively applied. ASU 2016-08, ASU 2016-10 and ASU 2016-12 have the same effective dates and transition requirements as ASU 2014-09. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows as the Company did not have any arrangements that were in the scope of ASC 606 on January 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new 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, respectively. 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 will be accounted for similar to existing guidance for operating leases today. ASU 2016-02 (Accounting Standards Codification ("ASC") (Topic 842) supersedes the previous leases standard, ASC 840, Leases. The standard is effective for public entities for annual periods beginning after December 15, 2018 including interim periods within those fiscal years. In July 2018, the FASB issued ASU 2018-11, *Leases, Targeted Improvements, ("ASU 2018-11"),* which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. ASU 2018-11 provides registrants with an option to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company adopted the new leasing standard on January 1, 2019, using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019. The Company is in the process of completing its review of its existing lease agreements under ASC 842 and does not expect the adoption of the new leasing standard to have a material impact on its financial position, results of operations or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted the standard retrospectively to all periods presented on the required effective date of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* ("ASU 2016-16"), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which requires restricted cash to be presented with cash and cash equivalents on the statement of cash flows and disclosure of how the statement of cash flows reconciles to the balance sheet if restricted cash is shown separately from cash and cash equivalents on the balance sheet. The Company adopted this standard on January 1, 2018. The adoption of ASU 2016-18 resulted in the

Company's cash, cash equivalents and restricted cash being included in the beginning and ending amounts for the periods shown on the statement of cash flows and was applied retroactively and reflected in the balances presented for any prior periods. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements and related disclosures.

The restricted cash as of December 31, 2018 and 2017 is held as letters of credit for the benefit of the landlords in connection with the Company's office leases and corporate credit cards.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the statement of cash flows.

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 30,754	$ 76,793
Restricted cash – current	101	—
Restricted cash – non-current	539	355
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 31,394	$ 77,148

In January 2017, FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"). The amendments in this update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In April 2017, the FASB issued ASU 2017-08, *Receivables – Nonrefundable Fees and Other Costs ("Subtopic 310-20")*. The new standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period for the premium to the earliest call date. Subtopic 310-20 calls for a modified retrospective application under which a cumulative-effect adjustment will be made to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The new standard will be effective beginning January 1, 2019 and early adoption is permitted for public entities. The Company adopted this guidance, effective January 1, 2019, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted this guidance, effective January 1, 2019, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("ASU 2018-05"). This standard amends ASC 740, Income Taxes ("ASC 740") to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act pursuant to Staff Accounting Bulletin No. 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Cuts and Jobs Act ("Tax Act") enactment date. This standard was effective upon issuance. The Company previously provided a provisional estimate of the effect of the Tax Act in its results of operations, cash flows and consolidated financial statements. In the fourth quarter of 2018, the Company completed its analysis to determine the effect of the Tax Act and concluded no adjustments were necessary.

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The new standard specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers. ASU 2018-07 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted this guidance, effective January 1, 2019, and its adoption had no material impact on the Company's financial position, results of operations or cash flows.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, ("ASU 2018-13").* The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, ("ASU 2018-15").* The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact that the adoption of ASU 2018-15 will have on its consolidated financial statements.

3. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value at December 31, 2018 and 2017, and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

	Fair Value Measurements as of December 31, 2018 Using:		
	Level 1	Level 3	Total
Assets:			
Cash equivalents - Money Market Funds	$ 29,836	$ —	$ 29,836
	$ 29,836	$ —	$ 29,836

	Fair Value Measurements as of December 31, 2017 Using:		
	Level 1	Level 3	Total
Assets:			
Cash equivalents - Money Market Funds	$ 70,891	$ —	$ 70,891
	$ 70,891	$ —	$ 70,891

There were no changes to the valuation methods during the years ended December 31, 2018 and 2017. There were no transfers within the fair value hierarchy during the years ended December 31, 2018 and 2017.

4. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2018	2017
Prepaid clinical trial costs	$ —	$ 257
Prepaid directors' and officers' and other corporate insurance	1,007	524
Prepaid other	359	348
	$ 1,366	$ 1,129

5. Property and Equipment, Net

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

	December 31,	
	2018	2017
Laboratory and office equipment	$ 1,676	$ 1,739
Furniture and fixtures	402	419
Leasehold improvements	298	297
Computer equipment and software	180	189
	2,556	2,644
Less: Accumulated depreciation and amortization	(2,271)	(2,223)
	$ 285	$ 421

Depreciation and amortization expense for the years ended December 31, 2018, 2017 and 2016 was $0.2 million, $0.2 million and $0.3 million, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued clinical trial costs	$ 294	$ 2,317
Accrued compensation and benefits	2,522	2,454
Accrued professional fees	1,156	510
Accrued other	144	498
	$ 4,116	$ 5,779

Accrued Clinical Trial Costs

In connection with the Company’s decision to discontinue the Phase 2 clinical trial for ASN100, spending and activities related to ASN100 significantly declined and the Company does not expect to incur material costs for this program in 2019.

Restructuring Costs

On August 10, 2018, the Company’s board of directors approved a reduction in workforce to reduce operating costs and better align the Company’s workforce with the needs of its business following the Company’s discontinuation of the clinical development of ASN100. As part of this reduction in workforce, the Company eliminated 28 positions across the company, representing approximately 65% of its workforce, through March 1, 2019.

Between August 2018 and November 2018, the Company’s board of directors approved employee retention arrangements to incentivize certain employees to remain with the Company through early 2019.

The Company currently estimates that it will incur total expenses relating to the reduction in workforce of approximately $5.9 million, which is comprised of employee severance and retention payments. The Company records these charges in accordance with

ASC 420, *Exit or Disposal Cost Obligations*. During the year ended December 31, 2018, the Company recorded severance and retention expense of approximately $3.5 million related to the reduction in workforce. The Company expects to record the remaining $2.4 million of severance and retention expense during the first quarter of 2019.

The following table summarizes the Company's restructuring activities for the year ended December 31, 2018, which is included in accrued compensation and benefits as a component of accrued expenses on the Company's consolidated balance sheet as of December 31, 2018 (in thousands):

	December 31, 2018
Employee severance benefits	$ 1,648
Employee retention benefits	1,886
Payments	(1,539)
Total	$ 1,995

7. Collaboration, License and Funding Arrangements

Adimab Collaboration Agreement

In May 2011, the Company entered into a collaboration agreement with Adimab, LLC ("Adimab"), a related party (see Note 17) (as amended, and together with certain applicable option exercise letters the Company has sent to Adimab, the "Adimab Collaboration Agreement"). Under the Adimab Collaboration Agreement, the Company and Adimab were required to use reasonable efforts to conduct certain research, which was funded by the Company, to discover and optimize antibodies directed against targets selected by the Company. With respect to each target that was the subject of the research, the Company had an exclusive option to obtain, with respect to a specified number of antibodies directed against such target and discovered or optimized by Adimab, (i) ownership of certain patent rights relating to such antibodies and (ii) exclusive and non-exclusive licenses in a specified field, with the right to grant sublicenses, under certain patent rights and know-how.

Under the Adimab Collaboration Agreement, for each target for which the Company has exercised an option, the Company is required to use commercially reasonable efforts to develop and commercialize at least one product in major markets. If the Company does not fulfill these diligence obligations, Adimab may consider it a material breach, allowing Adimab to terminate the Adimab Collaboration Agreement with respect to such target and all associated products.

The Company is obligated to pay Adimab royalties at a mid single-digit percentage of net sales made by the Company or its affiliates of products based on antibodies for which the Company exercised its option, or products that use or are based on any antibody discovered or optimized under the agreement, any derivative or modified version of any such antibody, or any sequence information as to any such antibody. In addition, if the Company sells or licenses to any third party, or otherwise grants rights to any third party to, any of the products for which the Company is obligated to pay Adimab royalties, either alone or as part of a package including specified patents not directed to these antibodies, the Company is obligated to pay Adimab either (i) the same royalties on net sales of such products by such third party or (ii) a percentage, ranging from the low double digits to a maximum of less than 30%, of the payments the Company receives from such third parties that are attributable to such grant of rights. In April 2017, the Company entered into a letter agreement with the Gates Foundation, pursuant to which the Company licensed to the Gates Foundation certain rights under its ASN100 program. The Company has no payment obligations under the Adimab Collaboration Agreement with respect to sales of certain antibody products if they are sold at cost in developing countries under its letter agreement with the Gates Foundation. However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess over cost will be subject to the royalty payment obligations described above.

If the Company (or one of its affiliates with rights under the agreement) undergoes a change in control and, at the time of such change in control, the Company has not sold or licensed to third parties all of its rights in antibodies for which the Company is obligated to pay Adimab royalties under the agreement, then the Company is obligated to either (i) pay Adimab a percentage, in the mid double digits, of the payments it receives from that change in control that are reasonably attributable to those rights and certain patents arising from the collaboration or (ii) require the Company's acquirer and all of its future third-party collaborators to pay to Adimab the royalties at a mid single-digit percentage of net sales based on those rights. If the Company grants rights to a third party under certain patents that are not directed to the antibodies for which the Company is obligated to pay Adimab royalties (as described above), the Company is also obligated to pay Adimab, in place of royalties or a percentage of payments received from the third party, a lump sum in the high six digits.

The Adimab Collaboration Agreement will expire on a country-by-country basis twelve years after the first commercial sale in such country of the last product for which the Company is obligated to pay Adimab royalties in such country under the Adimab Collaboration Agreement. The Company has the right to terminate the Adimab Collaboration Agreement for any reason by providing

Adimab with a specified amount of prior written notice. Adimab has the right to terminate the Adimab Collaboration Agreement if the Company materially breaches the agreement and fails to cure such breach within a specified cure period, including for its failure to use commercially reasonable efforts to develop and commercialize at least one product directed at a target for which the Company has exercised an option in major markets. If Adimab terminates the Adimab Collaboration Agreement for the Company's breach, or if the Company terminates the agreement for convenience, then the Company must transfer or license to Adimab certain rights and assets relating to targets and antibodies for which the Company has exercised its option. Adimab is then obligated to make payments to the Company with respect to these targets and antibodies that are similar to the payments the Company is required to make to Adimab during the term of the agreement. Certain of the Company's payment obligations relating to specified products and patents arising from the agreement survive expiration or termination of the agreement.

During the years ended December 31, 2018, 2017 and 2016, the Company recognized research and development expense of $0, $0, and less than $0.1 million, respectively, under the Adimab Collaboration Agreement.

Adimab Option and License Agreement

In February 2017, the Company entered into an option and license agreement with Adimab, a related party (the "Adimab Option Agreement"). Under the Adimab Option Agreement, Adimab has provided to the Company certain proprietary antibodies against respiratory syncytial virus ("RSV antibodies") for its evaluation during a specified option period and has granted the Company an exclusive, non-sublicensable license in a specified field under certain Adimab patent rights and know-how during the option period. Under the Adimab Option Agreement, the Company has an exclusive option, exercisable during the option period upon payment of an option fee to Adimab, to require Adimab to assign to the Company all rights in up to a specified number of RSV antibodies selected by the Company and certain patent rights owned by Adimab that cover these antibodies, and to obtain from Adimab a non-exclusive license in a specified field, with the right to grant sublicenses, under certain other patent rights and know-how owned by Adimab.

If the Company exercises its option under the Adimab Option Agreement, the Company is required to use commercially reasonable efforts to develop and commercialize at least one product based on a licensed RSV antibody in major markets and is obligated to pay Adimab an option fee of $0.3 million and make future milestone payments upon the achievement of specified clinical and regulatory milestones in the aggregate amount of up to $24.4 million. The Company is obligated to pay Adimab royalties at a mid single-digit percentage of net sales of products based on the initial RSV antibodies (including modified or derivative forms of those antibodies created by or for the Company) by the Company or any of its affiliates, licensees or sublicensees, regardless of whether these products practice any of the assigned or licensed patents or know-how. If the Company materially breaches these diligence obligations, Adimab will have the right to terminate the Adimab Option Agreement.

The Company has no payment obligations under the Adimab Option Agreement with respect to sales of products based on licensed RSV antibodies to the extent they are sold at cost in developing countries under the February 2017 Gates Foundation grant agreement, as amended and restated in August 2018, and the August 2018 Gates Foundation grant agreement (which are described in further detail below). However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess will be subject to the royalty payment obligations described in the preceding paragraph.

If the Company does not exercise its option, the Adimab Option Agreement will expire on the Company's achievement of specified preclinical milestones under the grant agreements with the Gates Foundation, but in any event no later than mid-2019. If the Company does exercise its option, the Adimab Option Agreement will expire on the last-to-expire royalty term (defined, on a product-by-product and country-by-country basis, as the period ending on the later of twelve years after the first commercial sale of such product in such country and the expiration of the last of a specified set of patents and patent applications covering such product in such country) for any and all products for which the Company is obligated to pay Adimab royalties under the Adimab Option Agreement. The Company has the right to terminate the Adimab Option Agreement for any reason by providing Adimab with a specified amount of prior written notice. Adimab has the right to terminate the Adimab Option Agreement if the Company materially breaches the agreement and fails to cure such breach within a specified cure period, including for the Company's failure to use commercially reasonable efforts to develop and commercialize at least one product based on a licensed RSV antibody in major markets. If Adimab terminates the Adimab Option Agreement for the Company's breach, if the Company terminates the agreement for convenience or if the agreement expires before the Company exercises its option, then the Company must return or destroy certain know-how, including all initial RSV antibodies, and all modified or derivative forms of those antibodies, in its possession other than those for which the Company has made all payments required under the Adimab Option Agreement, assign certain patents covering certain RSV antibodies to Adimab, grant Adimab a non-exclusive, royalty-free license under certain other patents, and grant Adimab a time-limited right of first negotiation to obtain an exclusive license to certain patents and know-how and the transfer and assignment of certain regulatory filings and approvals and other related assets related to products based on licensed RSV antibodies. Certain of the Company's payment obligations relating to specified products and patents arising from the agreement survive expiration or termination of the agreement.

During the years ended December 31, 2018 and 2017, the Company recognized research and development expense of $0.1 million and $0.1 million, respectively, in connection with the Adimab Option Agreement, which consisted of reimbursement for services performed by Adimab.

February 2017 Grant Agreement and August 2018 Amended and Restated Gates Foundation Grant Agreement

In February 2017, the Company entered into a grant agreement with the Gates Foundation, a related party, under which the Gates Foundation agreed to provide the Company up to $9.3 million to conduct preclinical development of monoclonal antibodies for the prevention of RSV infection in newborns (the "RSV project").

In connection with this grant agreement, the Company has granted to the Gates Foundation a non-exclusive, perpetual, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the funded developments and, to the extent incorporated into a funded development or required to use a funded development, any other technology created outside of the RSV project that was used as part of the RSV project, for the benefit of people in developing countries. This license survives any expiration or termination of the grant agreement.

The grant agreement expires on October 31, 2019. The Gates Foundation can modify, suspend or discontinue any payment under the grant agreement, or terminate the grant agreement, if it is not reasonably satisfied with the Company's progress on the RSV project; if there are significant changes to the Company's leadership or other factors that the Gates Foundation reasonably believes may threaten the RSV project's success; if the Company undergoes a change in control; if there is a change in the Company's tax status; if the RSV project is no longer aligned with the Gates Foundation's programmatic strategy; or if the Company fails to comply with the grant agreement. Any grant funds that have not been used for, or committed to, the RSV project upon the expiration or termination of the grant agreement must be returned to the Gates Foundation or otherwise used as directed by the Gates Foundation.

In March 2017, the Company received a payment of $1.6 million from the Gates Foundation under the grant agreement. The payment received from the Gates Foundation under the grant agreement was classified as restricted cash (current) in the consolidated balance sheet due to restrictions on the use of the funds imposed by the agreement (see Note 2). Such funds received from the Gates Foundation were no longer classified as restricted cash once the Company incurred qualifying expenses under the grant agreement and the restrictions no longer applied.

In August 2018, the Company entered into an amended and restated grant agreement which replaces the February 2017 grant agreement in its entirety. The amended and restated grant agreement includes amendments to conform to current Gates Foundation audit, reporting, and other administrative requirements, as well as to make the perpetual Gates Foundation license grant described below irrevocable.

During the years ended December 31, 2018 and 2017, the Company recognized grant income of $0 and $1.6 million, respectively, under the grant agreement with the Gates Foundation upon incurring qualifying expenses. As of December 31, 2018 and 2017, there were no amounts recorded as unearned income under the grant agreement with the Gates Foundation.

August 2018 Gates Foundation Grant Agreement

In August 2018, the Company entered into an additional grant agreement with the Gates Foundation pursuant to which the Gates Foundation granted to the Company up to $1.1 million to conduct preclinical development activities for the RSV project that were not included in the February 2017 grant agreement, as amended and restated in August 2018. In return, the Company has agreed to conduct the RSV project in a manner that ensures that the knowledge and information gained from the project will be promptly and broadly disseminated, and that the products, technologies, materials, processes and other intellectual property resulting from the RSV project (collectively referred to as the funded developments) will be made available and accessible at an affordable price to people most in need within developing countries. These obligations survive any expiration or termination of the grant agreement.

To this end, the Company has granted to the Gates Foundation a non-exclusive, perpetual, irrevocable, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, modify, create derivative works, publicly perform and display the funded developments and, to the extent incorporated into a funded development or required to use a funded development, any other technology created outside of the RSV project that was used as part of the RSV project, for the benefit of people in developing countries. The Company has also agreed to seek prompt publication of data and results developed under the RSV project under "open access" terms and conditions. This license and these publication obligations survive any expiration or termination of the grant agreements.

During the year ended December 31, 2018, the Company recognized grant income of $1.1 million, under the August 2018 grant agreement with the Gates Foundation upon incurring qualifying expenses. Accordingly, unearned income under the August 2018 grant

agreement with the Gates Foundation was $0 as of December 31, 2018. The August 2018 grant agreement expired during the year ended December 31, 2018.

Gates Foundation Letter Agreement and Investment

In April 2017, the Company entered into a letter agreement with the Gates Foundation. In connection with the letter agreement, the Gates Foundation purchased 2,464,799 shares of the Company's Series D redeemable convertible preferred stock (the "Series D preferred stock"), which converted into 722,179 shares of the Company's common stock in connection with the IPO after giving effect to a one-for-3.4130 reverse-stock-split. The Company committed to use the proceeds of $8.0 million from the investment by the Gates Foundation solely to advance the development of a specified monoclonal antibody program that involves the monoclonal antibodies ASN-1, ASN-2 and ASN-3 and the Company's product candidate, ASN100. Under the letter agreement, in addition to the initial project funded by the Gates Foundation with its initial investment, the Company also agreed to conduct up to four additional projects to be proposed and to be funded by the Gates Foundation.

The letter agreement contains certain global access obligations as well as requirements relating to the Company's use of the funds received from the Gates Foundation investment. In the event that the Company fails to comply with these obligations or requirements or any related U.S. legal obligations set forth in the letter agreement, the Gates Foundation will have the right, after expiration of a specified cure period, to require the Company to redeem all of the shares owned by the Gates Foundation or to locate a third party that will purchase such shares. For any redemption or purchase resulting from such default, the shares of the Company's stock held by the Gates Foundation will be redeemed at an amount equal to the greater of the original purchase price (plus specified interest) or the fair market value of such stock on the date of such redemption. The term of the letter agreement continues in perpetuity.

In connection with this letter agreement, the Company has granted to the Gates Foundation and/or Gates Foundation-supported entities certain licenses, including a non-exclusive, non-terminable, royalty-free (except as required under the Adimab Collaboration Agreement), sublicensable license to products, technologies, materials, processes and other intellectual property developed using funds provided by the Gates Foundation or a Gates Foundation-supported entity, or developed in connection with the Company's conduct of any funded project or additional funded project, as well as all of the Company's background intellectual property, to utilize and exploit products and services directed at pathogens or other targets subject to any funded project or additional funded project.

The proceeds received from the Gates Foundation in connection with the Company's sale and issuance of Series D preferred stock were incurred on qualifying expenses under the letter agreement during the year ended December 31, 2017.

During the years ended December 31, 2018 and 2017, the Company incurred qualifying expenses of $0 and $8.0 million, respectively, under the letter agreement with the Gates Foundation.

Funding Agreements with FFG

Between September 2011 and March 2017, the Company entered into a series of funding agreements with FFG that provided for loans and grants to fund between 50% and 70% of qualifying research and development expenditures of the Company's subsidiary in Austria on a project-by-project basis, as approved by FFG.

FFG Grants

For grants under the funding agreements with FFG, the Company recognized grant income of $0 million, $0.2 million and $0.6 million during the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, the Company recorded grant receivables from FFG of $0.1 million and $0.1 million, respectively, for qualifying expenses incurred that were reimbursable under the funding agreements. As of December 31, 2018 and 2017, there were no amounts recorded as unearned income in connection with the FFG grants.

FFG Loans

Loans under the funding agreements with FFG bear interest at rates that are below market rates of interest. The Company accounts for the imputed benefit arising from the difference between a market rate of interest and the rate of interest charged by FFG as additional grant funding from FFG. On the date that FFG loan proceeds are received, the Company recognizes the portion of the loan proceeds allocated to grant funding as a discount to the carrying value of the loan and as unearned income, which is recognized as additional grant income over the term of the funding agreement.

The Company recognized grant income of $0.7 million, $0.6 million and $0.4 million during the years ended December 31, 2018, 2017, and 2016, respectively, related to the recognition of the unearned income recorded for the imputed benefit of FFG loans at

below-market interest rates. Unearned income (current) related to the imputed benefit of FFG loans at below-market interest rates was $0.7 million and $0.7 million as of December 31, 2018 and 2017, respectively, and unearned income (non-current) related to such benefit was $1.1 million and $1.9 million as of December 31, 2018 and 2017, respectively.

Research and Development Incentive

The Company participates in a research and development incentive program provided by the Austrian government whereby the Company is entitled to reimbursement by the Austrian government for a percentage of qualifying research and development expenses incurred by the Company's subsidiary in Austria. Under the program, the reimbursement rate for qualifying research and development expenses incurred by the Company through its subsidiary in Austria was 14%, 12% and 12% for the years ended December 31, 2018, 2017 and 2016, respectively.

The Company recognizes incentive income from Austrian research and development incentives when qualifying expenses have been incurred, there is reasonable assurance that the payment will be received, and the consideration can be reliably measured. Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each reporting date, management estimates the reimbursable incentive income available to the Company based on available information at the time.

The Company recognized incentive income of $1.4 million, $1.4 million and $1.4 million during the years ended December 31, 2018, 2017 and 2016, respectively, in connection with the Austrian research and development incentive program. As of December 31, 2018 and 2017, the Company recorded receivables for amounts due under the program of $2.7 million and $1.5 million, respectively, which amounts were included in grant and incentive receivables in the consolidated balance sheet.

8. Loans Payable

The aggregate principal amount of debt outstanding as of December 31, 2018 and 2017 consisted of the following (in thousands):

	December 31,	
	2018	2017
Term loans under 2012 Loan Agreement	$ —	$ 4,667
FFG Loans	9,738	10,225
	$ 9,738	$ 14,892

Current and non-current debt obligations reflected in the consolidated balance sheets as of December 31, 2018 and 2017 consisted of the following (in thousands):

	December 31,	
	2018	2017
Current liabilities:		
Term loans under 2012 Loan Agreement	$ —	$ 2,333
FFG loans	—	—
Unamortized debt discount	—	(19)
Loans payable, net of discount	—	2,314
Non-current liabilities:		
Term loans under 2012 Loan Agreement	$ —	$ 2,334
FFG loans	9,738	10,225
Unamortized debt discount	(1,844)	(2,637)
Loans payable, net of discount and current portion	7,894	9,922
Total loans payable, net of discount	$ 7,894	$ 12,236

2012 Loan Agreement

On December 7, 2012, the Company entered into a loan and security agreement (the "2012 Loan Agreement") with Silicon Valley Bank ("SVB"), and borrowed an aggregate of $2.5 million in two separate tranches: $0.5 million in December 2012 and $2.0 million in February 2013.

On February 19, 2016, the Company entered into the First Amendment to the 2012 Loan Agreement (the "First Amendment"). The First Amendment provided for two additional advances not to exceed, in the aggregate, $3.5 million, with each advance being for a minimum of $0.5 million, and total borrowings under the 2012 Loan Agreement not to exceed $7.0 million. The Company borrowed the full $7.0 million available in two separate tranches: $3.5 million in February 2016, and $3.5 million in August 2016. Following the August 2016 borrowing, no additional amounts remained available for borrowing under the 2012 Loan Agreement.

In connection with the 2012 Loan Agreement, between December 2012 and August 2016, the Company issued to SVB warrants to purchase an aggregate of 11,013 shares of Series A-2 redeemable convertible preferred stock (the "Series A-2 preferred stock") at an exercise price of $4.54 per share and warrants to purchase an aggregate of 14,502 shares of Series B redeemable convertible preferred stock (the "Series B preferred stock") at an exercise price of $7.24 per share. The warrants became exercisable in connection with the Company's borrowings under the 2012 Loan Agreement and are fully exercisable. The warrant to purchase shares of Series A-2 preferred stock expires on December 6, 2022, and the warrant to purchase shares of Series B preferred stock expires on February 18, 2026.

Upon the closing of the IPO in November 2017, the Series A-2 warrants converted into common stock warrants to purchase up to 3,940 shares of common stock at an exercise price of $12.70 per share. The Series B warrants converted into common stock warrants to purchase up to 6,474 shares of common stock at an exercise price of $16.22 per share. At December 31, 2018, these warrants to purchase up to 3,940 shares of common stock at an exercise price of $12.70 and 6,474 shares of common stock at an exercise price of $16.22 remained outstanding.

Borrowings under the 2012 Loan Agreement bore interest at a rate per annum equal to the greater of 3.25% and The Wall Street Journal prime rate, in each case minus 0.25%; provided, however, that in an event of default, as defined in the 2012 Loan Agreement, the interest rate applicable to borrowings under the agreement would be increased by 4.0%.

The Company was required to make monthly interest-only payments through December 1, 2016 and was required to make equal monthly payments of principal as well as accrued interest from January 1, 2017 through December 1, 2019, when all unpaid principal and interest would become due and payable. The Company had the right to voluntarily prepay all, but not less than all, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee, which ranged from 1% to 2% of the outstanding principal if paid prior to February 19, 2018, which was the second anniversary of the First Amendment effective date. The prepayment fee was 0% subsequent to the second anniversary of the First Amendment effective date. A final payment of $0.4 million was due upon the earlier to occur of the maturity of the loan or the prepayment of all outstanding principal.

Borrowings under the 2012 Loan Agreement were collateralized by a pledge of substantially all of the Company's assets other than intellectual property, including 65% of the outstanding capital stock of the Company's subsidiary in Austria. The 2012 Loan Agreement contained customary affirmative and negative covenants, including restrictions on the Company's ability to pay dividends and encumber the Company's intellectual property, but did not contain any financial covenants.

The Company was in compliance with all covenants under the 2012 Loan Agreement as of December 31, 2017. In March 2018, the Company entered into an Option and License Agreement with BB100, LLC, a subsidiary of Bravos Biosciences, LLC, under which BB100, LLC secured an exclusive, worldwide preclinical development license, and an option to a clinical development and commercialization license, to mAbs targeting *E. coli* that were discovered by the Company in its ASN200 program. In June 2018, the Company entered into an Option and License Agreement with BB200, LLC, a portfolio company of Bravos Biosciences, LLC, under which BB200, LLC secured an exclusive, worldwide preclinical development license, and an option to a clinical development and commercialization license to selected mAbs targeting *K. pneumoniae* that were discovered by the Company in its ASN300 program, including lead preclinical development candidate, ASN-5. As a result of entering into such Option and License Agreements without obtaining prior written consent of SVB, and subsequently delivering compliance certificates under the 2012 Loan Agreement that did not disclose these violations, the Company became in default under the 2012 Loan Agreement. On August 8, 2018, the Company and SVB entered into a Forbearance Agreement (the "Forbearance Agreement"), pursuant to which SVB agreed to forbear from exercising its rights and remedies with respect to such default until the earlier to occur of (i) another event of default under the 2012 Loan Agreement or (ii) October 31, 2018.

On October 31, 2018, the Company voluntarily remitted payment on its outstanding obligations under the 2012 Loan Agreement with SVB. Total outstanding obligations paid to SVB under the 2012 Loan Agreement on October 31, 2018 consisted of $2.7 million of principal, $0.4 million of final payment and less than $0.1 million of interest. All obligations under the 2012 Loan Agreement were satisfied by the Company on October 31, 2018.

The Company recognized interest expense under the 2012 Loan Agreement, as amended, of $0.3 million, $0.4 million and $0.3 million during the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, the unamortized debt discount was $0 and less than $0.1 million, respectively.

FFG Loans

In connection with the funding agreements with FFG, the Company received loans from FFG. Loans from FFG were made on a project-by-project basis and had an aggregate principal amount outstanding of $9.7 million and $10.2 million as of December 31, 2018 and 2017, respectively. Amounts due under the FFG loans bear interest at rates ranging from 0.75% to 2.0% per annum. As of December 31, 2018, before giving effect to the Settlement Agreement (as defined below), the loans matured at various dates between June 2020 and March 2023. Interest on amounts due under the loans is payable semi-annually in arrears, with all principal and remaining accrued interest due upon maturity.

In addition, the Company has recorded a discount to the carrying value of each FFG loan for the portion of the loan proceeds allocated to grant funding, which is being amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2018 and 2017, the unamortized debt discount related to FFG loans was $1.8 million and $2.6 million, respectively.

The Company recognized interest expense of $0.8 million, $0.7 million and $0.5 million during the years ended December 31, 2018, 2017 and 2016, respectively, related to the FFG loans. There were no principal payments due or paid under the FFG loans during the years ended December 31, 2018, 2017 and 2016.

In the event that the underlying program research results in a scientific or technical failure, the principal then outstanding under any loan may be forgiven by FFG and converted to non-repayable grant funding on a project-by-project basis. The FFG loans are not secured by any of the Company's assets.

As of December 31, 2018, the aggregate minimum future principal payments due in connection with the FFG loans are summarized as follows (in thousands):

Year Ending December 31,	
2019	$ —
2020	4,948
2021	3,931
2022	859
2023	—
	$ 9,738

FFG Settlement

On February 4, 2019, the Company and its wholly owned subsidiary, Arsanis Biosciences GmbH, received letters from counsel to FFG (see Note 20) alleging that they breached reporting, performance and other obligations in connection with the grants and loans made by FFG to Arsanis Biosciences GmbH between September 2011 and March 2017 to fund qualifying research and development expenditures (collectively, the "Subsidies").

The letters demanded the immediate repayment of all Subsidies, totaling approximately EUR 18.1 million ($20.4 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019), on or before February 19, 2019. The repayment amount consisted of approximately EUR 7.2 million ($8.1 million) for the reimbursement of grants previously received by the Company, approximately EUR 8.5 million ($9.6 million) for the repayment of outstanding loan principal and approximately EUR 2.4 million ($2.7 million) for assessed interest (collectively, the "FFG Demands"). FFG reserved all rights and remedies in connection with the Subsidies.

The Company is party to a series of Patronatserklärung ("parent-company support letters") for the benefit of Arsanis Biosciences GmbH under Austrian law, pursuant to which the Company has agreed to take certain steps including, in some instances, to maintain the ability of Arsanis Biosciences GmbH to pay its debts and liabilities, or to enable Arsanis Biosciences GmbH to meet its obligations and to prevent Arsanis Biosciences GmbH from becoming insolvent, subject to the terms and conditions set forth in the parent-company support letters.

On March 8, 2019, the Company, Arsanis Biosciences GmbH, X4 and Artemis AC Corp. ("Merger Sub"), a wholly owned subsidiary of the Company, entered into a settlement agreement (the "Settlement Agreement") with FFG in respect of the FFG Demands (see Note 20).

As the Company believes it was not in breach of its reporting, performance and other obligations as set forth by FFG, which resulted in FFG's demand for the immediate repayment of all Subsidies, the Company did not present such repayment amounts as current on the consolidated balance sheet for the year ended December 31, 2018.

9. Convertible Promissory Notes

2015 Notes

In December 2015, the Company issued an aggregate of $4.0 million of convertible promissory notes, or the 2015 Notes. The 2015 Notes accrued interest at a rate of 0.56% per annum, with a maturity date of December 16, 2016, unless earlier converted under the terms of the 2015 Notes. All principal and interest accrued under the 2015 Notes, totaling $4.0 million, was converted into 461,396 shares of Series C redeemable convertible preferred stock (the "Series C preferred stock") at a price equal to 90% of the $9.65 per share in April 2016.

2016 Notes

In April 2016, the Company issued an aggregate of $5.5 million of convertible promissory notes, or the 2016 Notes, which accrued interest at a rate of 0.7% per annum and had a maturity date of October 12, 2017, unless earlier converted under the terms of the 2016 Notes. All principal and interest accrued under the 2016 Notes, totaling $5.5 million, was automatically converted into 1,896,297 shares of Series D preferred stock at a price equal to 90% of $3.2457 per share in April 2017.

2017 Notes

In January 2017, the Company issued an aggregate of $4.9 million of convertible promissory notes, or the 2017 Notes. The 2017 Notes accrued interest at a rate of 0.96% per annum, with a maturity date of October 12, 2017, unless earlier converted under the terms of the 2017 Notes. All principal and interest accrued under the 2017 Notes, totaling $4.9 million, was automatically converted into 1,524,107 shares of Series D preferred stock at a price equal to $3.2457 per share in April 2017.

There were no outstanding convertible promissory notes as of December 31, 2018 and 2017.

10. Redeemable Convertible Preferred Stock

Series A-1 Redeemable Convertible Preferred Stock

In September 2010, the Company issued and sold 200,001 shares of Series A-1 redeemable convertible preferred stock (the "Series A-1 preferred stock" and, collectively with the Series A-2 preferred stock, the Series B preferred stock, the Series C preferred stock and the Series D preferred stock, the "Preferred Stock") at a price of $2.00 per share, for proceeds of $0.4 million, net of issuance costs of $27,000.

Series A-2 Redeemable Convertible Preferred Stock

In January 2011, the Company issued and sold 2,114,538 shares of Series A-2 preferred stock, at a price of $4.54 per share, for proceeds of $9.6 million, net of issuance costs of $8,000.

Series B Redeemable Convertible Preferred Stock

In July 2013, the Company issued and sold 1,795,580 shares of Series B preferred stock, at a price of $7.24 per share, for proceeds of $12.9 million, net of issuance costs of $68,000.

In May 2015, the Company issued and sold an additional 966,851 shares of Series B preferred stock, at a price of $7.24 per share, for proceeds of $7.0 million, net of issuance costs of $12,000.

Series C Redeemable Convertible Preferred Stock

In April 2016, the Company issued and sold 569,946 shares of Series C preferred stock, at a price of $9.65 per share, for proceeds of $5.4 million, net of issuance costs of $0.1 million. In addition, in connection with the issuance and sale of the Company's Series C preferred stock, all outstanding principal and accrued interest under the 2015 Notes was automatically converted into an aggregate of 461,396 shares of Series C preferred stock.

Series D Redeemable Convertible Preferred Stock

In April 2017, the Company issued and sold 10,799,880 shares of Series D preferred stock, at a price of $3.2457 per share, for proceeds of $34.8 million, net of issuance costs of $0.2 million. In addition, in connection with the Company's issuance and sale of Series D preferred stock, all of the outstanding principal and accrued interest under the 2016 Notes and 2017 Notes were automatically converted into an aggregate of 1,896,297 shares and 1,524,107 shares, respectively, of Series D preferred stock.

In addition, the Series D preferred stock purchase agreement provided that Company would use commercially reasonable efforts to sell up to an additional 1,540,508 shares of Series D preferred stock at a price of $3.2457 per share within 180 days of the initial Series D preferred stock closing. The Company concluded that its commitment to use commercially reasonable efforts to sell such shares did not represent a future tranche right of the holders of the Series D preferred stock and that no separate accounting was required related to such commitment.

In September 2017, the Company issued and sold 1,540,500 shares of Series D preferred stock, at a price of $3.2457 per share, for cash proceeds of $5.0 million, with no issuance costs.

Conversion to Common Stock

Upon the closing of the IPO, all of the outstanding shares of redeemable convertible preferred stock automatically converted into 7,180,483 shares of common stock. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding.

11. Common Stock

As of December 31, 2018 and 2017, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 200,000,000 shares of common stock and 10,000,000 shares of preferred stock, all with a par value of $0.001 per share.

As of December 31, 2018, each share of common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote. The holders of common stock are entitled to remove directors of the Company for cause by vote of at least 75% of the votes that all of the Company's stockholders would be entitled to cast in an annual election of the directors. In addition, the Company's bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to the Company's board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Company's board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to the Company's secretary of the stockholder's intention to bring such business before the meeting. Common stockholders are also entitled to receive dividends, as may be declared by the board of directors, if any. Through December 31, 2018, no dividends have been declared or paid.

As of December 31, 2018 and 2017, the Company had reserved 2,731,203 shares and 2,187,252 shares of common stock, respectively, for the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2017 Equity Incentive Plan and 2017 Employee Stock Purchase Plan and the exercise of outstanding warrants to purchase shares of common stock.

12. Stock-Based Compensation

2017 Equity Incentive Plan

The Company's 2017 Equity Incentive Plan (the "2017 Plan") provides for the grant by the Company of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Awards other than incentive stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company. Following the adoption of the 2017 Plan, no further grants will be made under the Company's 2010 Special Stock Incentive Plan ("Special Plan") and 2011 Stock Incentive Plan ("2011 Plan").

Upon its adoption, the number of shares of the Company's common stock initially reserved for issuance under the 2017 Plan was the sum of 585,994 shares, plus the number of shares of the Company's common stock available for issuance under the Special Plan and the 2011 Plan immediately prior to the effectiveness of the 2017 Plan. In addition, the number of shares of the Company's common stock subject to outstanding awards under the Special Plan and 2011 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right will be

available for future grant under the 2017 Plan. The number of shares of common stock reserved for issuance under this plan will automatically increase on January 1 of each year, through January 1, 2027, in an amount equal to the lowest of 1,025,490 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on January 1 of each year and an amount determined by the Company's board of directors.

The 2017 Plan is administered by the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant and the term of stock options may not be greater than 10 years. Stock options awarded under the 2017 Plan expire 10 years after the grant date, unless the board of directors sets a shorter term. Vesting periods for awards under the 2017 Plan are determined at the discretion of the board of directors. Incentive stock options granted to employees and restricted stock awards granted to employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over four years. Non-statutory options granted to employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over three or four years.

Shares that are expired, terminated, surrendered or canceled under the 2017 Plan without having been fully exercised will be available for future awards. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

2017 Employee Stock Purchase Plan

The Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP") provides participating employees with the opportunity to purchase shares of the Company's common stock at defined purchase prices over six month offering periods. A total of 219,748 shares were initially reserved for issuance under the 2017 ESPP. The number of shares of common stock reserved for issuance under this plan will automatically increase on January 1 of each year, beginning on January 1, 2019 and continuing through January 1, 2029, in an amount equal to the lowest of 512,745 shares of the Company's common stock, 2% of the number of shares of the Company's common stock outstanding on January 1 of each year and an amount determined by the Company's board of directors. During the year ended December 31, 2018, 637 shares of common stock were issued under the 2017 ESPP.

Stock Option Valuation

The assumptions that the Company used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.72%	1.96%	1.26%
Expected term (in years)	6.00	6.02	5.80
Expected volatility	77.4%	75.7%	75.3%
Expected dividend yield	0%	0%	0%

The Company recorded stock-based compensation expense for options granted to employees and directors of $5.6 million, $0.9 million and $0.6 million during the years ended December 31, 2018, 2017, and 2016, respectively.

The assumptions that the Company used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to non-employees in 2016 were as follows, presented on a weighted average basis:

	Year Ended December 31,
	2016
Risk-free interest rate	2.08%
Expected term (in years)	8.82
Expected volatility	77.8%
Expected dividend yield	0%

The Company did not grant any stock options to non-employees during the years ended December 31, 2018 and 2017. The Company recorded stock-based compensation expense for options granted to non-employees of $13,000, $7,000 and $15,000 during the years ended December 31, 2018, 2017 and 2016, respectively.

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2017 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	1,403,119	$ 6.26	8.81	$ 9,128
Granted	829,500	17.19		
Exercised	(27,226)	6.51		
Forfeited	(262,003)	12.11		
Outstanding as of December 31, 2018	1,943,390	$ 10.13	8.00	$ 49
Options exercisable as of December 31, 2018	1,053,481	$ 8.26	7.27	$ 49
Options unvested as of December 31, 2018	889,909	$ 12.35	8.86	$ —

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2018, 2017 and 2016 was $11.77, $3.62 and $6.02, respectively.

The total fair value of options vested during the year ended December 31, 2018 was $4.5 million, of which approximately $2.5 million relates to the modification of awards of the Company's former President and Chief Executive Officer and Chief Scientific Officer. The total fair value of options vested during the years ended December 31, 2017 and 2016 was $0.8 million and $0.5 million, respectively.

Restricted Common Stock

The Company has granted restricted common stock with time-based vesting conditions. The exercise price of the restricted stock awards is determined by the board of directors. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award. The Company has the option to repurchase the restricted stock awards at the original purchase price if the grantee terminates its working relationship with the Company prior to the stock becoming vested. The following table summarizes the Company's restricted common stock activity:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2017	—	—
Issued	250,000	$ 4.12
Vested	—	—
Unvested restricted common stock as of December 31, 2018	250,000	$ 4.12

The total expense related to employee and non-employee restricted stock for the years ended December 31, 2018, 2017, and 2016 was approximately $25,000, $0 and $1,000, respectively.

As of December 31, 2018, the Company had unrecognized stock-based compensation expense related to its employee and non-employee unvested restricted stock awards of $1.0 million which is expected to be recognized over a remaining weighted average vesting period of 3.9 years.

Stock-Based Compensation Expense

Stock-based compensation expense related to stock option awards, restricted common stock awards and the 2017 ESPP are classified in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development expenses	$ 1,079	$ 329	$ 294
General and administrative expenses	4,541	577	350
	$ 5,620	$ 906	$ 644

As of December 31, 2018 and 2017, total unrecognized compensation cost related to the unvested stock option awards, restricted common stock awards and the 2017 ESPP was $7.2 million and $4.0 million, respectively, which is expected to be recognized over weighted average periods of 2.78 years and 2.76 years, respectively.

13. License Revenue

Janssen License and Option Agreement

On December 12, 2018, the Company entered into a patent license and option agreement with Janssen Pharmaceuticals, Inc. (“Janssen”), (the “Janssen License and Option Agreement”). Pursuant to the Janssen License and Option Agreement, the Company granted to Janssen (i) a non-exclusive license to specified patents in the Company’s portfolio related to the ASN200 E. coli program, and (ii) an option for Janssen to acquire these patents in the future if specified conditions are met. Janssen agreed to pay the Company $3.5 million within 15 business days after the December 12, 2018 effective date of the Janssen License and Option Agreement, in addition to a future $0.5 million payment in the event Janssen exercises its option to acquire the relevant patents. The Company received the $3.5 million payment from Janssen in December 2018.

The Company assessed this arrangement in accordance with Topic 606 and concluded that at the date of contract inception, only one performance obligation, consisting of delivery of the license which was satisfied at contract inception, was identified. Accordingly, the entire nonrefundable license fee of $3.5 million was recognized as revenue upon contract execution given there were no other unsatisfied performance obligations in the arrangement as the time of contract inception. Because the single performance obligation was previously satisfied, Janssen’s option to the relevant patents will be recognized as revenue in full in the period in which the option exercise occurs. Janssen’s option to acquire such patents are not considered probable of being achieved until specified conditions are met. As the specified conditions are not within the Company’s control or the licensee’s control, this option is constrained and excluded from the transaction price until such time the conditions are met and Janssen exercises its option to acquire the relevant patents.

14. Income Taxes

During the years ended December 31, 2018, 2017 and 2016, the Company recorded no income tax benefits for the net operating losses incurred and research and development tax credits earned in each year or interim period, due to its uncertainty of realizing a benefit from those items. The Company’s losses before income taxes were generated in the United States and Austria.

Loss before the provision for income taxes for the years ended December 31, 2018, 2017 and 2016 consisted of the following (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	$ (32,022)	$ (24,618)	$ (12,969)
Foreign (Austria)	(10,999)	(9,259)	(10,006)
	$ (43,021)	$ (33,877)	$ (22,975)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2018	2017	2016
U.S. federal statutory income tax rate	(21.0)%	(35.0)%	(35.0)%
State income taxes, net of federal benefit	(4.5)	(3.5)	(2.8)
Foreign rate differential	(1.0)	1.6	3.2
Research and development tax credits	(0.5)	(0.4)	(1.0)
Nondeductible expenses	0.1	1.2	0.7
Uncertain tax position reserves	0.2	0.2	0.5
Stock-based compensation	0.7	0.5	0.3
Change in rates due to tax reform	—	16.5	—
Change in deferred tax asset valuation allowance	26.0	18.9	34.1
Effective income tax rate	— %	— %	— %

Net deferred tax assets as of December 31, 2018, 2017 and 2016 consisted of the following (in thousands):

	December 31,		
	2018	2017	2016
Net operating loss carryforwards	$ 26,519	$ 20,216	$ 13,134
Research and development tax credit carryforwards	493	317	264
Start-up costs	7,755	4,350	3,917
Accrued expenses and other	1,460	850	689
Total deferred tax assets	36,227	25,733	18,004
Valuation allowance	(36,227)	(25,733)	(18,004)
Net deferred tax assets	$ —	$ —	$ —

As of December 31, 2018, the Company had U.S. federal and state net operating loss carryforwards of $38.8 million (of which $14.5 million was generated in 2018 and has an indefinite life) and $34.9 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2031 and 2036, respectively. In addition, as of December 31, 2018, the Company had foreign net operating loss carryforwards of $64.7 million, which do not expire. As of December 31, 2018, the Company also had U.S. federal and state research and development tax credit carryforwards of $0.4 million and $0.1 million, respectively, which begin to expire in 2032 and 2031, respectively. As of December 31, 2018, uncertain tax position reserves recorded were $0.2 million for U.S. federal research and development tax credits and less than $0.1 million for state research and development tax credits.

Utilization of the U.S. net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the U.S. net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2018, 2017 and 2016. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2018, 2017 and 2016 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards and were as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Valuation allowance at beginning of year	$ (25,733)	$ (18,004)	$ (10,367)
Increases recorded to income tax provision	(10,494)	(7,729)	(7,637)
Valuation allowance at end of year	$ (36,227)	$ (25,733)	$ (18,004)

Changes in unrecognized tax benefits consisted of the following (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Unrecognized tax benefits at beginning of year	$ 192	$ 126	$ 21
Increases for tax positions taken in current year	94	66	105
Unrecognized tax benefits at end of year	$ 286	$ 192	$ 126

The Company’s U.S. federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2015 through December 31, 2017. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period. The Company’s policy is to record interest and penalties related to income taxes as part of its income tax provision.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act ("Tax Reform Legislation"), which made significant changes to U.S. federal income tax law. The Company expects that certain aspects of the Tax Reform Legislation will positively impact the Company’s future after-tax earnings in the U.S., primarily due to the lower federal statutory tax rate. Set forth below is a discussion of certain provisions of the Tax Reform Legislation and the Company’s assessment of the effect of such provisions on the Company’s results of operations, cash flows and consolidated financial statements.

Beginning January 1, 2018, the Company’s U.S. income is taxed at a 21 percent federal corporate rate. Further, the Company is required to recognize the effect of this rate change on its deferred tax assets and liabilities and deferred tax asset valuation allowances in the period the tax rate change is enacted. The Company does not expect any material non-cash impact from this rate change, with adjustments to deferred tax balances offset by adjustments to deferred tax valuation allowances. Further, the Tax Reform Legislation provides for a one-time “deemed repatriation” of accumulated foreign earnings for the year ended December 31, 2017. The Company does not expect to pay U.S. federal cash taxes on the deemed repatriation due to an accumulated deficit in foreign earnings for tax purposes. The Company does not expect that its future foreign earnings will be subject to U.S. federal income tax.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued, which allowed the Company to record provisional amounts during a measurement period not to exceed beyond one year of the enactment date. As a result, the Company previously provided a provisional estimate of the effect of the Tax Act in its results of operations, cash flows and consolidated financial statements. In the fourth quarter of 2018, the Company completed its analysis to determine the effect of the Tax Act and concluded no adjustments were necessary.

15. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net loss	$ (43,021)	$ (33,877)	$ (22,975)
Accretion of redeemable convertible preferred stock to redemption value	—	(44)	(25)
Net loss attributable to common stockholders	$ (43,021)	$ (33,921)	$ (23,000)
Denominator:			
Weighted average common shares outstanding—basic and diluted	14,307,934	2,061,845	513,527
Net loss per share attributable to common stockholders— basic and diluted	$ (3.01)	$ (16.45)	$ (44.79)

The Company's potentially dilutive securities, which include stock options, warrants to purchase shares of Preferred Stock and common stock, unvested restricted stock, convertible promissory notes and Preferred Stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2018	2017	2016
Options to purchase common stock	1,943,390	1,403,119	548,903
Restricted common stock	250,000	—	—
Redeemable convertible preferred stock (as converted to common stock)	—	—	1,789,704
Warrants to purchase common stock	10,414	10,414	—
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	—	—	7,475
	2,203,804	1,413,533	2,346,082

16. Commitments and Contingencies

Lease Agreements

In November 2010, the Company entered into a lease agreement for office, laboratory, parking and storage space in Vienna, Austria ("Vienna Lease"), which expires on April 30, 2021. The Company has the option to extend the lease agreement for an additional year. The Vienna Lease includes a rent escalation clause based on an inflation index. The Company provided a security deposit of approximately $0.3 million during the year ended December 31, 2010, which is included as a component of restricted cash on the Company's consolidated balance sheet as of December 31, 2018.

In July 2015, the Company entered into a lease agreement for an animal-use facility in Vienna, Austria ("Animal-use Lease"). The lease initially had a one-year noncancelable term, which expired in June 2016, after which the lease became cancelable by either party upon six months' prior written notice. Base rent for the Animal-use Lease is approximately $0.4 million annually, accordingly, rent expense is being recognized on a straight-line basis over the lease term.

On August 31, 2018 and in accordance with the terms of the Animal-use Lease, the Company provided the landlord with written notice that the lease agreement will terminate no later than February 28, 2019. As of March 1, 2019, the Company had vacated the animal-use facility and the Company's Animal-use Lease agreement with the landlord was terminated.

In November 2015, the Company entered into a lease agreement for office and laboratory space in Waltham, MA ("Waltham Lease"), which expired on January 31, 2019. The Waltham Lease includes a rent escalation clause, and accordingly, rent expense is being recognized on a straight-line basis over the lease term.

In June 2018, the Company entered into a lease agreement for office space in Waltham, MA ("Lease Agreement") with BP Bay Colony LLC (the "Lessor"). The Company amended the Lease Agreement in August 2018 ("Amended Lease Agreement"). Under the terms of the Amended Lease Agreement, the Company will relocate its Waltham, MA office to a new location with 5,711 square feet of office space as compared to the 10,290 square feet premises in the original Lease Agreement. The term of the Amended Lease Agreement commences on January 1, 2019 (the "Commencement Date") and expires approximately five years from the Commencement Date. The Company has the option to extend the term for one additional five-year period upon the Company's written notice to the Lessor at least nine months and no more than 12 months in advance of the extension. Base rent is approximately $0.3 million annually, accordingly, rent expense will be recognized on a straight-line basis over the lease term. In addition to the base rent, the Company is also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the Amended Lease Agreement. The Company provided a security deposit of approximately $0.3 million during the year ended December 31, 2018, which is included as a component of restricted cash on the Company's consolidated balance sheet as of December 31, 2018.

The Company recognizes rent expense over the respective lease period and has recorded deferred rent for rent expense incurred but not yet paid.

The Company recorded rent expense of $1.3 million, $1.2 million and $1.2 million during the years ended December 31, 2018, 2017, and 2016, respectively.

The following table summarizes the future minimum lease payments due under the Company's operating leases as of December 31, 2018 (in thousands):

Year Ending December 31,		
2019	$	884
2020		789
2021		438
2022		263
2023		263
	$	2,637

License Agreements

The Company entered into the Adimab Option Agreement in February 2017 under which it is obligated to make contingent and non-contingent payments should the Company exercise its option to obtain rights to certain RSV antibodies (see Note 5). If the Company chose to exercise its option, it would be obligated to pay Adimab an option fee of $0.3 million and make clinical and regulatory milestone payments of up to $24.4 million, as well as royalty payments on a product-by-product and country-by-country basis of a mid single-digit percentage based on net sales by the Company, its affiliates, licensees or sublicensees of products based on certain RSV antibodies during the applicable term for such product in that country. The Company may choose to exercise its option under the terms of the Adimab Option Agreement at any time on or before August 31, 2019. As of December 31, 2018 and 2017, the Company had not exercised its option under the Adimab Option Agreement.

Manufacturing Commitments

In July 2016, the Company entered into an agreement with Boehringer Ingelheim International GmbH ("BI"), a contract manufacturing organization, for the manufacture and supply of ASN100 drug product for the Company's completed Phase 1 and discontinued Phase 2 clinical trials. In March 2016, the Company entered into an agreement with Cytovance Biologics, Inc. ("Cytovance") for process development and the manufacture and supply of ASN100 drug product. Under such agreements, the Company is obligated to pay BI and Cytovance development and manufacturing milestones, in addition to reimbursement of certain material production-related costs. Additionally, the Company is required to make prepayments for process development services and manufacture and delivery of ASN100 material. The terms of these agreements require future delivery and formal acceptance of the clinical material upon delivery from BI and Cytovance. Formal acceptance includes validation of the clinical material and that established specifications have been met and good manufacturing practices, or GMP, standards have been followed during the manufacture of the material. It is only after acceptance that title and risks and rewards of ownership pass to the Company and at that time advance payments will be applied to the purchase of clinical materials required to be produced under the agreements. The purchase of the clinical material will, at the point of delivery, be charged to research and development expense. The Company's policy is to expense research and development costs as incurred (i.e., as services are provided by the Company's vendors or as qualifying materials are delivered).

As of December 31, 2018, BI and Cytovance have completed the development activities and manufacturing of ASN100 drug product, accordingly, the Company expensed all advance payments previously made to BI and Cytovance and accrued for any final payments owed. All commitments and obligations under the manufacture and supply agreements pertaining to the workorders with BI and Cytovance for the delivery of the clinical materials were met by BI, Cytovance and the Company as of December 31, 2018.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2018, 2017 or 2016.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

17. Related Party Transactions

Agreements with Adimab, LLC

In May 2011, the Company entered into the Adimab Collaboration Agreement with Adimab. The chairman of the Company's board of directors is a co-founder of Adimab and currently serves as Adimab's Chief Executive Officer. During the years ended December 31, 2018, 2017 and 2016, the Company made payments to Adimab of $0, $0 and $0.1 million, respectively, under the Adimab Collaboration Agreement. During the years ended December 31, 2018, 2017 and 2016, the Company recognized research and development expense of $0, $0 and $8,000, respectively, in connection with the Adimab Collaboration Agreement. As of December 31, 2018 and 2017, no amounts were due to Adimab under the Adimab Collaboration Agreement.

In February 2017, the Company entered into the Adimab Option Agreement with Adimab. During the years ended December 31, 2018 and 2017, the Company made payments to Adimab of $0.1 million and $0.1 million, respectively, under the Adimab Option Agreement. The Company recognized $0.1 million and $0.1 million during the years ended December 31, 2018 and 2017, respectively, of research and development expense under the Adimab Option Agreement. As of December 31, 2018 and 2017, the Company owed $0 and $21,000 to Adimab under the Adimab Option Agreement.

Services and Facilities Agreement with EveliQure Biotechnologies GmbH

The Company's wholly owned subsidiary, Arsanis Biosciences GmbH, leases office and lab space in Vienna, Austria from a third party. In February 2015, Arsanis Biosciences GmbH entered into a services and facilities agreement with EveliQure Biotechnologies GmbH ("EveliQure") under which the Company provided certain laboratory services and sublet office and lab space to EveliQure. Tamas Henics, the husband of Eszter Nagy, the Company's former Chief Scientific Officer, serves as Chief Scientific Officer at EveliQure.

On June 28, 2018 and in accordance with the terms of this agreement with EveliQure, the Company provided EveliQure with written notice that the services and facilities agreement will terminate and EveliQure will vacate the sublet space no later than December 31, 2018. As of December 31, 2018, the Company had vacated the office and lab space and the Company's services and facilities agreement with EveliQure was terminated.

During the years ended December 31, 2018, 2017 and 2016, the Company received payments from EveliQure under the agreement of $0.2 million, less than $0.1 million and less than $0.1 million, respectively. During the years ended December 31, 2018, 2017 and 2016, the Company recognized other income under the agreement of $0.1 million, $0.1 million and less than $0.1 million, respectively. As of December 31, 2018 and 2017, amounts due from EveliQure total less than $0.1 million and $0.1 million, respectively.

18. 401(k) Savings Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Company's board of directors. The Company made no contributions to the plan during the years ended December 31, 2018, 2017 and 2016.

19. Selected Quarterly Financial Information (Unaudited)

Selected quarterly results from operations for the years ended December 31, 2018 and 2017 are as follows:

	2018 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	$ —	$ —	$ —	$ 3,500
Operating Expenses	10,950	12,616	12,847	12,972
Net Loss	(10,630)	(12,133)	(10,900)	(9,358)
Basic and diluted net loss per common share	$ (0.74)	$ (0.85)	$ (0.76)	$ (0.65)

	2017 Quarter Ended			
	March 31	June 30	September 30	December 31
Operating Expenses	$ 5,827	$ 5,644	$ 13,056	$ 11,606
Net Loss	(5,385)	(5,705)	(11,600)	(11,187)
Basic and diluted net loss per common share	$ (10.49)	$ (11.13)	$ (22.60)	$ (1.68)

20. Subsequent Events

FFG Settlement

On February 4, 2019, the Company and its wholly owned subsidiary, Arsanis Biosciences GmbH, received letters from counsel to FFG (see Notes 2, 7 and 8) alleging that they breached reporting, performance and other obligations in connection with the grants and loans made by FFG to Arsanis Biosciences GmbH between September 2011 and March 2017 to fund qualifying research and development expenditures (collectively, the "Subsidies").

The letters demanded the immediate repayment of all Subsidies, totaling approximately EUR 18.1 million ($20.4 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019), on or before February 19, 2019. The repayment amount consisted of approximately EUR 7.2 million ($8.1 million) for the reimbursement of grants previously received by the Company, approximately EUR 8.5 million ($9.6 million) for the repayment of outstanding loan principal and approximately EUR 2.4 million ($2.7 million) for assessed interest (collectively, the "FFG Demands"). FFG reserved all rights and remedies in connection with the Subsidies.

The Company is party to a series of Patronatserklärung ("parent-company support letters") for the benefit of Arsanis Biosciences GmbH under Austrian law, pursuant to which the Company has agreed to take certain steps including, in some instances, to maintain the ability of Arsanis Biosciences GmbH to pay its debts and liabilities, or to enable Arsanis Biosciences GmbH to meet its obligations and to prevent Arsanis Biosciences GmbH from becoming insolvent, subject to the terms and conditions set forth in the parent-company support letters.

On March 8, 2019, the Company, Arsanis Biosciences GmbH, X4 and Artemis AC Corp. ("Merger Sub"), a wholly owned subsidiary of the Company, entered into a settlement agreement (the "Settlement Agreement") with FFG in respect of the FFG Demands.

Pursuant to the terms of the Settlement Agreement, in exchange for FFG's waiver of all claims against the Company and Arsanis Biosciences GmbH except for its claims for repayment of the loans and regular interest, including its waiver of claims for repayment of grants and interest exceeding regular interest, subject to compliance by the Company and Arsanis Biosciences GmbH with the terms of the Settlement Agreement, Arsanis Biosciences GmbH has agreed to repay the outstanding loan principal equal to EUR 8,505,204 ($9.5 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019) (plus regular interest accrued thereon) on an accelerated payment schedule of three years instead of five years, with the final accelerated installment due and payable on June 30, 2021. The parties have also agreed that (i) the portion of such loans to be repaid in 2019 is EUR 2,596,320 ($2.9 million, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019) (the "2019 Payment") and such payment will be

made on March 31, 2019, (ii) until all of the loans have been repaid and subject to other terms specified in the Settlement Agreement, a minimum cash balance equal to 70% of the then-outstanding principal amount of the loans will be maintained at Arsanis Biosciences GmbH in an account held with an Austrian bank (the "minimum cash requirement"), (iii) at least until December 31, 2021 and subject to other terms specified in the Settlement Agreement, Arsanis Biosciences GmbH will maintain a physical premises in Austria with a minimum of eight full-time equivalent employees, retain ownership rights to intellectual property ("IP") which generated or may be generated (if any) from or in relation to the projects that are subject to the subsidy agreements with FFG in Austria, and to the extent that it licenses such IP to any third party it will receive arm's length compensation as consideration and (iv) Arsanis Biosciences GmbH will comply with specified quarterly financial reporting obligations. The Company agreed (i) to procure the timely transfer of sufficient funds to Arsanis Biosciences GmbH to ensure the minimum cash requirement is met, (ii) to use its best efforts to enable Arsanis Biosciences GmbH to comply with specified obligations and (iii) to refrain from any instructions and measures that might endanger compliance with the specified obligations. X4 and Merger Sub agreed (i) to use commercially reasonable efforts to enable Arsanis Biosciences GmbH and the Company to comply with their above-mentioned obligations and (ii) to refrain from any instructions and measures that might endanger compliance with such specified obligations. If the Company or Arsanis Biosciences GmbH breaches specified obligations under the Settlement Agreement (and fails to cure such breach during any applicable grace period), FFG is entitled to accelerate the repayment of any outstanding loans. In addition, subject to the fulfillment of Arsanis Biosciences GmbH's obligations and commitments under the Settlement Agreement, FFG has agreed that effective as of December 31, 2021, it will release the parties, as applicable, from all obligations and claims arising in relation to the subsidies and their commitments provided under the Settlement Agreement and under other documents in favor of Arsanis Biosciences GmbH, as in effect as of the date of the Settlement Agreement.

As the Company believes it was not in breach of its reporting, performance and other obligations as set forth by FFG, which resulted in FFG's demand for the immediate repayment of all Subsidies, the Company did not present such repayment amounts as current on the consolidated balance sheet for the year ended December 31, 2018.

Merger Agreement Amendment

In connection with the Settlement Agreement, on March 8, 2019, the Company, Merger Sub and X4 entered into a Second Amendment to Agreement and Plan of Merger (the "Merger Agreement Amendment") to the Merger Agreement.

Pursuant to the Merger Agreement Amendment, the Company and X4 have agreed to amend the terms of their previously announced Merger Agreement to reflect the Company's agreement that 1/3rd of the 2019 Payment, which equals EUR 865,440 (approximately $968,600, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019) (the "Arsanis accelerated payment amount"), would be deducted from the Company's "net cash" at closing (as defined in the Merger Agreement) and as a result would increase the exchange ratios for the X4 common stock and X4 preferred stock in the merger. Specifically, the Merger Agreement currently excludes the approximately EUR 8.5 million principal amount of FFG loans to Arsanis Biosciences GmbH from the deduction for unpaid indebtedness that otherwise reduces the Company's "net cash" at closing. The Merger Agreement Amendment provides that this excluded amount (and thus "net cash") be reduced by the Arsanis accelerated payment amount, to approximately EUR 7.6 million.

Lease Termination Agreement and Sublease Agreement

On February 26, 2019, Arsanis Biosciences GmbH entered into a lease termination agreement (the "Termination Agreement") effective as of February 28, 2019, with Wüstenrot Marxbox GmbH & Co OG (the "Landlord") to terminate the lease dated November 26, 2010, by and between the Landlord (as successor-in-interest to Marxbox Bauprojekt GmbH & Co. OG) and Arsanis Biosciences GmbH for its facility in Vienna, Austria (the "Lease"). The Termination Agreement was conditioned upon a new tenant, Hookipa Biotech GmbH ("Hookipa"), entering into a binding agreement to lease a portion of the premises subject to the Lease. Hookipa entered into its lease effective as of March 1, 2019.

In consideration for the termination of the Lease, Arsanis Biosciences GmbH agreed to make a lump sum payment to the Landlord in the amount of EUR 45,000 (approximately $50,600, based on an exchange rate of US$1.12 per EUR 1.00 on March 7, 2019), plus 20% value-added tax, in full satisfaction of its obligations under the Lease.

In connection with the Lease Termination Agreement, Arsanis Biosciences GmbH also entered into a sublease agreement with Hookipa, dated as of February 25, 2019, pursuant to which Arsanis Biosciences GmbH agreed to sublease approximately 400 square meters of the premises subject to the original Lease from Hookipa with a term beginning on March 1, 2019 (the "Sublease"), to be used for laboratory and office space. The Sublease has a term of two years and is terminable by Arsanis Biosciences GmbH upon three months' notice. The monthly rent for the Sublease is approximately EUR 11,400 ($12,800, based on an exchange rate of US$1.12 per

EUR 1.00 on March 7, 2019). In addition, Arsanis Biosciences GmbH agreed to sell certain laboratory equipment and office furniture to Hookipa.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-229377) and Form S-8 (Nos. 333-221622, 333-223539) of Arsanis, Inc. of our report dated March 11, 2019 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, MA
March 11, 2019

CERTIFICATIONS

I, Michael Gray, certify that:

1. I have reviewed this Annual Report on Form 10-K of Arsanis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluation the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2019

/s/ Michael Gray

Michael Gray
President and Chief Executive Officer, Chief Financial Officer
(principal executive officer and principal financial and accounting officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Arsanis, Inc. (the "Company") for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Gray, President, Chief Executive Officer and Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2019

/s/ Michael Gray
Michael Gray
President and Chief Executive Officer, Chief Financial Officer
(principal executive officer and principal financial and accounting officer)