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Filed Pursuant to Rule 424(b)(1)  
Registration No. 333-221050

## PROSPECTUS

## 4,000,000 Shares



This is an initial public offering of common stock by Arsanis, Inc. We are selling 4,000,000 shares of common stock. The initial public offering price is \$10.00 per share.

We have granted the underwriters an option to purchase up to 600,000 additional shares of common stock to cover over-allotments, if any.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol "ASNS."

### Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page 11 of this prospectus.

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

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

	<u>Per share</u>	<u>Total</u>
Initial public offering price	\$ 10.00	\$40,000,000
Underwriting discounts and commissions <sup>(1)</sup>	\$ 0.70	\$ 2,800,000
Proceeds to Arsanis, before expenses <sup>(2)</sup>	\$ 9.30	\$37,200,000

<sup>(1)</sup> We refer you to "Underwriting" beginning on page 179 for additional information regarding underwriter compensation.

<sup>(2)</sup> Total gross proceeds from this offering and the concurrent private placement to New Enterprise Associates 16, L.P. are \$60,000,000. Such proceeds less underwriting discounts and commissions and placement agent fees are \$55,800,000.

Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

In addition, New Enterprise Associates 16, L.P. has agreed to purchase 2,000,000 shares of our common stock at the initial per share public offering price in a private placement expected to close concurrently with this offering. The underwriters for this offering will serve as placement agents for such concurrent private placement and will receive a placement agent fee that will be a percentage of the total purchase price of the private placement shares equal to the percentage discount the underwriters will receive on shares sold in this offering. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

The underwriters expect to deliver the shares of common stock to purchasers on or about November 20, 2017.

**Citigroup**

**Cowen**

**Piper Jaffray**

November 15, 2017

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We are responsible for the information contained in this prospectus. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

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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 prospectus are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this prospectus 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.

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### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Unless the context otherwise requires, we use the terms “company,” “we,” “us” and “our” in this prospectus to refer to Arsanis, Inc. and our wholly owned subsidiary.

#### Overview

We are a clinical-stage biopharmaceutical company focused on applying monoclonal antibody immunotherapies to address serious infectious diseases. Monoclonal antibodies, or mAbs, are a well-established therapeutic class across many disease areas; however, they have yet to be broadly utilized for the prevention or treatment of acute bacterial and viral infections, where they hold the potential to address serious unmet medical needs. Unlike antibiotics that propagate resistance, disrupt both disease-causing and beneficial bacteria and have adverse off-target effects, mAbs have the ability to precisely bind only to an intended target, thereby avoiding these undesired consequences. Our expertise lies in applying our deep understanding of infectious disease pathogenesis paired with our ability to access some of the most advanced mAb discovery techniques and platforms available today. We have used this expertise to discover and develop novel mAbs with multiple mechanisms of action and high potency against their intended targets.

Our lead product candidate, ASN100, is a first-in-class mAb therapeutic in Phase 2 clinical development for the prevention of *Staphylococcus aureus*, or *S. aureus*, pneumonia in high-risk, mechanically ventilated patients, a potentially life-threatening and costly infection for which there are no approved preventive therapies. ASN100 is a fully human mAb product candidate that we developed specifically to neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis, a scientific advancement that has not previously been achieved. Given its unique mechanism of action, we believe that ASN100 could improve the standard of care for mechanically ventilated patients who are heavily colonized with *S. aureus* and are therefore at high risk of developing life-threatening pneumonia. In addition to ASN100, our preclinical pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus, or RSV.

#### Our Pipeline

The following chart summarizes information about our product candidates and programs:

Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Key Commentary and Next Anticipated Milestones	
<b>ASN100</b>	<b><i>Staphylococcus aureus</i></b> Prevention of pneumonia in high-risk, mechanically ventilated patients						1H18: Phase 2 trial power analysis results 2H18: Phase 2 trial top-line safety and efficacy results
<b>ASN500</b>	<b>Respiratory Syncytial Virus</b> Prevention of RSV infection						2019: Phase 1 trial initiation
<b>ASN300</b>	<b><i>Klebsiella pneumoniae</i></b> Prevention and treatment of bacterial infections						Lead candidate selected Seeking external funding
<b>ASN200</b>	<b><i>Escherichia coli</i></b> Prevention and treatment of bacterial infections						Lead candidate selected Seeking external funding

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[Table of Contents](#)**Our Strategy**

Our goal is to be a leader in the discovery, development and commercialization of monoclonal antibody immunotherapies for serious infectious diseases. Our strategy includes the following key components:

- rapidly advance our lead product candidate, ASN100, through clinical development and regulatory approval;
- apply our expertise in *S. aureus* pathogenesis to expand the indications for ASN100;
- pursue a rapid development strategy for advancing ASN500 into clinical trials;
- maximize the global commercial value of ASN100 and ASN500; and
- advance our early-stage pipeline.

***S. aureus* in Mechanically Ventilated Patients**

*S. aureus* is the leading cause of pneumonia in mechanically ventilated patients in the United States and the second leading cause of pneumonia in this patient population in Europe. Mechanical ventilation is used to assist or replace spontaneous breathing in patients who need respiratory support while recovering from medical conditions, surgical procedures or traumatic events. The endotracheal tube used to deliver oxygen from a ventilator to a patient's lungs serves as a conduit through which *S. aureus* and other pathogens can readily transit from the patient's normal microflora and external environment to invade and persist in the lungs. There are more than one million mechanically ventilated patients in the United States each year. Based on published epidemiology data, up to approximately 20% of mechanically ventilated patients become heavily colonized with *S. aureus* in their respiratory secretions, putting them at high risk of progressing to *S. aureus* pneumonia, which occurs at a rate of approximately 30% to 40% in this patient population, even when best-available prevention strategies are used. Despite the availability of antibiotic treatments, outcomes of ventilator-associated pneumonia, or VAP, are poor, with high mortality rates and incremental hospital costs of approximately \$40,000 per case. Given the serious outcomes associated with VAP, costly time- and resource-intensive prevention strategies are routinely employed in intensive care units, or ICUs. These activities can take up to four hours of nursing time per patient per day and interfere with other critical patient care activities. There are currently no therapeutic options for proactively addressing this serious infection.

**Key Advantages of ASN100**

We believe ASN100 has the potential to improve the standard of care for *S. aureus* pneumonia in mechanically ventilated patients from suboptimal prevention and treatment to efficient and effective pre-emptive therapy. Moreover, given its product profile, ASN100 aligns well with accepted preventive hospital quality measures and antimicrobial stewardship efforts to reduce infections and antibiotic use. We believe that the following key attributes of ASN100 differentiate it from existing therapies.

- **First-in-class therapeutic with novel mechanism of action.** ASN100 is the first and only therapy in development that neutralizes all six of the cytotoxins critical to the pathogenesis of *S. aureus* pneumonia.
- **Mitigates the risk of resistance.** ASN100 precisely and specifically targets *S. aureus* cytotoxins and not the bacteria directly, thereby potentially reducing the emergence and propagation of resistant bacterial strains.
- **Well tolerated with no off-target effects.** In a Phase 1 clinical trial, ASN100, a fully human mAb product candidate, was well tolerated with no dose-limiting toxicities observed. The precise nature of ASN100's mechanism to specifically target and neutralize *S. aureus* cytotoxins also allows the patient's healthy microbiome to remain unaffected by this therapy.
- **Clinical trials designed for superiority.** Unlike many clinical trials of antibiotics that are designed to demonstrate non-inferiority, our ASN100 Phase 2 clinical trial has been designed to demonstrate

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superiority to placebo. In the first half of 2018, we plan to have an independent data review committee conduct an interim analysis to assess the probability that the trial will succeed as currently designed. We expect that any Phase 3 clinical trial of ASN100 will be similarly designed for superiority.

- **One-time dosing and seamless integration with current preventive practices.** ASN100 is being developed as a single dose to protect a targeted set of patients who are at high risk for *S. aureus* pneumonia. We believe that ASN100 has the potential to be easily integrated into, and to improve the effectiveness of, current inefficient and inadequate preventive approaches.
- **Positive impact on health-economic and quality metrics.** We believe that ASN100 has the potential to show a meaningful and quantifiable impact on important health-economic and hospital quality metrics such as a reduction in *S. aureus* pneumonia rates and related lengths of ICU stay and days on mechanical ventilation.

### **ASN100 Clinical Trials**

In early 2017, we initiated a Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. We plan to enroll 354 patients in this double-blind, placebo-controlled superiority trial. The primary endpoint is the proportion of patients who develop *S. aureus* pneumonia during the 21-day period following a single dose of ASN100 as compared to placebo. The superiority design of the trial differs from traditional antibiotic trials, which are consistently designed to demonstrate non-inferiority compared to the applicable standard of care. We are in the early stages of this Phase 2 clinical trial and have only recently begun to dose patients. In the first half of 2018, by which we expect approximately one-third of the 354 total target patients will have been dosed and assessed through 21 days following dosing, we plan to have an independent data review committee conduct an interim analysis to assess the probability that the trial will succeed as designed. The analysis will either confirm the assumptions underlying our trial design, resulting in a recommendation that we continue the trial as designed, recommend an increase in the total number of patients to be dosed or advise that the trial is unlikely to be successful. We will remain blinded to the data and calculations underlying the analysis and will only receive recommendations on how to proceed. Assuming that this analysis does not identify any recommended changes in the number of patients to be enrolled and recommends that the trial continue, we expect to report top-line efficacy results from completion of the trial in the second half of 2018. Assuming positive top-line safety and efficacy results from our Phase 2 clinical trial, we expect to use these data to design a pivotal Phase 3 clinical trial as well as inform the potential clinical development of ASN100 in additional indications.

We have completed a Phase 1 dose-ranging trial in 52 healthy volunteers, in which 18 of these healthy volunteers received ASN100 at doses equivalent to or greater than the Phase 2 clinical trial dose. ASN100 was well tolerated across all doses tested, including doses greater than twice the Phase 2 clinical trial dose, 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. Based on these results, we believe that a single preventive dose of ASN100 may be able to safely neutralize *S. aureus* cytotoxins and prevent pneumonia in high-risk, mechanically ventilated patients.

### **ASN500**

Our second program, ASN500, targets RSV, a virus that afflicts in aggregate over two million young children and elderly and immunocompromised patients annually in the United States, and can cause serious respiratory tract infections. We are currently evaluating mAbs that have exhibited exceptionally high potency against RSV in a laboratory setting, which may support development of a preventive therapy for use in numerous high-risk patient populations not addressed by the currently approved therapy. We expect to advance this mAb into Phase 1 clinical trials in 2019.

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[Table of Contents](#)**ASN300 and ASN200**

Our Gram-negative programs, ASN300 for *Klebsiella pneumoniae* and ASN200 for *Escherichia coli*, apply a precise and multi-modal mAb approach against novel targets to allow for potential use in both preventive and treatment settings, with a goal of providing safe and effective alternatives to small molecule antibiotics, particularly against multi-drug resistant strains. We have selected lead development candidates for our ASN300 and ASN200 programs based on data generated in *in vitro* assays, *in vivo* infection models, manufacturability assessments and toxicology studies. In these studies, we have observed, among other things, activity of these product candidates in *in vivo* models of infection prevention and, with respect to ASN200, potentiation of antibiotic effect in *in vitro* assays. We are currently conducting preclinical studies to further characterize the mechanisms of action of these product candidates and discover biomarkers that may help identify high-risk patient populations to support future clinical development. We are currently seeking external funding to further the preclinical and future potential clinical development of these programs.

**Leadership**

Our efforts are led by a proven management team that has highly relevant industry experience in the discovery, development and commercialization of over 20 marketed anti-infective drugs and biologics at companies such as Cubist Pharmaceuticals, a leading anti-infective company that was acquired by Merck in 2015, and Bristol-Myers Squibb. Our programs are further supported by the expertise of our founding scientists, who are widely recognized experts in mAb discovery, and the capabilities of our broader scientific team, which span immunology, bacterial and viral pathogenesis and monoclonal antibody drug discovery.

**Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history. We have incurred significant losses since inception and, as of September 30, 2017, we had an accumulated deficit of \$81.1 million. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.
- Even if this offering is successful, we will not have sufficient funding to complete the clinical development of ASN100, including any pivotal Phase 3 clinical trial. Accordingly, we will need to raise 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.
- 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.
- In the near term, we are dependent on the success of ASN100, which is in clinical development. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize ASN100, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.
- Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes.
- We rely and expect to continue to rely on third parties to conduct our clinical trials and 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.

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- Our reliance on third parties to manufacture our product candidates increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- 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 our products and technology may be adversely affected.
- Our rights to develop and commercialize our 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.
- 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 our product candidates, our business will be substantially harmed.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- After this offering, our executive officers, directors and principal stockholders will beneficially own a significant percentage of our outstanding shares of capital stock. In addition, five of our directors are affiliated with our principal stockholders. If these stockholders were to act together, they would be able to control all matters submitted to our stockholders for approval.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.

**Concurrent Private Placement**

New Enterprise Associates 16, L.P., or NEA, has agreed to purchase 2,000,000 shares of our common stock at the initial per share public offering price in a private placement expected to close concurrently with this offering. The shares sold in the concurrent private placement will constitute restricted securities under the Securities Act of 1933, as amended. The underwriters for this offering will serve as placement agents for such concurrent private placement and will receive a placement agent fee that will be a percentage of the total purchase price of the private placement shares equal to the percentage discount the underwriters will receive on shares sold in this offering. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

**Our Corporate Information**

We were incorporated under the laws of the state of Delaware on August 2, 2010 under the name Arsanis, Inc. Our principal executive offices are located at 890 Winter Street, Suite 230, Waltham, Massachusetts 02451, and our telephone number is (781) 819-5704. Our website address is [www.arsanis.com](http://www.arsanis.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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[Table of Contents](#)**Implications of Being an Emerging Growth Company**

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. As a result, we may take advantage of reduced reporting requirements that are otherwise applicable to public companies, including delaying auditor attestation of internal control over financial reporting, providing only two years of audited financial statements and related Management’s Discussion and Analysis of Financial Condition and Results of Operations and reducing executive compensation disclosures.

We may remain an emerging growth company for up to five years from the date of the first sale in this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenue exceeds \$1.07 billion, or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests. However, we have irrevocably elected not to avail ourselves of the extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.



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<b>THE OFFERING</b>	
Common stock offered in this offering	4,000,000 shares (approximately 29.2% (or 32.2% if the underwriters exercise in full their option to purchase additional shares of common stock to cover over-allotments, if any) of the shares of our common stock to be outstanding immediately following this offering and the concurrent private placement)
Common stock offered in the concurrent private placement	NEA has agreed to purchase 2,000,000 shares of our common stock at the initial per share public offering price of \$10.00 per share in a private placement expected to close concurrently with this offering.
Common stock to be outstanding immediately following this offering assuming completion of the concurrent private placement	13,694,383 shares
Over-allotment option	600,000 shares
Use of proceeds	We estimate that the net proceeds from this offering will be \$34.2 million (or approximately \$39.8 million if the underwriters exercise in full their option to purchase up to 600,000 additional shares of common stock to cover over-allotments, if any), based on the initial public offering price of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. In addition, we expect to receive net proceeds of \$18.6 million from the sale of shares of common stock to NEA in the concurrent private placement, after deducting placement agent fees payable by us. We intend to use the net proceeds from this offering and net proceeds from the concurrent private placement, if any, together with our existing cash, to fund the development of ASN100 for the prevention of <i>S. aureus</i> pneumonia in mechanically ventilated patients, to fund the development of ASN100 for other indications, to advance our current pipeline of preclinical candidates and to research and develop additional preclinical product candidates and for working capital and other general corporate purposes. See “Use of Proceeds.”
Risk factors	You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Global Market symbol	“ASNS”

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The number of shares of our common stock to be outstanding after this offering, assuming completion of the concurrent private placement, is based on 513,900 shares of our common stock outstanding as of September 30, 2017, and excludes:

- 1,197,120 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2017, at a weighted average exercise price of \$5.61 per share;
- 760,005 shares of common stock available for future issuance under our 2017 Equity Incentive Plan;
- 219,748 shares of common stock available for future issuance under our 2017 Employee Stock Purchase Plan; and
- 10,414 shares of common stock issuable following the closing of this offering upon the exercise of warrants outstanding as of September 30, 2017, at a weighted average exercise price of \$14.89 per share.

Unless otherwise indicated, all information in this prospectus reflects and assumes:

- no exercise of the outstanding options and warrants described above;
- no exercise by the underwriters of their option to purchase additional shares of our common stock to cover over-allotments;
- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 7,180,483 shares of our common stock upon the closing of this offering;
- all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 10,414 shares of common stock upon the closing of this offering;
- the filing and effectiveness of our restated certificate of incorporation and the adoption of our amended and restated bylaws upon the closing of this offering; and
- a one-for-3.4130 reverse stock split of our common stock effected on November 3, 2017.

Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 of the 4,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

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**SUMMARY CONSOLIDATED FINANCIAL DATA**

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2015 and 2016 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated statement of operations data for the nine months ended September 30, 2016 and 2017 and the consolidated balance sheet data as of September 30, 2017 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of results that may be expected in any future period, and our results for any interim period are not necessarily indicative of results that may be expected for any full year.

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
(in thousands, except per share amounts)				
<b>Consolidated Statement of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 12,706	\$ 17,831	\$ 13,604	\$ 18,898
General and administrative	2,119	6,515	5,042	5,629
Total operating expenses	<u>14,825</u>	<u>24,346</u>	<u>18,646</u>	<u>24,527</u>
Loss from operations	<u>(14,825)</u>	<u>(24,346)</u>	<u>(18,646)</u>	<u>(24,527)</u>
Other income (expense):				
Grant and incentive income	2,155	2,390	1,829	3,180
Interest expense	(472)	(2,515)	(1,723)	(1,716)
Change in fair value of warrant liability	1	39	11	16
Change in fair value of derivative liability	—	1,388	822	762
Loss on extinguishment of debt	—	(35)	(35)	(462)
Other income (expense), net	(77)	104	88	57
Total other income, net	<u>1,607</u>	<u>1,371</u>	<u>992</u>	<u>1,837</u>
Net loss	<u>(13,218)</u>	<u>(22,975)</u>	<u>(17,654)</u>	<u>(22,690)</u>
Accretion of redeemable convertible preferred stock to redemption value	<u>(19)</u>	<u>(25)</u>	<u>(19)</u>	<u>(36)</u>
Net loss attributable to common stockholders	<u>\$ (13,237)</u>	<u>\$ (23,000)</u>	<u>\$ (17,673)</u>	<u>\$ (22,726)</u>
Net loss per share attributable to common stockholders—basic and diluted <sup>(1)</sup>	<u>\$ (26.02)</u>	<u>\$ (44.79)</u>	<u>\$ (34.42)</u>	<u>\$ (44.22)</u>
Weighted average common shares outstanding—basic and diluted <sup>(1)</sup>	<u>509</u>	<u>514</u>	<u>513</u>	<u>514</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (7.85)</u>		<u>\$ (4.08)</u>
Pro forma weighted average common shares outstanding—basic and diluted (unaudited) <sup>(1)</sup>		<u>2,932</u>		<u>5,568</u>

<sup>(1)</sup> See Note 15 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders and on the calculation of pro forma basic and diluted net loss per share attributable to common stockholders.

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	As of September 30, 2017		
	Actual	Pro Forma <sup>(3)</sup> (in thousands)	Pro Forma As Adjusted <sup>(4)</sup>
<b>Consolidated Balance Sheet Data:</b>			
Cash	\$ 26,254	\$ 26,254	\$ 79,849
Restricted cash <sup>(1)</sup>	5,468	5,468	5,468
Working capital <sup>(2)</sup>	20,014	20,014	74,931
Total assets	37,162	37,162	88,640
Loan payable, net of discount, including current portion	12,518	12,518	12,518
Warrant liability	31	—	—
Redeemable convertible preferred stock	90,821	—	—
Total stockholders' equity (deficit)	(79,252)	11,600	64,400
<sup>(1)</sup> Restricted cash as of September 30, 2017 consisted of (i) \$4.7 million received under a letter agreement with the Bill & Melinda Gates Foundation, or the Gates Foundation, which is restricted to use on specified development activities in our ASN100 program, (ii) \$0.4 million received under a grant agreement with the Gates Foundation, which is restricted to use on specified preclinical development activities in our ASN500 program, and (iii) \$0.4 million subject to letters of credit in connection with our office leases. See Notes 2 and 7 to our consolidated financial statements appearing at the end of this prospectus.			
<sup>(2)</sup> We define working capital as current assets less current liabilities.			
<sup>(3)</sup> The pro forma balance sheet data give effect to: <ul style="list-style-type: none"> <li>• the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 7,180,483 shares of common stock upon closing of this offering; and</li> <li>• all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 10,414 shares of our common stock upon closing of this offering.</li> </ul>			
<sup>(4)</sup> The pro forma as adjusted balance sheet data give further effect to (i) our issuance and sale of 4,000,000 shares of our common stock in this offering at the initial public offering price of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) our issuance and sale of 2,000,000 shares of our common stock at a price per share equal to the initial public offering price of \$10.00 per share in the concurrent private placement to NEA, after deducting placement agent fees payable by us.			

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*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 prospectus, including our financial statements and the related notes appearing at the end of this prospectus. 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 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 \$22.7 million for the nine months ended September 30, 2017, \$23.0 million for the year ended December 31, 2016 and \$13.2 million for the year ended December 31, 2015. As of September 30, 2017, we had an accumulated deficit of \$81.1 million. We have funded our operations to date primarily with proceeds from 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 organizing and staffing our company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights, conducting discovery, research and development activities for our programs and planning for potential commercialization. We expect that it could be several years, if ever, before we have a commercialized product candidate. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if, and as, we:

- pursue the clinical development of ASN100 and our other product candidates;
- leverage our programs to advance other product candidates into preclinical and clinical development;
- 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 our 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.

To become and remain profitable, we or any potential future collaborators must develop and eventually commercialize product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would

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decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

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

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

- completing preclinical and clinical development of our product candidates and identifying and developing new product candidates;
- seeking and obtaining marketing approvals for any of our product candidates;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate coverage and reimbursement by hospitals, government and third-party payors for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference or infringement claims, if any; and
- attracting, hiring and retaining qualified personnel.

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

***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 our 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

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demonstrated the ability to initiate or complete Phase 3 clinical trials of our 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.

Assuming we obtain marketing approval for any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

***Even if this offering is successful, we will need to raise 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.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate further clinical trials of and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates that we plan to commercialize ourselves, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain additional funding in connection with our continuing operations. We may raise this additional funding through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions and funding under government or other contracts. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

We believe that the anticipated net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into mid 2019, including the completion of our ongoing Phase 2 clinical trial of ASN100 and initiation of a subsequent pivotal Phase 3 clinical trial, assuming a successful outcome in our Phase 2 clinical trial. Without giving effect to the anticipated net proceeds from this offering or the concurrent private placement to New Enterprise Associates 16, L.P., or NEA, we expect that our existing cash will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments through June 30, 2018. To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern within one year after the October 20, 2017 issuance date of our interim financial statements for the nine months ended September 30, 2017. See Note 1 to our consolidated financial statements appearing at the end of this prospectus for additional information on our assessment.

We have based our estimates regarding our ability to fund our operating expenses, capital expenditure requirements and debt service payments with our existing cash and the anticipated net proceeds from this offering on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;

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- the revenue, if any, received from commercial sale of our products, should any of our 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; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

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 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.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. 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. In addition, if we elect to obtain any additional debt financing, our ability to do so may be limited by covenants we have made under our loan and security agreement with Silicon Valley Bank, or SVB. For example, we have made a negative pledge in favor of SVB with respect to our intellectual property under the loan and security agreement, meaning that we will not pledge any of our intellectual property to a third party as collateral for a loan while the loan and security agreement with SVB is in effect. This negative pledge could further limit our ability to obtain additional debt financing on favorable terms.

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 of our research and development programs or any future commercialization efforts.

***Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.***

The report from our independent registered public accounting firm for the year ended December 31, 2016 includes an explanatory paragraph stating that our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, 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 audited financial statements, and it is likely that investors will lose all or a part of their investment. After this offering, future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. 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, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.



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***Raising additional capital may cause dilution to our stockholders, including purchasers of our common stock in this offering, 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. 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 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. If we are unable to raise additional funds through equity or debt financings when needed, we will 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.

***Our existing and any future indebtedness could adversely affect our ability to operate our business.***

Under our loan and security agreement with SVB, principal amounts outstanding totaled \$7.0 million as of December 31, 2016 and \$5.3 million as of September 30, 2017. We are required to repay outstanding indebtedness under our loan and security agreement with SVB in monthly installments through December 2019. In addition, borrowings under our loan and security agreement with SVB are collateralized by a pledge of 65% of the outstanding capital stock of our subsidiary in Austria. Under our loans from Österreichische Forschungsförderungsgesellschaft mbH, or FFG, principal amounts outstanding totaled \$8.0 million as of December 31, 2016 and \$10.0 million as of September 30, 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 2020 to 2022. We do not currently intend to use the net proceeds from this offering or the concurrent private placement to NEA to prepay outstanding indebtedness. We could in the future incur additional indebtedness beyond our borrowings from SVB and FFG.

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

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, and 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 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

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existing debt instruments could result in an event of default and acceleration of amounts due. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments. If we are unable to make payments when due under our loan and security agreement with SVB, SVB would have the right to foreclose on the collateral under the agreement, which would result in it becoming the majority stockholder of our Austrian subsidiary.

***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, 2016, we had U.S. federal and state net operating loss carryforwards of \$8.3 million and \$4.4 million, respectively, which begin to expire in 2030 and 2035, respectively. In addition, as of December 31, 2016, we had foreign net operating loss carryforwards of \$40.1 million, which do not expire. As of December 31, 2016, we also had U.S. federal and state research and development tax credit carryforwards of \$0.2 million and \$0.1 million, respectively, which begin to expire in 2031 and 2035, 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, 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. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, including this offering, 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.

### **Risks Related to the Development of Our Product Candidates**

***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 of our product candidates in ongoing or later-stage clinical trials or in obtaining marketing approval thereafter. For example, we have not yet advanced a product candidate beyond Phase 2 clinical development.

In addition, we have never had a product candidate receive approval from the FDA, 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 our product candidates than we expect, such delays could materially and adversely affect our business, financial condition, results of operations and prospects.

***We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.***

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our mAb programs. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources. Although our product candidates are currently in preclinical or clinical development, we may fail to identify other potential product candidates for

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clinical development for several reasons. Similarly, a key element of our business plan is to expand the breadth of indications for ASN100. A failure to find additional indications for which ASN100 may be a viable treatment could harm our business prospectus.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. For example, we currently intend to focus our capital resources primarily on the development of ASN100. However, the development of ASN100 may be ultimately prove to be unsuccessful or less successful than another product candidate in our pipeline that we might have chosen to pursue on a more aggressive basis with our capital resources. Our estimates regarding the potential market for our product candidates could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***In the near term, we are dependent on the success of ASN100, which is in clinical development. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize ASN100, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.***

We currently have no products approved for sale and are investing a significant portion of our efforts and financial resources in the development of ASN100. Our prospects are substantially dependent on our ability, or that of any future collaborator, to develop and obtain marketing approval for, and successfully commercialize ASN100 in one or more disease indications.

The success of ASN100 will depend on several factors, including the following:

- 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;
- satisfying the regulations applicable to the development and market authorization of combination drugs in the United States or outside the United States, as ASN100 is a combination of two mAbs;
- 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;

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- 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 ASN100, 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 our product candidates, particularly ASN100, 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 our product candidates, we 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, such as our current Phase 2 clinical trial of ASN100, 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 our 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 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;

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- 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 make manufacturing or formulation changes to our product candidates, we may need to conduct additional trials to bridge our modified product candidates to earlier versions. For example, for our ASN100 program, in 2016, we transferred manufacturing technology from a third-party manufacturer that fulfilled our preclinical, Phase 1 and Phase 2 drug supply and drug product requirements to a new third-party manufacturer that is working to improve the manufacturing process as well produce drug product for a potential Phase 3 clinical trial. We anticipate that we will conduct a small clinical trial in 2018 to bridge the potential Phase 3 drug product with the drug product used in our earlier studies. 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 Data Review Committee, or 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.

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.

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

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.

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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 our 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.

***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. Our product candidates 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 the preclinical studies and Phase 1 clinical trial of ASN100 or the preclinical studies of our other product candidates ultimately will result in success in currently ongoing or potential future clinical trials of these product candidates. In addition, we cannot assure you that we will be able to achieve the same or similar success in our preclinical studies and clinical trials of our other product candidates.

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 from proceeding with clinical trials of our product candidates.***

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow-up periods. For example, in our Phase 2 clinical trial of ASN100, we are seeking to enroll mechanically ventilated patients to screen for levels of *Staphylococcus aureus*, or *S. aureus*, bacteria, but we are only dosing patients in this trial who are heavily colonized with *S. aureus*. As a result, we may experience challenges at trial sites in both enrolling patients for screening, and in the subsequent

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identification of enrolled patients who are heavily colonized with *S. aureus* and therefore eligible for dosing in this trial. Our ASN100 Phase 2 clinical trial will also face efforts by competitors to conduct clinical trials for their product candidates in similar indications, which may hamper our ability to enroll a sufficient number of patients in our Phase 2 trial of ASN100. In addition, we have experienced, and may continue to 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 our ongoing or planned clinical trials could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our 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 our 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 are conducting, and intend in the future to conduct, clinical trials for certain of our 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 are conducting, and intend in the future to conduct, one or more of our clinical trials with one or more trial sites that are located outside the United States. For example, we include multiple trial sites outside of the United States in our Phase 2 clinical trial of ASN100.

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

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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 ASN100 or 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 our 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 may fail to demonstrate safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities.***

If the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our 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 our product candidates, we may need to abandon or limit our development of that product candidate.***

If our 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. For example, the pharmacokinetic properties, such as the longer half-life of ASN100, could lead to side effects that were not observed in our Phase 1 clinical trial and the consequences of such side effects could be more severe than have been seen with other mAbs that have shorter half-lives, or more frequent dosing regimens, or are dosed at lower concentrations than we expect for ASN100. Furthermore, in its currently ongoing Phase 2 clinical trial, ASN100 is being studied in mechanically ventilated patients at high risk for



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developing *S. aureus* pneumonia who often have significant underlying disease or conditions that may make them more likely to have side effects from ASN100 treatment. 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 elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed and our ability to generate product revenue from such product candidate 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 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 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 our product candidates or in the manufacturing facilities in which our 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 our 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 of our 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 our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our 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 of our 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 our 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 our product candidates, 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

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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.

For example, we are aware of two products targeting *S. aureus* cytotoxin in clinical development: MedImmune's MEDI4893 and Ardis Pharmaceuticals' AR301, each of which targets only the cytotoxin Hla and is in Phase 2 clinical development. If ASN100 is approved, it may compete with each of these product candidates. ASN100 may also compete with mAb products that may be developed to target *S. aureus* through different mechanisms of action, including XBiotech's 514G3, which targets *S. aureus* surface Protein A and is in Phase 2 clinical development, and Genentech's RG7861, which is comprised of a *S. aureus* bacterial-surface-targeting mAb attached to an antibiotic and is in Phase 1 clinical development.

If approved for the prevention of respiratory syncytial virus, or 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.

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. 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.

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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.

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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 prospectus also apply to the activities of any future collaborators.

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

We may seek collaborations to advance the development of our current or future 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 rely and expect to continue to rely on third parties to conduct our clinical trials and 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 independently conduct clinical trials of any of our product candidates. We rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our 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 our 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.

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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](http://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 ongoing 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 our product candidates increases the risk that we will not have sufficient quantities of our 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 own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating in our research program. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of our 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 of our 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 our products may shorten the expiry of our products and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of our product candidates 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.

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Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of our product candidates as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our product candidates. For example, for our ASN100 program, in 2016 we transferred manufacturing technology from a third-party manufacturer that fulfilled our preclinical, Phase 1 and Phase 2 drug supply and drug product requirements to a new third-party manufacturer that is working to improve the manufacturing process as well produce drug product for a potential Phase 3 clinical trial. Any failure or delay of this new third-party manufacturer to successfully and timely produce adequate drug product would result in potentially significant delays to our ASN100 clinical development plan, including the initiation of a potential Phase 3 clinical trial.

Even after a third-party manufacturer has gained significant experience in manufacturing our 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 our 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 of our product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of our 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 our product candidates.

Our product candidates and any products that we may 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 our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our 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.

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[Table of Contents](#)***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. See “Business—Collaboration and License Agreements—Adimab, LLC.” 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 our Product Candidates*****If we are unable to establish sales, medical affairs and marketing capabilities or enter into agreements with third parties to market and sell our 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, 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 our 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 our 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 our product candidates, if approved, will depend substantially on the extent to which the costs of our 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;

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- 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 our 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 our 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 our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product 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 our product candidates. We expect to experience pricing pressures in connection with the sale of any of our 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 of our 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 our product candidates, if approved, will significantly depend on the acceptance of physicians, hospitals and healthcare payors of our 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 our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of 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;



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- 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 our 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 our 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**

***Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.***

We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

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

***If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.***

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our product candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and product candidates requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

***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 our 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

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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 U.S. Foreign Corrupt Practices Act, or 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 expect to adopt a code of conduct and implement 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.

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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.

### **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 our 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 our 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 our 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 our 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.

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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 our 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 our 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 our 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

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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 our 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 Bill & Melinda Gates Foundation, or 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 our product candidates. 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 our 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—Adimab, LLC." 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,

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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 and 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,

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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 “Business—Collaboration and License Agreements—The Bill & Melinda Gates Foundation.”

In February 2017, we entered into a grant agreement with the Gates Foundation. 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. 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 this agreement 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.



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

If 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 our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with,

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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 our product candidates approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any of our product candidates or technologies covered by the asserted third-party patents. 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 our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects.***

While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. For example, a third party may claim an ownership interest in one or more of our, or our licensors', patents or other proprietary or intellectual property rights. A third party could bring legal actions against us 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.

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***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-

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

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

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[Table of Contents](#)**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 our 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.

Our product candidates 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 of our 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 of our 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 our product candidates.

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

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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.

***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. In November 2016, the FDA notified us that we obtained Fast Track designation for ASN100 for the prevention of *S. aureus* pneumonia in mechanically ventilated patients who are at high risk for *S. aureus* pneumonia. 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 some or all of our 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 our 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. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates 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.

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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 our product candidates 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 our product candidates in certain countries. In addition, if we or our collaborators fail to obtain the non-U.S. approvals required to market our 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 our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

***Even if we, or any future collaborators, obtain marketing approvals for our product candidates, 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 of our 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

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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 one or more of our 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 of our 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 of our 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 of our 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;



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- 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.

***The efforts of the presidential administration to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.***

The current presidential 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. On January 30, 2017, President Trump issued an executive order, applicable to all executive agencies, including the FDA, that 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. 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. 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;

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- *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.

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The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The draft Data Protection Regulation currently going through the adoption process is expected to introduce new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. If the draft Data Protection Regulation is adopted in its current form it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

***Recently enacted and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our 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 our 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 of our product candidates and 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;

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- 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 of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

With the new Administration and Congress, there may be additional legislative changes, including potentially repeal and replacement of certain provisions of the ACA. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation will provide and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. For example, 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 provisions.

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 or commercialize product candidates. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare, Medicaid and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors.

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

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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 revenue and become profitable could be impaired.

***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

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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 this Offering and Ownership of Our Common Stock**

*After this offering and the concurrent private placement, our executive officers, directors and principal stockholders will maintain the ability to significantly influence all matters submitted to stockholders for approval.*

Assuming the sale by us of 4,000,000 shares of common stock in this offering (or 4,600,000 shares if the underwriters exercise their option to purchase additional shares to cover over-allotments in full) and the sale by us of an additional 2,000,000 shares of common stock in the concurrent private placement to NEA, and based on the number of shares outstanding as of September 30, 2017, assuming the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering will, in the aggregate, beneficially own shares representing approximately 46.0% of our capital stock (or 44.1% if the underwriters exercise their option to purchase additional shares in full), not including any shares purchased by these stockholders in this offering. In addition, five of our directors are affiliated with stockholders who each owned more than 5% of our outstanding common stock before this offering. If these stockholders were to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they act together, would significantly influence 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 our company on terms that other stockholders may desire or result in management of our company that our public stockholders disagree with.

Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The foregoing discussion does not reflect any potential purchases by these potential purchasers.

*A significant portion of our total outstanding shares are restricted from immediate resale but may 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 certain restrictions described below. 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. After this offering, we will have outstanding 13,694,383 shares of common stock based on the number of shares outstanding as of September 30, 2017, assuming the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering and the sale by us of an additional 2,000,000 shares of common stock in the concurrent private placement to NEA (or 14,294,383 shares if the underwriters exercise their option to purchase additional shares in full). Of the 13,694,383 shares to be outstanding immediately after the closing of this offering and the concurrent private placement, the 4,000,000 shares sold in this offering (assuming the underwriters do not exercise their option to purchase additional shares) may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining 9,694,383 shares will be restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as

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described in the “Shares Eligible for Future Sale” and “Underwriting” sections of this prospectus. Moreover, after this offering and the concurrent private placement, holders of an aggregate of approximately 9,180,483 shares of our common stock (which includes shares held by certain of our principal investors and founders and shares issuable upon conversion of our preferred stock) will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the “Underwriting” section of this prospectus.

Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. Shares purchased by certain of these investors would not be able to be resold in the public market immediately following this offering as a result of restrictions under securities laws and lock-up agreements, but would be able to be sold following the expiration of these restrictions as described in the “Shares Eligible for Future Sale” section of this prospectus. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The foregoing discussion does not reflect any potential purchases by these potential purchasers.

***If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.***

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. To the extent outstanding options or warrants are exercised, you will incur further dilution. Based on the initial public offering price of \$10.00 per share and assuming the sale by us of 2,000,000 shares of our common stock to NEA in the concurrent private placement at a price per share equal to the initial public offering price of \$10.00 per share, you will experience immediate dilution of \$5.30 per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the initial public offering price. See “Dilution.”

***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.

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

Our stock price is likely to be volatile. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. 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;

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- commencement or termination of collaborations;
- 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;
- 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. 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.

***An active trading market for our common stock may not develop.***

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. Although our common stock has been approved for listing on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares, or at all.

***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 have broad discretion in the use of our cash and cash equivalents, including the net proceeds from this offering and the concurrent private placement, and may not use them effectively.***

Our management will have broad discretion in the application of our cash and cash equivalents, including the net proceeds from this offering and the concurrent private placement, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash and cash equivalents, including the net proceeds from this offering and the concurrent private placement, in a manner that does not produce income or that loses value. See “Use of Proceeds.”



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***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. We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30. 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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- 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.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting requirements in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC and we have presented only two years of audited financial statements and correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

As a public company, and particularly after we are no longer an 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 Stock 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

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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 that will become effective upon the closing of this offering 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;

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- 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, 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 certificate of incorporation will provide 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 certificate of incorporation, which will be effective upon the closing of this offering, will provide 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 Delaware General Corporation Law or as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim arising pursuant to our certificate of incorporation or our 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 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 is currently restricted by the terms of our loan and security agreement with SVB and 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.

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[Table of Contents](#)**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA**

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this prospectus, 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 prospectus include, among other things, statements about:

- our ongoing clinical trials, including our Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* in high-risk, mechanically ventilated patients;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and need for additional financing;
- our plans to develop and, if approved, subsequently commercialize ASN100 and any other product candidates;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for ASN100 and other product candidates;
- our expectations regarding our ability to fund our operating expenses, capital expenditure requirements and debt service payments with our cash and proceeds from this offering and the concurrent private placement;
- the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expectations related to the use of proceeds from this offering and the concurrent private placement;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to establish collaborations or obtain additional funding; and
- our expectations regarding the time during which we will be an emerging growth company under 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 prospectus, 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.

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You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

This prospectus 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.

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[Table of Contents](#)**USE OF PROCEEDS**

We estimate that the net proceeds from our issuance and sale of 4,000,000 shares of our common stock in this offering will be approximately \$34.2 million, based on the initial public offering price of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares of our common stock in full, we estimate that the net proceeds from this offering will be approximately \$39.8 million. We also expect to receive net proceeds of \$18.6 million from the sale of shares of common stock to New Enterprise Associates 16, L.P., or NEA, in the concurrent private placement, based on the initial public offering price of \$10.00 per share and after deducting placement agent fees payable by us, for aggregate net proceeds to be raised by us in this offering and the concurrent private placement of \$52.8 million.

As of September 30, 2017, we had cash of \$26.3 million. We currently estimate that we will use the net proceeds from this offering, together with our existing cash, as follows:

- approximately \$34 million to fund the development of ASN100 for the prevention of *S. aureus* pneumonia in mechanically ventilated patients;
- approximately \$7 million to fund the development of ASN100 for other indications;
- approximately \$6 million to advance our current pipeline of preclinical candidates other than ASN500, which, in the near term, we plan to advance entirely with funding from the Bill & Melinda Gates Foundation, or the Gates Foundation, and to research and develop additional preclinical product candidates; and
- the remainder for working capital and other general corporate purposes.

We currently estimate that, if we receive additional net proceeds of \$18.6 million from the sale of shares of common stock to NEA in the concurrent private placement, we will use such net proceeds as follows:

- approximately \$6 million to fund the development of ASN100 for the prevention of *S. aureus* pneumonia in mechanically ventilated patients;
- approximately \$1 million to fund the development of ASN100 for other indications;
- approximately \$3 million to advance our current pipeline of preclinical candidates other than ASN500 and to research and develop additional preclinical product candidates; and
- the remainder for working capital and other general corporate purposes.

The foregoing cash of \$26.3 million as of September 30, 2017 does not include restricted cash of \$5.5 million, consisting of (i) \$4.7 million received under a letter agreement with the Gates Foundation, which is restricted to use on specified development activities in our ASN100 program, (ii) \$0.4 million received under a grant agreement with the Gates Foundation, which is restricted to use on specified preclinical development activities in our ASN500 program, and (iii) \$0.4 million subject to letters of credit in connection with our office leases.

This expected use of net proceeds from this offering and the concurrent private placement to NEA and our existing cash represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, the timing of regulatory submissions and the outcome of regulatory review, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and the concurrent private placement to NEA.

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We believe that the anticipated net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into mid 2019, including the completion of our ongoing Phase 2 clinical trial of ASN100 and initiation of a subsequent pivotal Phase 3 clinical trial, assuming a successful outcome in our Phase 2 clinical trial. We expect that we will require additional funding to complete the clinical development of ASN100, commercialize ASN100, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates, if any. Due to the numerous risks and uncertainties associated with product development, including the risks and uncertainties with respect to successful enrollment and completion of clinical trials, at this time, we cannot reasonably estimate the amount of additional funding that will be necessary to complete the clinical development of ASN100 or any of our other product candidates. If we receive regulatory approval for ASN100 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.

Pending our use of the net proceeds from this offering and the concurrent private placement to NEA, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

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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. In addition, our ability to pay cash dividends is currently restricted by the terms of our loan and security agreement with Silicon Valley Bank, and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. 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.



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The following table sets forth our cash and our capitalization as of September 30, 2017:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 7,180,483 shares of common stock upon closing of this offering;
  - all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 10,414 shares of our common stock upon closing of this offering; and
  - the filing and effectiveness of our amended and restated certificate of incorporation upon closing of this offering; and
- on a pro forma as adjusted basis to give further effect to (i) our issuance and sale of 4,000,000 shares of our common stock in this offering at the initial public offering price of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) our issuance and sale of 2,000,000 shares of our common stock at a price per share equal to the initial public offering price of \$10.00 per share in the concurrent private placement to New Enterprise Associates 16, L.P., after deducting placement agent fees payable by us.

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You should read this information together with our consolidated financial statements and related notes appearing at the end of this prospectus and the information set forth under the headings “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of September 30, 2017		
	Actual	Pro Forma	Pro Forma
	(in thousands, except share and per share data)		
Cash	\$ 26,254	\$ 26,254	\$ 79,849
Loans payable, net of discount, including current portion	\$ 12,518	\$ 12,518	\$ 12,518
Warrant liability	31	—	—
Redeemable convertible preferred stock (Series A-1, A-2, B, C and D), \$0.001 par value; 21,894,619 shares authorized, 21,869,096 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	90,821	—	—
Stockholders’ equity (deficit):			
Preferred stock, \$0.001 par value; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.001 par value; 31,000,000 shares authorized, 513,900 shares issued and outstanding, actual; 200,000,000 shares authorized, 7,694,383 shares issued and outstanding, pro forma; 200,000,000 shares authorized, 13,694,383 shares issued and outstanding, pro forma as adjusted	1	8	14
Additional paid-in capital	1,582	92,427	145,221
Accumulated other comprehensive income	243	243	243
Accumulated deficit	(81,078)	(81,078)	(81,078)
Total stockholders’ equity (deficit)	<u>(79,252)</u>	<u>11,600</u>	<u>64,400</u>
Total capitalization	<u>\$ 24,118</u>	<u>\$ 24,118</u>	<u>\$ 76,918</u>

The table above is based on the number of shares of common stock outstanding as of September 30, 2017, and excludes:

- 1,197,120 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2017, at a weighted average exercise price of \$5.61 per share;
- 760,005 shares of common stock available for future issuance under our 2017 Equity Incentive Plan;
- 219,748 shares of common stock available for future issuance under our 2017 Employee Stock Purchase Plan; and
- 10,414 shares of common stock issuable following the closing of this offering upon the exercise of warrants outstanding as of September 30, 2017, at a weighted average exercise price of \$14.89 per share.

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### DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering and the concurrent private placement to New Enterprise Associates 16, L.P., or NEA.

Our historical net tangible book value (deficit) as of September 30, 2017 was \$(81.4) million, or \$(158.34) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 513,900 shares of our common stock outstanding as of September 30, 2017.

Our pro forma net tangible book value as of September 30, 2017 was \$9.5 million, or \$1.23 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 7,180,483 shares of common stock upon closing of this offering and (ii) all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 10,414 shares of our common stock upon closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2017, after giving effect to the pro forma adjustments described above.

After giving further effect to (i) our issuance and sale of 4,000,000 shares of our common stock in this offering at the initial public offering price of \$10.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) our issuance and sale of 2,000,000 shares of our common stock at a price per share equal to the initial public offering price of \$10.00 per share in the concurrent private placement to NEA, after deducting placement agent fees payable by us, our pro forma as adjusted net tangible book value as of September 30, 2017 would have been \$64.4 million, or \$4.70 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$3.47 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$5.30 to new investors purchasing common stock in this offering or the concurrent placement. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		\$10.00
Historical net tangible book value (deficit) per share as of September 30, 2017	\$(158.34)	
Increase per share attributable to the pro forma adjustments described above	<u>159.57</u>	
Pro forma net tangible book value per share as of September 30, 2017	1.23	
Increase in pro forma net tangible book value per share attributable to new investors purchasing common stock in this offering or the concurrent private placement	<u>3.47</u>	
Pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement		<u>4.70</u>
Dilution per share to new investors purchasing common stock in this offering or the concurrent private placement		<u>\$ 5.30</u>

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If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement would be \$4.90, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$3.67 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$5.10 to new investors purchasing common stock in this offering or the concurrent private placement, based on the initial public offering price of \$10.00 per share.

The following table summarizes, as of September 30, 2017, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering and the concurrent private placement at the initial public offering price of \$10.00 per share, before deducting underwriting discounts and commissions, placement agent fees and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders	7,694,383	56.2%	\$ 90,076,926	60.0%	\$ 11.71
New investors	6,000,000	43.8	60,000,000	40.0	\$ 10.00
Total	<u>13,694,383</u>	<u>100.0%</u>	<u>\$150,076,926</u>	<u>100.0%</u>	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' exercise their option to purchase additional shares in full, the number of shares of our common stock held by existing stockholders would be reduced to 53.8% of the total number of shares of our common stock outstanding after this offering and the concurrent private placement, and the number of shares of common stock held by new investors participating in the offering and the concurrent private placement would be increased to 46.2% of the total number of shares of our common stock outstanding after this offering and the concurrent private placement.

The discussion and tables above are based on the number of shares of our common stock outstanding as of September 30, 2017, and exclude:

- 1,197,120 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2017, at a weighted average exercise price of \$5.61 per share;
- 760,005 shares of common stock available for future issuance under our 2017 Equity Incentive Plan;
- 219,748 shares of common stock available for future issuance under our 2017 Employee Stock Purchase Plan; and
- 10,414 shares of common stock issuable following the closing of this offering upon the exercise of warrants outstanding as of September 30, 2017, at a weighted average exercise price of \$14.89 per share.

To the extent that stock options are exercised, new stock options are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

Certain of our existing principal stockholders have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering. The foregoing discussion and tables do not reflect any potential purchases by these existing stockholders or their affiliated entities.

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You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the consolidated statement of operations data for the years ended December 31, 2015 and 2016 and the consolidated balance sheet data as of December 31, 2015 and 2016 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated statement of operations data for the nine months ended September 30, 2016 and 2017 and the consolidated balance sheet data as of September 30, 2017 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of results that may be expected in any future period, and our results for any interim period are not necessarily indicative of results that may be expected for any full year.

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
	(in thousands, except per share amounts)			
<b>Consolidated Statement of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 12,706	\$ 17,831	\$ 13,604	\$ 18,898
General and administrative	2,119	6,515	5,042	5,629
Total operating expenses	<u>14,825</u>	<u>24,346</u>	<u>18,646</u>	<u>24,527</u>
Loss from operations	<u>(14,825)</u>	<u>(24,346)</u>	<u>(18,646)</u>	<u>(24,527)</u>
Other income (expense):				
Grant and incentive income	2,155	2,390	1,829	3,180
Interest expense	(472)	(2,515)	(1,723)	(1,716)
Change in fair value of warrant liability	1	39	11	16
Change in fair value of derivative liability	—	1,388	822	762
Loss on extinguishment of debt	—	(35)	(35)	(462)
Other income (expense), net	<u>(77)</u>	<u>104</u>	<u>88</u>	<u>57</u>
Total other income, net	<u>1,607</u>	<u>1,371</u>	<u>992</u>	<u>1,837</u>
Net loss	<u>(13,218)</u>	<u>(22,975)</u>	<u>(17,654)</u>	<u>(22,690)</u>
Accretion of redeemable convertible preferred stock to redemption value	<u>(19)</u>	<u>(25)</u>	<u>(19)</u>	<u>(36)</u>
Net loss attributable to common stockholders	<u>\$(13,237)</u>	<u>\$(23,000)</u>	<u>\$(17,673)</u>	<u>\$(22,726)</u>
Net loss per share attributable to common stockholders—basic and diluted <sup>(1)</sup>	<u>\$ (26.02)</u>	<u>\$ (44.79)</u>	<u>\$ (34.42)</u>	<u>\$ (44.22)</u>
Weighted average common shares outstanding—basic and diluted <sup>(1)</sup>	<u>509</u>	<u>514</u>	<u>513</u>	<u>514</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (7.85)</u>		<u>\$ (4.08)</u>
Pro forma weighted average common shares outstanding—basic and diluted (unaudited) <sup>(1)</sup>		<u>2,932</u>		<u>5,568</u>

<sup>(1)</sup> See Note 15 to our consolidated financial statements appearing at the end of this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders and on the calculation of pro forma basic and diluted net loss per share attributable to common stockholders.

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	As of December 31,		As of
	2015	2016 (in thousands)	September 30, 2017
<b>Consolidated Balance Sheet Data:</b>			
Cash	\$ 6,759	\$ 3,035	\$ 26,254
Restricted cash <sup>(1)</sup>	388	394	5,468
Working capital (deficit) <sup>(2)</sup>	1,710	(6,344)	20,014
Total assets	9,510	7,604	37,162
Convertible promissory notes, net of discount	2,240	2,863	—
Loans payable, net of discount, including current portion	4,954	12,426	12,518
Warrant liability	26	47	31
Derivative liability	1,793	2,593	—
Redeemable convertible preferred stock	29,948	39,838	90,821
Total stockholders' deficit	(34,322)	(56,562)	(79,252)

<sup>(1)</sup> Restricted cash as of December 31, 2015 and 2016 consisted of amounts subject to letters of credit in connection with our office leases and corporate credit cards. Restricted cash as of September 30, 2017 consisted of (i) \$4.7 million received under a letter agreement with the Bill & Melinda Gates Foundation, or the Gates Foundation, which is restricted to use on specified development activities in our ASN100 program, (ii) \$0.4 million received under a grant agreement with the Gates Foundation, which is restricted to use on specified preclinical development activities in our ASN500 program, and (iii) \$0.4 million subject to letters of credit in connection with our office leases. See Notes 2 and 7 to our consolidated financial statements appearing at the end of this prospectus.

<sup>(2)</sup> We define working capital (deficit) as current assets less current liabilities.

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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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business 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 prospectus, our actual results could differ materially from the results described in or implied by these forward-looking statements.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on applying monoclonal antibody immunotherapies to address serious infectious diseases. We believe that our monoclonal antibodies, or mAbs, offer a novel approach to address serious infections. Unlike antibiotics that propagate resistance, disrupt both disease-causing and beneficial bacteria and have adverse off-target effects, mAbs have the ability to precisely bind only to the intended target, thereby avoiding these undesired consequences. Our lead product candidate, ASN100, is a first-in-class mAb therapeutic in Phase 2 clinical development for the prevention of *Staphylococcus aureus* pneumonia in high-risk, mechanically ventilated patients, a potentially life-threatening and costly infection for which there are no approved preventive therapies. In addition to ASN100, our preclinical pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus, or RSV.

Since our inception in 2010, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights, conducting discovery, research and development activities for our programs and planning for potential commercialization. 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 September 30, 2017 primarily with proceeds from the following sources:

- net cash proceeds of \$75.1 million from sales of our preferred stock;
- 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 \$10.0 million of grant and loan proceeds, respectively, from our funding agreements with Österreichische Forschungsförderungsgesellschaft mbH, or FFG;
- proceeds of \$4.8 million of research and development incentive payments received from the Austrian government; and
- proceeds of \$1.6 million from a grant agreement with the Bill & Melinda Gates Foundation, or the Gates Foundation.

Since our inception, we have incurred significant operating losses. 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 \$13.2 million and \$23.0 million for the years ended December 31, 2015 and 2016, respectively, and \$22.7 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of \$81.1 million. We expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from

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discovery through preclinical development and clinical trials and seek regulatory approval of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations with proceeds from outside sources, with a majority of such proceeds to be derived from sales of equity, including the anticipated net proceeds from this offering and the concurrent private placement to New Enterprise Associates 16, L.P., or NEA. We also plan to pursue additional funding from outside sources, including proceeds from our existing grant and potential future grant agreements with the Gates Foundation; our expansion of, or our entry into, new borrowing arrangements; grants and loans under our existing funding agreements with FFG; research and development incentive payments from the Austrian government; and our entry into potential future collaboration agreements for one or more of our 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 of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, 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 our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2017, we had cash of \$26.3 million. We believe that the anticipated net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into mid 2019. 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.”

Without giving effect to the anticipated net proceeds from this offering or the concurrent private placement to NEA, we expect that our existing cash will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments through June 30, 2018. To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern within one year after the October 20, 2017 issuance date of our interim financial statements for the nine months ended September 30, 2017. See Note 1 to our consolidated financial statements appearing at the end of this prospectus for additional information on our assessment.

Similarly, in its report on our financial statements for the year ended December 31, 2016, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern.

### **Components of Our Results of Operations**

#### ***Revenue***

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval or license agreements with third parties, we may generate revenue in the future from product sales.



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We recognize proceeds received from grants under our funding agreements with FFG, our research and development incentives from the Austrian government and our grant agreement 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 our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, that are primarily engaged in the oversight and conduct of our clinical trials; contract manufacturing organizations, or CMOs, that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs, as well as investigative sites and consultants that conduct our 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 and benefits, 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 outside consultants, CROs, CMOs and central laboratories 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 these 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 for managing 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.

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

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
	(in thousands)			
ASN100	\$ 5,846	\$ 9,722	\$ 7,583	\$12,608
ASN200	—	138	94	47
ASN300	333	59	44	120
ASN400	807	166	131	50
ASN500	—	3	3	603
ASN650	—	—	—	71
Unallocated research and development expenses	5,720	7,743	5,749	5,399
Total research and development expenses	<u>\$12,706</u>	<u>\$17,831</u>	<u>\$13,604</u>	<u>\$18,898</u>

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years as we increase personnel costs, including stock-based compensation, continue our ongoing Phase 2 clinical trial of ASN100, seek to advance one or more additional product candidates, advance our preclinical programs and prepare regulatory filings for our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our 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 U.S. Food and Drug Administration, or 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.

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We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our 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 our 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 our 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, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

### **Other Income (Expense), Net**

**Grant and Incentive Income.** Grant and incentive income consists of grant income recognized in connection with grants we receive under our 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 agreement 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.

**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 classify the warrants as a liability on our consolidated balance sheet. We remeasure this warrant liability to fair value at each reporting date and recognize changes in the fair value of the warrant liability as a component of other income (expense), net in our consolidated statement of operations. We will continue to recognize changes in the fair value of the warrant liability until the warrants are exercised, expire or qualify for equity classification.

Upon the closing of this offering, the preferred stock warrants will become exercisable for common stock instead of preferred stock, and the remeasured fair value of the warrant liability will be reclassified to additional paid-in capital. As a result, following the closing of this offering, we will no longer recognize changes in the fair value of the warrant liability as other income (expense) in our consolidated statement of operations.

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***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 classified these derivative instruments as a liability on our consolidated balance sheet. We remeasured this derivative liability to fair value at each reporting date and recognized changes in the fair value of the derivative liability as a component of other income (expense), net in our consolidated statement of operations.

In April 2017, in connection with the sale of our Series D convertible preferred stock, the convertible promissory notes that we issued in 2016 and 2017 were automatically converted into shares of Series D convertible preferred stock. Subsequent to this conversion, no convertible promissory notes remained outstanding. As a result, subsequent to this conversion, we no longer have a derivative liability recorded on our consolidated balance sheet and we no longer recognize changes in the fair value of the derivative liability in our consolidated statement of operations.

***Loss on the Extinguishment of Debt.*** In April 2016, in connection with the sale of our Series C convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes that we issued in 2015 was automatically converted into shares of Series C convertible preferred stock. We recorded a loss on extinguishment of debt related to this conversion.

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, 2016, we had U.S. federal and state net operating loss carryforwards of \$8.3 million and \$4.4 million, respectively, which begin to expire in 2030 and 2035, respectively. In addition, as of December 31, 2016, we had foreign net operating loss carryforwards of \$40.1 million, which do not expire. As of December 31, 2016, we also had U.S. federal and state research and development tax credit carryforwards of \$0.2 million and \$0.1 million, respectively, which begin to expire in 2031 and 2035, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

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**Results of Operations**
**Comparison of the Nine Months Ended September 30, 2016 and 2017**

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2017:

	Nine Months Ended September 30,		Change
	2016	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 13,604	\$ 18,898	\$ 5,294
General and administrative	5,042	5,629	587
Total operating expenses	<u>18,646</u>	<u>24,527</u>	<u>5,881</u>
Loss from operations	<u>(18,646)</u>	<u>(24,527)</u>	<u>(5,881)</u>
Other income (expense):			
Grant and incentive income	1,829	3,180	1,351
Interest expense	(1,723)	(1,716)	7
Change in fair value of warrant liability	11	16	5
Change in fair value of derivative liability	822	762	(60)
Loss on extinguishment of debt	(35)	(462)	(427)
Other income (expense), net	88	57	(31)
Total other income, net	<u>992</u>	<u>1,837</u>	<u>845</u>
Net loss	<u>\$ (17,654)</u>	<u>\$ (22,690)</u>	<u>\$ (5,036)</u>

**Research and Development Expenses.**

	Nine Months Ended September 30,		Change
	2016	2017	
	(in thousands)		
Direct research and development expenses by program:			
ASN100	\$ 7,583	\$12,608	\$5,025
ASN200	94	47	(47)
ASN300	44	120	76
ASN400	131	50	(81)
ASN500	3	603	600
ASN650	—	71	71
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	4,125	3,971	(154)
Other	1,624	1,428	(196)
Total research and development expenses	<u>\$13,604</u>	<u>\$18,898</u>	<u>\$5,294</u>

Research and development expenses were \$13.6 million for the nine months ended September 30, 2016, compared to \$18.9 million for the nine months ended September 30, 2017. The increase of \$5.3 million was primarily due to an increase of \$5.0 million in direct costs for our ASN100 program and an increase of \$0.6 million in direct costs for our ASN500 program, which were partially offset by a decrease of \$0.4 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.

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Our ASN500 program was initiated in March 2017. Direct costs for our ASN500 program during the nine months ended September 30, 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 decrease in unallocated research and development expenses was primarily due to a decrease in unallocated animal facility costs and other overhead expenses.

**General and Administrative Expenses.** General and administrative expenses were \$5.0 million for the nine months ended September 30, 2016, compared to \$5.6 million for the nine months ended September 30, 2017. The increase of \$0.6 million was primarily due to an increase of \$0.3 million in personnel-related costs (including an increase in stock-based compensation of \$0.2 million) and an increase of \$0.4 million in professional fees. The increase in personnel-related costs was due to 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 nine months ended September 30, 2016 related to redesigning our website and establishing our communications and marketing programs that were not similarly incurred in the nine months ended September 30, 2017.

**Other Income (Expense), Net.** Other income, net was \$1.0 million for the nine months ended September 30, 2016, compared to \$1.8 million for the nine months ended September 30, 2017. The increase of \$0.8 million in other income, net was primarily due to an increase in grant and incentive income of \$1.4 million from our grant agreement with the Gates Foundation, partially offset by 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 gains recognized as a result of decreases in the fair value of the derivative liability associated with our convertible promissory notes.

### **Comparison of the Years Ended December 31, 2015 and 2016**

The following table summarizes our results of operations for the years ended December 31, 2015 and 2016:

	Year Ended December 31,		Change
	2015	2016	
		(in thousands)	
Operating expenses:			
Research and development	\$ 12,706	\$ 17,831	\$ 5,125
General and administrative	2,119	6,515	4,396
Total operating expenses	<u>14,825</u>	<u>24,346</u>	<u>9,521</u>
Loss from operations	<u>(14,825)</u>	<u>(24,346)</u>	<u>(9,521)</u>
Other income (expense):			
Grant and incentive income	2,155	2,390	235
Interest expense	(472)	(2,515)	(2,043)
Change in fair value of warrant liability	1	39	38
Change in fair value of derivative liability	—	1,388	1,388
Loss on extinguishment of debt	—	(35)	(35)
Other income (expense), net	<u>(77)</u>	<u>104</u>	<u>181</u>
Total other income, net	<u>1,607</u>	<u>1,371</u>	<u>(236)</u>
Net loss	<u><u>\$ (13,218)</u></u>	<u><u>\$ (22,975)</u></u>	<u><u>\$ (9,757)</u></u>

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**Research and Development Expenses.**

	Year Ended December 31,		Change
	2015	2016 (in thousands)	
Direct research and development expenses by program:			
ASN100	\$ 5,846	\$ 9,722	\$3,876
ASN200	—	138	138
ASN300	333	59	(274)
ASN400	807	166	(641)
ASN500	—	3	3
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	3,726	5,451	1,725
Other	1,994	2,292	298
Total research and development expenses	<u>\$12,706</u>	<u>\$17,831</u>	<u>\$5,125</u>

Research and development expenses were \$12.7 million for the year ended December 31, 2015, compared to \$17.8 million for the year ended December 31, 2016. The increase of \$5.1 million was primarily due to increases of \$3.9 million in direct costs for our ASN100 program, \$2.0 million in unallocated research and development expenses and \$0.1 million in direct costs for our ASN200 program, all partially offset by decreases of \$0.6 million in direct costs for our ASN400 program and \$0.3 million in direct costs for our ASN300 program.

The increase in direct costs for our ASN100 program was primarily due to costs incurred for CRO fees for preparations for our Phase 2 clinical trial of ASN100, which was initiated in January 2017.

The decreases in direct costs for our ASN300 and ASN400 programs were due to management's determination in the first half of 2016 to focus our financial resources toward the clinical development of ASN100.

The increase in unallocated research and development expenses was due to an increase of \$1.7 million in personnel-related costs (including an increase in stock-based compensation of \$0.3 million) and an increase of \$0.3 million in other costs, which primarily related to facility and other overhead expenses. The increase in personnel-related costs was primarily due to the hiring of additional personnel in our research and development functions, particularly those responsible for partnering with CROs on the conduct and oversight of our Phase 2 clinical trial of ASN100, including the hiring of our Chief Medical Officer and our Senior Vice President of Clinical Operations during the first half of 2016.

**General and Administrative Expenses.** General and administrative expenses were \$2.1 million for the year ended December 31, 2015, compared to \$6.5 million for the year ended December 31, 2016. The increase of \$4.4 million was primarily due to increases of \$2.2 million in personnel-related costs (including an increase in stock-based compensation of \$0.3 million), \$1.6 million in professional fees, \$0.2 million in corporate communication and investor relations expenses, \$0.2 million in facility-related costs and \$0.2 million of infrastructure costs. The increase in personnel-related costs was due to the hiring of additional personnel in our general and administrative functions, including the appointment of our President and Chief Executive Officer and the hiring of our Chief Financial Officer and Chief Business Officer during the first half of 2016 as well as the hiring of personnel for other finance and accounting positions in mid-2016, as we began building out our U.S. operations in anticipation of the initiation of our Phase 2 clinical trial of ASN100. Professional fees increased due to legal costs incurred in connection with maintaining and registering worldwide patents and costs associated with our ongoing business operations. The increase in corporate communication and investor relations expenses related to redesigning our website and establishing our communications and marketing programs. The increase in infrastructure costs related to establishing our principal executive offices and building out our U.S. operations in Waltham, Massachusetts.

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**Other Income (Expense), Net.** Other income, net was \$1.6 million for the year ended December 31, 2015, compared to \$1.4 million for the year ended December 31, 2016. The decrease of \$0.2 million in other income, net was primarily due to an increase in interest expense of \$2.0 million due to interest on borrowings we made in February and August 2016 under the 2012 Loan Agreement and interest due under the convertible promissory notes we issued in April 2016. The increase was partially offset by a \$1.4 million gain that we recognized for the year ended December 31, 2016 as a result of a decrease in the fair value of the derivative liability associated with our convertible promissory notes, a \$0.2 million increase in grant and incentive income primarily attributable to income recognized under the research and development incentive program provided by the Austrian government and a \$0.2 million increase in other income, net, primarily related to foreign currency transaction gains.

### Liquidity and Capital Resources

Since our inception, we have not generated any revenue from any sources, including 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 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 and proceeds from a grant agreement with the Gates Foundation. Through September 30, 2017, we had received net cash proceeds of \$75.1 million from sales of our preferred 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 \$10.0 million of grant and loan proceeds, respectively, from our funding agreement with FFG, \$4.8 million of research and development incentive payments received from the Austrian government and \$1.6 million of proceeds from our grant agreement with the Gates Foundation.

### Cash Flows

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

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
	(in thousands)			
Net cash used in operating activities	\$(10,816)	\$(21,639)	\$(18,477)	\$(14,964)
Net cash used in investing activities	(247)	(138)	(138)	(5,101)
Net cash provided by financing activities	11,505	18,147	17,926	42,914
Effect of exchange rate changes on cash	(122)	(94)	(18)	370
Net increase (decrease) in cash	<u>\$ 320</u>	<u>\$ (3,724)</u>	<u>\$ (707)</u>	<u>\$ 23,219</u>

**Operating Activities.** During the nine months ended September 30, 2017, operating activities used \$15.0 million of cash, resulting from our net loss of \$22.7 million, partially offset by cash provided by changes in our operating assets and liabilities of \$5.7 million and net non-cash charges of \$2.0 million. Cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2017 consisted primarily of a \$2.3 million increase in accounts payable, a \$2.1 million increase in accrued expenses, a \$0.9 million decrease in prepaid expenses and other current assets and a \$0.3 million increase 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 and an increase in professional fees incurred in connection with our planned initial public offering as well as the timing of vendor invoices and payments. The decrease in prepaid expenses and other current assets was primarily due to our use in the period of prepaid clinical materials related to our Phase 2 clinical trial of ASN100. The increase in unearned income was primarily due to the payment of \$1.6 million we received in March 2017 under our grant agreement with the Gates Foundation, of which \$1.2 million was recognized as grant income as we incurred qualifying expenses under the agreement.



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During the nine months ended September 30, 2016, operating activities used \$18.5 million of cash, resulting from our net loss of \$17.7 million and net cash used by changes in our operating assets and liabilities of \$2.3 million, partially offset by net non-cash charges of \$1.5 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2016 consisted primarily of a \$1.9 million increase in prepaid expenses and other assets primarily due to prepayments for clinical materials and investigator fees related to our Phase 2 clinical trial of ASN100, a \$0.6 million increase in grant and incentive receivables related to an increase in the amount of qualifying expenditures as well as the timing of receipt of cash from FFG Grants and a \$0.1 million decrease in unearned income related to FFG grant income, all partially offset by a \$0.3 million increase in accounts payable and a \$0.1 million increase in accrued expenses, which were due to an increase in research, development and clinical trial activities performed by CROs and CMOs.

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 current 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 current 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.

During the year ended December 31, 2015, operating activities used \$10.8 million of cash, resulting from our net loss of \$13.2 million, partially offset by net non-cash charges of \$1.0 million and net cash provided by changes in our operating assets and liabilities of \$1.4 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2015 consisted primarily of a \$0.8 million increase in accrued expenses, which was due to an increase in professional fees and personnel costs associated with establishing our principal executive offices and building out our U.S. operations in Waltham, Massachusetts and a \$0.7 million increase in unearned income related to FFG grant income.

**Investing Activities.** During the nine months ended September 30, 2017, we used \$5.1 million of cash in investing activities, consisting primarily of net increases in restricted cash related to funding received under our grant and letter agreements with the Gates Foundation as a result of restrictions on the use of funds imposed by those agreements.

During the nine months ended September 30, 2016, we used \$0.1 million of cash in investing activities, consisting of purchases of property and equipment and net increases in restricted cash.

During the year ended December 31, 2016, we used \$0.1 million of cash in investing activities, consisting of \$0.1 million in purchases of property and equipment and an increase in restricted cash of \$0.1 million attributable to the letter of credit associated with our operating leases.

During the year ended December 31, 2015, we used \$0.2 million of cash in investing activities, consisting primarily of purchases of property and equipment.

**Financing Activities.** During the nine months ended September 30, 2017, net cash provided by financing activities was \$42.9 million, consisting primarily of net cash proceeds of \$39.9 million from our issuances of

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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 \$1.8 million of principal repayments under the 2012 Loan Agreement and the payment of \$0.8 million of initial public offering costs.

During the nine months ended September 30, 2016, net cash provided by financing activities was \$17.9 million, consisting primarily of net proceeds of \$7.0 million from borrowings under the 2012 Loan Agreement, net 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 \$0.3 million from loans under our funding agreements with FFG, all partially offset by \$0.3 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.

During the year ended December 31, 2015, net cash provided by financing activities was \$11.5 million, consisting primarily of net proceeds of \$7.0 million from our issuance of Series B convertible preferred stock, net proceeds of \$4.0 million from our issuance of convertible promissory notes in December 2015 and proceeds of \$1.5 million from loans under our funding agreements with FFG, all partially offset by \$1.0 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. As of December 31, 2016 and September 30, 2017, the outstanding principal amount under the 2012 Loan Agreement was \$7.0 million and \$5.3 million, respectively.

Borrowings under the 2012 Loan Agreement bear 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 will be increased by 4.0%. Under the agreement, we were required to make monthly interest-only payments through December 1, 2016 and are 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 becomes due and payable. We may 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 ranges from 0% to 2% of the outstanding principal. A final payment of \$0.4 million is 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.

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Borrowings under the 2012 Loan Agreement are collateralized by a pledge of 65% of the outstanding capital stock of our subsidiary in Austria. The 2012 Loan Agreement contains customary affirmative and negative covenants, including restrictions on our ability to pay dividends and encumber our intellectual property, but does 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 our Austrian subsidiary on a project-by-project basis, as approved by FFG. As of December 31, 2016 and September 30, 2017, the outstanding principal amount under loans from FFG was \$8.0 million and \$10.0 million, respectively, 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. The FFG loans mature at varying dates between June 2020 and March 2023. 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 contain no affirmative, negative or financial covenants and are not secured by any of our assets.

As of September 30, 2017, the funding agreements with FFG are expected to provide us additional loans of approximately \$1.0 million and additional grants of approximately \$0.1 million if and when we incur specified amounts of qualifying expenditures.

***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***

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, upon the closing of

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this offering, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- leverage our programs to advance other product candidates into preclinical and clinical development;
- 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 our 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.

We believe that the anticipated net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into mid 2019, including the completion of our ongoing Phase 2 clinical trial of ASN100 and initiation of a subsequent pivotal Phase 3 clinical trial, assuming a successful outcome in our Phase 2 clinical trial. 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 ASN100, commercialize ASN100, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for ASN100 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize ASN100 ourselves.

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:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product 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 of our 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;

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- the extent to which we acquire or in-license other product candidates and technologies; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

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. 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 September 30, 2017 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 (in thousands)	4 to 5 Years	More than 5 Years
Debt obligations <sup>(1)</sup>	\$15,888	\$ 2,589	\$ 8,278	\$4,130	\$ 891
Operating lease commitments <sup>(2)</sup>	2,440	1,028	1,117	295	—
Total	<u>\$18,328</u>	<u>\$ 3,617</u>	<u>\$ 9,395</u>	<u>\$4,425</u>	<u>\$ 891</u>

<sup>(1)</sup> Amounts in the table reflect the contractually required principal and interest payable as of September 30, 2017 pursuant to outstanding borrowings under the 2012 Loan Agreement and loans from 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, as well as a final payment of \$0.4 million due under the 2012 Loan Agreement upon repayment of all outstanding amounts under the agreement. The 2012 Loan Agreement bears interest at a variable rate of interest equal to the greater of 3.25% and The Wall Street Journal prime rate, in each case minus 0.25%. The table reflects interest payments due under the 2012 Loan Agreement calculated using an interest rate of 4.00%, which was the applicable interest rate as of September 30, 2017.

<sup>(2)</sup> 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 April 2021. Amounts in the table also reflect noncancelable payments due for our lease of an animal-use facility, which is cancelable by either party upon six months' written notice.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

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We have not included any contingent payment obligations, such as milestone payments and royalties, in the preceding table as the amount, timing and likelihood of such payments are not known. Such contingent payment obligations are described below.

Under our collaboration agreement with Adimab, 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. 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.

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 pursuant to which 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, 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.

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[Table of Contents](#)**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 prospectus, 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.

***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 agreement 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 agreement 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.

***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

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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.

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

We measure stock options and other stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method.

For stock-based awards granted to consultants and non-employees, we recognize compensation expense 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 our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.



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**Determination of the Fair Value of Common Stock.** As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering third-party valuations of our common stock as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using the option-pricing method, or OPM, which used a market approach to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of \$8.33 per share as of December 31, 2015, \$9.39 per share as of April 22, 2016, \$5.36 per share as of December 31, 2016 and \$4.00 as of April 24, 2017. Our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and planned clinical trials for our product candidates;
- our stage of development and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Following the closing of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

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**Options Granted.** The following table sets forth by grant date the number of shares subject to options granted from January 1, 2016 through September 30, 2017, the per share exercise price of the options, the fair value of common stock per share on each grant date, and the per share estimated fair value of the options:

<u>Grant Date</u>	<u>Number of Shares Subject to Options Granted</u>	<u>Per Share Exercise Price of Options</u>	<u>Fair Value per Common Share on Grant Date</u>	<u>Per Share Estimated Fair Value of Options</u>
February 4, 2016	20,946	\$ 8.33	\$ 8.33	\$ 5.47
February 4, 2016	4,686	\$ 8.33	\$ 8.33	\$ 4.41
July 20, 2016	272,532	\$ 9.39	\$ 9.39	\$ 6.08
September 28, 2016	23,438	\$ 9.39	\$ 9.39	\$ 6.18
June 19, 2017	657,882	\$ 4.00	\$ 4.00	\$ 2.70

***Valuation of Warrant Liability***

In connection with the 2012 Loan Agreement, we issued to SVB warrants to purchase shares of our preferred stock. We classify the warrants as a liability on our consolidated balance sheet because these warrants are free-standing financial instruments that may require us to transfer assets upon exercise. The warrant liability was initially recorded at fair value upon the date of each warrant issuance and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the consolidated statement of operations. We will continue to recognize changes in the fair value of the warrant liability until the warrants are exercised, expire or qualify for equity classification.

We utilize the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value these warrants. We assess these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying equity instruments issuable upon exercise of the warrants, remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the underlying preferred stock by taking into consideration our most recent sales of our convertible preferred stock and additional factors that we deem relevant. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We have estimated a 0% dividend yield based on the expected dividend yield and the fact that we have never paid or declared dividends.

Upon the closing of this offering, the preferred stock warrants will become exercisable for common stock instead of preferred stock, and the remeasured fair value of the warrant liability will be reclassified to additional paid-in capital. As a result, following the closing of this offering, we will no longer recognize changes in the fair value of the warrant liability as other income (expense) in our consolidated statement of operations.

***Valuation 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 classified these derivative instruments as a liability on our consolidated balance sheet because the contingent put option provided for the accelerated repayment of the notes at a substantial premium upon the occurrence of specified events and the conversion feature was not clearly and closely related to its host instrument and met the definition of a derivative. The derivative liability was initially recorded at its fair value upon issuance of the convertible promissory notes and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability were recognized as a component of other income (expense), net in our consolidated statement of operations. We recognized changes in the fair value of the derivative liability until the convertible promissory notes were converted to equity.

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The fair value of the derivative liability was determined using the probability-weighted expected return method, or PWERM, which considered as inputs the type, timing and probability of occurrence of a change-of-control event, future equity financing and cash settlement of the convertible promissory notes; the potential amount of the payment under each of the potential settlement scenarios; and the risk-adjusted discount rate reflecting the expected risk profile for each of the potential settlement scenarios. The estimates were based, in part, on subjective assumptions. Changes to these assumptions could have had a significant impact on the fair value of the derivative liability.

In April 2017, in connection with the sale of our Series D convertible preferred stock, the convertible promissory notes that we issued in 2016 and 2017 were automatically converted into shares of Series D convertible preferred stock. Subsequent to this conversion, no convertible promissory notes remained outstanding. As a result, subsequent to this conversion, we no longer have a derivative liability recorded on our consolidated balance sheet and we no longer recognize changes in the fair value of the derivative liability in our consolidated statement of operations.

### **Emerging Growth Company Status**

The Jumpstart Our Business Startups Act of 2012 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 Securities and Exchange Commission.

### **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 prospectus.

### **Quantitative and Qualitative Disclosures about Market Risks**

#### ***Interest Rate Risk***

As of December 31, 2016 and September 30, 2017, we had \$7.0 million and \$5.3 million of borrowings outstanding under the 2012 Loan Agreement. Borrowings under the 2012 Loan Agreement bear 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%, which resulted in applicable interest rates of 3.50% as of December 31, 2016 and 4.00% as of September 30, 2017. Based on the principal amounts outstanding as of December 31, 2016 and September 30, 2017, an immediate 10% change in the interest rate would not have a material impact on our debt-related obligations, financial position or results of operations.

As of December 31, 2016 and September 30, 2017, we had \$5.5 million and \$0, respectively, of borrowings outstanding under our convertible promissory notes and we had \$8.0 million and \$10.0 million, respectively, of borrowings outstanding under the FFG loans. Amounts outstanding under these agreements bear interest at fixed interest rates and, therefore, do not expose us to interest rate risk.

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[Table of Contents](#)***Foreign Currency Exchange Risk***

We are 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. The majority of our research and development costs are incurred by our subsidiary in Austria, whose functional currency is the euro. During the year ended December 31, 2015 and the nine months ended September 30, 2017, we recognized foreign currency transaction losses of \$0.1 million and less than \$0.1 million, respectively. During each of the year ended December 31, 2016 and the nine months ended September 30, 2016, we recognized foreign currency transaction gains of less than \$0.1 million. These gains and losses primarily related to unrealized and realized foreign currency gains and 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 gains and 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.

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[Table of Contents](#)**BUSINESS****Overview**

We are a clinical-stage biopharmaceutical company focused on applying monoclonal antibody immunotherapies to address serious infectious diseases. We believe that our monoclonal antibodies, or mAbs, offer a novel approach to address serious infections. Unlike antibiotics that propagate resistance, disrupt both disease-causing and beneficial bacteria and have adverse off-target effects, mAbs have the ability to precisely bind only to the intended target, thereby avoiding these undesired consequences. Our lead product candidate, ASN100, is a first-in-class mAb therapeutic in Phase 2 clinical development for the prevention of *Staphylococcus aureus*, or *S. aureus*, pneumonia in high-risk, mechanically ventilated patients, a potentially life-threatening and costly infection for which there are no approved preventive therapies. In addition to ASN100, our preclinical pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus, or RSV.

Monoclonal antibodies are a well-established therapeutic class across many disease areas; however, they have yet to be broadly utilized for the prevention or treatment of acute bacterial and viral infections, where they hold the potential to address serious unmet medical needs. Our expertise lies in applying our deep understanding of the pathogenesis of infection paired with our ability to access some of the most advanced mAb discovery techniques and platforms available today. We have used this expertise to discover and develop novel mAbs with multiple mechanisms of action and high potency against their intended targets.

Our lead product candidate, ASN100, is a combination of two fully human mAbs that we are developing to address *S. aureus* cytotoxins, which are bacterial toxins that destroy human cells. 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 specifically to neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis, a scientific advancement that has not previously been achieved.

*S. aureus* is the leading cause of pneumonia in mechanically ventilated patients in the United States and the second leading cause of pneumonia in this patient population in Europe. There are more than one million mechanically ventilated patients in the United States each year, most of whom are treated in intensive care units, or ICUs. Based on published epidemiology data, up to approximately 20% of these patients are at high risk of progressing to *S. aureus* pneumonia, even when best-available prevention strategies are used. Despite the availability of antibiotic treatments, outcomes of ventilator-associated pneumonia, or VAP, are poor, with high mortality rates and incremental hospital costs of approximately \$40,000 per case. We believe ASN100 has the potential to improve the standard of care from suboptimal prevention and treatment to efficient and effective pre-emptive therapy. Moreover, given its product profile, ASN100 aligns well with accepted preventive hospital quality measures and antimicrobial stewardship efforts to reduce infections and antibiotic use.

In early 2017, we initiated a Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. We plan to enroll 354 patients in this double-blind, placebo-controlled superiority trial. The primary endpoint is the proportion of patients who develop *S. aureus* pneumonia during the 21-day period following a single dose of ASN100 as compared to placebo. The superiority design of the trial differs from traditional antibiotic trials, which are consistently designed to demonstrate non-inferiority compared to the applicable standard of care. We are in the early stages of this Phase 2 clinical trial and have only recently begun to dose patients. In the first half of 2018, by which we expect approximately one-third of the 354 total target patients will have been dosed and assessed through 21 days following dosing, we plan to have an independent data review committee conduct an interim analysis to assess the probability that the trial will succeed as designed. The analysis will either confirm the assumptions underlying our trial design, resulting in a recommendation that we continue the trial as designed, recommend an increase in the total number of patients to

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be dosed or advise that the trial is unlikely to be successful. We will remain blinded to the data and calculations underlying the analysis and will only receive recommendations on how to proceed. Assuming that this analysis does not identify any recommended changes in the number of patients to be enrolled and recommends that the trial continue, we expect to report top-line efficacy results from completion of the trial in the second half of 2018. Assuming positive top-line safety and efficacy results, we expect to use these data to design a pivotal Phase 3 clinical trial as well as inform the potential clinical development of ASN100 in additional indications.

We have completed a Phase 1 dose-ranging trial in 52 healthy volunteers, in which 18 of these healthy volunteers received ASN100 at doses equivalent to or greater than the Phase 2 clinical trial dose. ASN100 was well tolerated across all doses tested, including doses greater than twice the Phase 2 clinical trial dose, 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. Based on these results, we believe that a single preventive dose of ASN100 may be able to safely neutralize *S. aureus* cytotoxins and prevent pneumonia in high-risk, mechanically ventilated patients.

Our second program, ASN500, targets RSV, a virus that afflicts in aggregate over two million young children and elderly and immunocompromised patients annually in the United States, and can cause serious respiratory tract infections. We are currently evaluating mAbs that have exhibited exceptionally high potency against RSV in a laboratory setting, which may support development of a preventive therapy for use in multiple high-risk patient populations not addressed by the currently approved therapy. We expect to advance this mAb into Phase 1 clinical trials in 2019.

We are also pursuing two programs targeting Gram-negative infections, ASN300 for *Klebsiella pneumoniae* and ASN200 for *Escherichia coli*, by applying a precise and multi-modal mAb approach against novel targets to allow for potential use in both preventive and treatment settings, with a goal of providing safe and effective alternatives to small molecule antibiotics, particularly against multi-drug resistant strains. We have selected lead development candidates for each of these programs and are currently conducting preclinical studies to further characterize the mechanisms of action of these product candidates and discover biomarkers that may help identify high-risk patient populations to support future clinical development.

We have assembled a proven management team with years of highly relevant experience to enable the successful advancement of our product candidates. Our team has been collectively involved in the discovery, development and commercialization of over 20 marketed anti-infective drugs and biologics. Several members of our team previously held management positions at Cubist Pharmaceuticals, a leading anti-infective company that was acquired by Merck in 2015, and Bristol-Myers Squibb. Our programs are derived from the expertise of our founding scientists, who are widely recognized experts in mAb discovery, and the capabilities of our broader scientific team, which span immunology, bacterial and viral pathogenesis and monoclonal antibody drug discovery.

We are backed by leading life sciences investors, including OrbiMed, Polaris and SV Health Partners. We have also received funding from the Bill & Melinda Gates Foundation, or the Gates Foundation. Our clinical and scientific advisory boards are comprised of preeminent experts in infectious diseases, critical care and bacterial and viral pathogenesis.

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### Our Pipeline

The following chart summarizes information about our product candidates and programs.

Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Key Commentary and Next Anticipated Milestones	
<b>ASN100</b>	<b><i>Staphylococcus aureus</i></b> Prevention of pneumonia in high-risk, mechanically ventilated patients						<b>1H18:</b> Phase 2 trial power analysis results <b>2H18:</b> Phase 2 trial top-line safety and efficacy results
<b>ASN500</b>	<b>Respiratory Syncytial Virus</b> Prevention of RSV infection						<b>2019:</b> Phase 1 trial initiation
<b>ASN300</b>	<b><i>Klebsiella pneumoniae</i></b> Prevention and treatment of bacterial infections						Lead candidate selected Seeking external funding
<b>ASN200</b>	<b><i>Escherichia coli</i></b> Prevention and treatment of bacterial infections						Lead candidate selected Seeking external funding

### Our Strategy

Our goal is to be a leader in the discovery, development and commercialization of monoclonal antibody immunotherapies for serious infectious diseases. Our strategy includes the following key components:

- **Rapidly advance our lead product candidate, ASN100, through clinical development and regulatory approval.** We believe ASN100 has the potential to improve clinical and health-economic outcomes and healthcare quality measures by improving the standard of care from suboptimal prevention and treatment to efficient and effective pre-emptive therapy. In early 2017, we initiated a Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. We plan to enroll 354 patients in this double-blind, placebo-controlled superiority trial. The superiority design of the trial differs from traditional antibiotic trials, which are consistently designed to demonstrate non-inferiority compared to the applicable standard of care. Assuming positive results from the Phase 2 clinical trial, we expect to use these data to design a pivotal Phase 3 clinical trial as well as inform the potential clinical development of ASN100 in additional indications.
- **Apply our expertise in *S. aureus* pathogenesis to expand the indications for ASN100.** In addition to pneumonia, *S. aureus* is a leading cause of many other prevalent serious infections. The cytotoxins targeted by ASN100 are relevant to the pathogenesis of many of these particular infections. We are currently evaluating ASN100 in preclinical models of selected *S. aureus* infections, and if supported by the data generated in these studies as well as from our ongoing Phase 2 clinical trial of ASN100, we intend to initiate additional clinical trials in other *S. aureus* infection indications.
- **Pursue a rapid development strategy for advancing ASN500 into clinical trials.** We are seeking to rapidly advance our highest priority preclinical program, ASN500, for RSV prevention. We believe ASN500 has the potential to offer benefits over existing therapies in terms of potency, dosing strategy, manufacturing and route of administration, to better serve both new and existing target populations globally. We expect to advance this mAb into Phase 1 clinical trials in 2019.
- **Maximize the global commercial value of ASN100 and ASN500.** We have retained global commercialization rights to all of our product candidates. We expect to commercialize ASN100, if

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approved, directly using a specialized ICU-targeted sales force in the United States as well as potentially in Europe. In other markets, we plan to evaluate the merits of entering into commercialization agreements with partners who have local market expertise and capabilities. For ASN500, we may seek to enter into one or more strategic relationships if we pursue RSV indications beyond the hospital setting.

- **Advance our early-stage pipeline.** We are seeking to advance the development of our preclinical Gram-negative programs, ASN300 for *Klebsiella pneumoniae* and ASN200 for *Escherichia coli*, for potential use in both preventive and treatment settings, with a goal of providing safe and effective alternatives to small molecule antibiotics, particularly against multi-drug resistant strains. We are currently conducting preclinical studies and seeking external funding to support future potential clinical development of these programs.

### **The Need for New Approaches for the Management of Infectious Diseases**

The management of infectious diseases is a global problem that is inadequately addressed by currently marketed anti-infective drugs. Infections remain among the leading causes of preventable deaths worldwide, cause significant morbidity and place a substantial cost burden on healthcare systems. For decades, the standard of care for bacterial infections has been antibiotic-based treatment. However, the extensive use of antibiotics has led to the spread of antibiotic resistance, rendering these therapies increasingly ineffective in addressing serious infections and resulting in a global health crisis.

Despite the fact that outcomes of many serious infections remain poor, the current approach to many of these infections is to treat rather than proactively prevent them. Currently marketed antibiotics are often inappropriate for preventive therapy for a variety of reasons. For example, as the lack of specificity of antibiotics results in the propagation of resistance and indiscriminate damage to beneficial host bacteria, often referred to as a patient's microbiome, as well as adverse off-target effects. In addition, for certain viral diseases, preventive vaccinations are not available to many in-need patient populations or are ineffective. For example, the low potency and short half-life of currently available RSV antibody prophylaxis leads to high cost and the need for monthly injections, and is therefore used only in the highest-risk newborns in developed countries, leaving many young children and elderly and immunocompromised patients unserved and at risk of infection. We believe that our highly potent and selective mAb product candidates have the potential to yield safe and effective preventive therapies while addressing the shortcomings of current therapies.

### **Our Approach: Monoclonal Antibodies**

Monoclonal antibodies offer the potential to prevent and treat serious infections, while reducing the threat of antibiotic resistance and supporting hospital quality and antimicrobial stewardship initiatives. We are developing our mAb immunotherapies to minimize the shortcomings associated with currently approved anti-infective therapies. Unlike antibiotics, which target bacteria indiscriminately, our mAbs selectively target disease-causing bacteria indirectly by disarming their pathogenic processes, as is the case with ASN100, and also in some cases directly by targeting cell surface molecules.

Our lead mAb programs target two important pathogens: *S. aureus*, the most prevalent hospital pathogen in many serious acute infections, with high rates of antibiotic resistance and poor clinical and health-economic outcomes, and RSV, a respiratory pathogen that can cause serious lower respiratory infections requiring hospitalization in young children and elderly and immunocompromised patients.

### **Our Product Candidates**

#### ***Our Lead Product Candidate: ASN100***

ASN100, a first-in-class monoclonal antibody product candidate, is a combination of two fully human mAbs that are co-administered intravenously to neutralize the six cytotoxins critical to *S. aureus* pneumonia pathogenesis. By specifically targeting only these cytotoxins, we believe ASN100 can prevent infection and

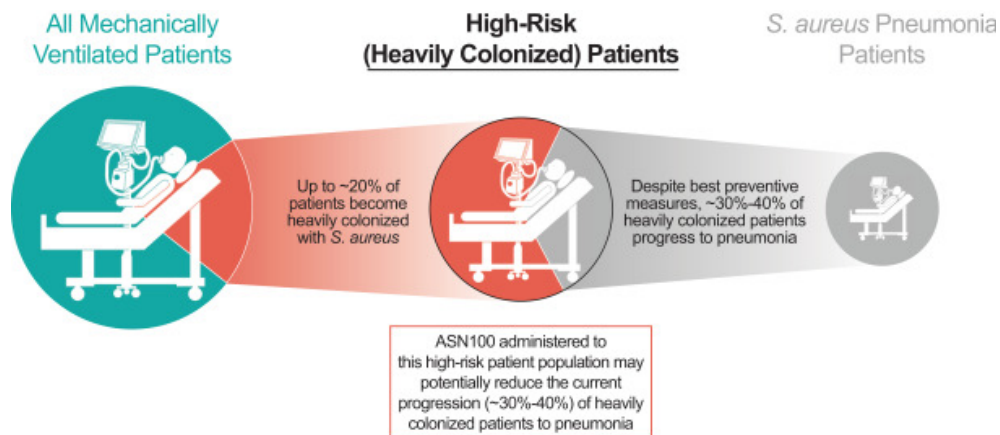


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avoid the shortcomings of antibiotics. ASN100 is currently in a Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in mechanically ventilated patients at high risk for *S. aureus* pneumonia, and has received Fast Track designation from the U.S. Food and Drug Administration, or FDA, for this indication.

### ***S. aureus* in Mechanically Ventilated Patients**

Mechanical ventilation is used to assist or replace spontaneous breathing in patients who need respiratory support while recovering from medical conditions, surgical procedures or traumatic events. There are over one million mechanically ventilated patients each year in the United States. The endotracheal tube used to deliver oxygen from a ventilator to a patient's lungs serves as a conduit through which *S. aureus* and other pathogens can readily transit from the patient's normal microflora and external environment to invade and persist in the lungs. We refer to the presence of *S. aureus* in the lungs without the signs and symptoms of active infection as colonization. *S. aureus* typically appears as one of the first colonizing bacteria within eight days of the initiation of mechanical ventilation. Based on published epidemiology data, up to approximately 20% of mechanically ventilated patients become heavily colonized with *S. aureus* in their respiratory secretions, putting them at high risk of progressing to *S. aureus* pneumonia, which occurs at a rate of approximately 30% to 40% in this patient population, even when best-available prevention strategies are used.



VAP is a preventable hospital-acquired infection that is responsible for significant clinical and health-economic consequences. The specific adverse consequences of VAP, whether caused by *S. aureus* or any other pathogen, include high mortality, significant resource and cost burden to ICUs and negative impact on hospital quality metrics. In particular, all-cause mortality associated with VAP ranges from 20% to 50%, and VAP is associated with extension of the duration of mechanical ventilation and hospital stay by approximately 12 and 13 days, respectively, with associated incremental cost to the hospital of approximately \$40,000 per case, despite the use of best-available antibiotic treatment. Furthermore, the consequences of VAP in mechanically ventilated patients who are heavily colonized with *S. aureus* in particular are similarly severe, with an approximate two-fold increase in all-cause mortality and increased duration of mechanical ventilation and hospital stay of four and seven days, respectively.

Given the serious outcomes associated with VAP, costly time- and resource-intensive prevention strategies are routinely employed in ICUs. These activities can take up to four hours of nursing time per patient per day and interfere with other critical patient care activities. Due to the potential undesirable consequences of antibiotic therapy and documented lack of efficacy in addressing colonization, the Infectious Diseases Society of America,

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or IDSA, and the American Thoracic Society, or ATS, recommend against providing preventive antibiotic therapy in heavily colonized patients, leaving no therapeutic options for proactively addressing this serious infection.

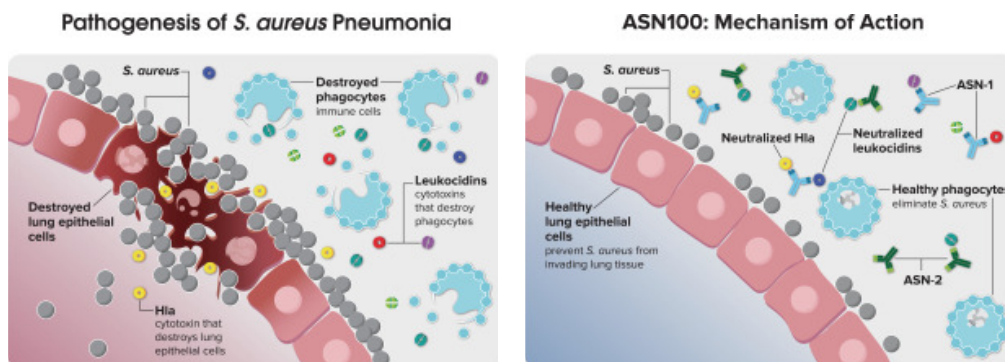
### *S. aureus* Pneumonia – Mechanism of Disease

Recently, it has been discovered 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. These cytotoxins comprise alpha-hemolysin, or Hla, and five leukocidins. Hla damages lung epithelial cells, allowing *S. aureus* to penetrate the lung epithelium, the cellular lining of lung tissue. This facilitates progression to pneumonia and other systemic infections. Leukocidins are cytotoxins that destroy human immune cells, eliminating patients' ability to harness their immune systems to eradicate *S. aureus* through phagocytosis, the natural process of human immune cells, or phagocytes, ingesting and eliminating harmful pathogens. *S. aureus* can produce up to five potent leukocidins: HlgAB, HlgCB, Panton-Valentine Leukocidin (PVL), LukED and LukGH.

Cytotoxin expression varies by *S. aureus* strain type and within strains over time. The vast majority of *S. aureus* strains carry the genes necessary to produce Hla and three of the leukocidins (HlgAB, HlgCB and LukGH). Up to 75% of strains carry the genes necessary to produce LukED, and up to 10% of strains carry the genes necessary to produce PVL. In order to broadly address *S. aureus* disease-causing potential, or virulence, in the lung, we believe that all six cytotoxins must be comprehensively and consistently addressed.

### Our Solution: ASN100

ASN100 utilizes a novel, anti-cytotoxin approach to prevent both tissue damage and the destruction of phagocytes caused by *S. aureus* cytotoxins, thereby reducing the virulence, invasiveness and pathogenicity of *S. aureus*. ASN100 is a combination of two co-administered fully human mAbs, ASN-1 and ASN-2, that together neutralize the six *S. aureus* cytotoxins critical to *S. aureus* pneumonia pathogenesis. ASN-1 is unique among known mAbs in its ability to neutralize Hla and four of the five leukocidins. Together, these mAbs are able to protect both the integrity of lung epithelial cells and phagocytes, potentially preventing *S. aureus* bacteria from invading lung tissue and allowing phagocytes to eliminate *S. aureus*. The pathogenesis of *S. aureus* pneumonia and the mechanism of action of ASN100 are depicted in the figures below.



Our mAbs were generated by applying our deep understanding of the pathogenesis of infection to identify antibody targets, paired with our ability to access state-of-the-art mAb discovery tools to effectively engage these targets. For example, in the case of ASN100, we identified and characterized the six *S. aureus* cytotoxin targets, revealing a common feature of five of these cytotoxins, Hla and four leukocidins. We then selected ASN-1, after

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interrogation of approximately 10 billion human mAb sequences, as the only mAb able to bind to and neutralize these five distinct targets, which it is able to do with high affinity. The sixth cytotoxin target, LukGH, has multiple sequence variants, and we selected ASN-2 for its high affinity and ability to bind to and neutralize all known sequence variants. We own or have the exclusive rights to these antibodies and antibody targets.

### ***Key Advantages of ASN100***

Multiple antibiotics are approved for the treatment of *S. aureus* pneumonia in mechanically ventilated patients, but none are approved for its prevention. In addition to the inherent limitations of targeting treatment rather than prevention, antibiotics leave bacterial virulence factors unaddressed while their lack of specificity can result in the propagation of antibiotic resistance, cause indiscriminate damage to the patient's microbiome and result in other off-target adverse safety effects. In light of suboptimal clinical outcomes associated with antibiotics for *S. aureus* pneumonia and the resulting healthcare costs and burden, we believe that a new therapeutic paradigm is needed and that ASN100 will offer the following specific benefits:

- **First-in-class therapeutic with novel mechanism of action.** ASN100 is the first and only therapy in development that neutralizes all six of the cytotoxins critical to the pathogenesis of *S. aureus* pneumonia, thereby protecting both lung epithelial cells and human immune cells. Other anti-cytotoxin monoclonal antibodies currently in development for *S. aureus* target only one of these six cytotoxins, Hla. We believe that, if ASN100 is approved, its novel mechanism of action will enable it to improve the standard of care from suboptimal prevention and treatment to efficient and effective pre-emptive therapy.
- **Mitigates the risk of resistance.** ASN100 precisely and specifically targets *S. aureus* cytotoxins and not the bacteria directly. Therefore, we expect ASN100 will mitigate the risk of resistance in *S. aureus* strains and normal microbiome bacteria that is typically observed with antibiotics. Additionally, we believe that ASN100 will be effective in neutralizing all six *S. aureus* cytotoxins implicated in pneumonia pathogenesis regardless of the antibiotic resistance profile of the strain of *S. aureus*.
- **Well tolerated with no off-target effects.** ASN100, a fully human monoclonal antibody product candidate, precisely targets only pathogenic *S. aureus* cytotoxins. In preclinical studies, ASN100 demonstrated no effect on human cell targets. In a Phase 1 clinical trial, ASN100 was well tolerated with no dose-limiting toxicities observed. The precise nature of ASN100's mechanism to specifically target and neutralize *S. aureus* cytotoxins also allows the patient's microbiome to remain unaffected by this therapy.
- **Clinical trials designed for superiority.** With no therapies approved for the prevention of *S. aureus* pneumonia, our Phase 2 clinical trial evaluating ASN100 has been designed and powered to demonstrate superiority to placebo. In the first half of 2018, we plan to have an independent data review committee conduct an interim analysis to assess the probability that the trial will succeed as currently designed. We expect that any Phase 3 clinical trial of ASN100 will be similarly designed and powered for superiority. This is in contrast to antibiotics, which treat infections only after they occur and are consistently benchmarked to be non-inferior to the applicable standard of care. Due to the superiority design of our ASN100 clinical trials, we believe that positive findings would provide a compelling demonstration to hospitals and health systems of the clinical and health-economic advantages of ASN100.
- **One-time dosing and seamless integration with current preventive practices.** ASN100 is being developed as a single-dose therapeutic to protect a targeted set of patients who are at high risk for *S. aureus* pneumonia. As part of daily ventilator hygiene practice, respiratory secretions are cleared from patients' endotracheal tubes frequently and can be readily tested for the presence of heavy *S. aureus* colonization using standard microbiologic diagnostics, allowing for easy identification of these patients. For these reasons, ASN100 has the potential to be easily integrated into, and to improve the effectiveness of, current inefficient and inadequate preventive approaches.
- **Positive impact on health economic and quality metrics.** We believe that ASN100 has the potential to show a meaningful and quantifiable impact on important health economic and hospital quality metrics. Specifically, we believe that ASN100 may demonstrate a reduction in *S. aureus* pneumonia rates and

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related lengths of ICU stay and days on mechanical ventilation, ultimately saving hospital costs and improving quality of care.

### **Phase 2 Clinical Trial**

In early 2017, we dosed the first patient with ASN100 in our Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. This trial is a double-blind, placebo-controlled superiority trial evaluating the efficacy and safety of ASN100 administered as a single dose. We plan to enroll 354 patients in the United States, Europe and multiple additional countries, randomized in a 1:1 ratio between study drug and placebo. The superiority design of the trial differs from traditional antibiotic trials, which are consistently designed to demonstrate non-inferiority compared to the applicable standard of care. The primary efficacy endpoint of the trial is the proportion of patients who develop *S. aureus* pneumonia through 21 days after dosing. The trial is designed to detect a 50% reduction in the occurrence of *S. aureus* pneumonia in the ASN100 arm when compared to placebo pneumonia rates based on published epidemiology data. Secondary endpoints include 28-day all-cause mortality, as well as length of stay in the ICU and days on mechanical ventilation. We will also gather ASN100 safety and pharmacokinetic data, including data on the pharmacokinetics of ASN100 in the lung, the site of infection. The trial is being conducted under an investigational new drug application, or IND, that we submitted to the FDA in July 2016 for the development of ASN100 for the treatment and prevention of *S. aureus* infections.

We are in the early stages of this Phase 2 clinical trial and have only recently begun to dose patients. In the first half of 2018, by which we expect approximately one-third of the 354 total target patients will have been dosed and assessed through 21 days following dosing, we plan to have an independent data review committee conduct an interim analysis to assess the probability that the trial will succeed as designed. The analysis will either confirm the assumptions underlying our trial design, resulting in a recommendation that we continue the trial as designed, recommend an increase in the total number of patients to be dosed or advise that the trial is unlikely to be successful. We will remain blinded to the data and calculations underlying the analysis and will only receive recommendations on how to proceed. Assuming that this analysis does not identify any recommended changes in the number of patients to be enrolled and recommends that the trial continue, we expect to report top-line efficacy results from completion of the trial in the second half of 2018. Assuming positive top-line safety and efficacy results from our Phase 2 trial, we expect to use these data to design a pivotal Phase 3 clinical trial as well as inform the potential clinical development of ASN100 in additional indications.

### **Phase 1 Clinical Data**

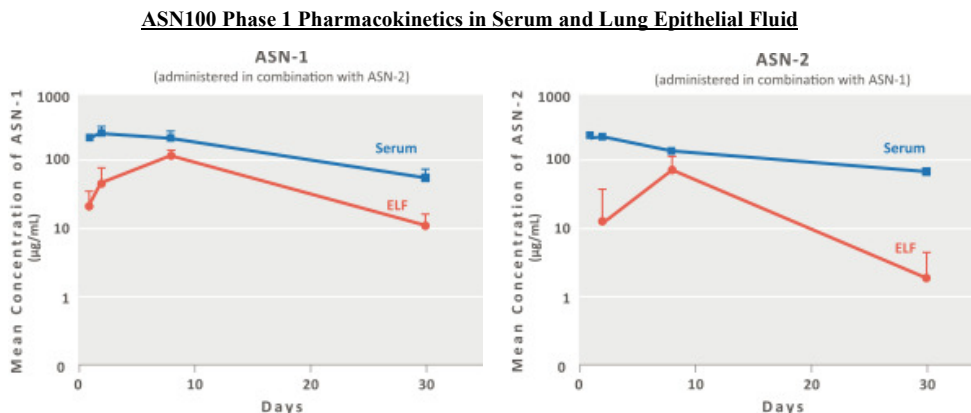
We successfully completed a Phase 1 single ascending dose clinical trial in 52 healthy volunteers to assess the safety, tolerability and pharmacokinetics of ASN100, both in the bloodstream and the lung. Forty-two volunteers received one dose of ASN-1 alone, ASN-2 alone or ASN-1 and ASN-2 in combination as ASN100, at doses of up to 4,000 mg of ASN-1 and ASN-2 alone and up to 8,000 mg of ASN100 (4,000 mg of each of ASN-1 and ASN-2 co-administered). Eighteen of these healthy volunteers received ASN100 at doses equivalent to or greater than the Phase 2 clinical trial dose. Thirty volunteers were randomized to receive active drug while 10 healthy volunteers received placebo. Twelve additional volunteers were treated in two open-label cohorts with ASN100 to gain more safety data and sample lung epithelial lining fluid, or ELF, by bronchoalveolar lavage to determine ASN100 lung penetration at 3,600 mg and 8,000 mg doses.

ASN100 was demonstrated to be well tolerated and no dose-limiting toxicities were observed. A total of 91 treatment-emergent adverse events were reported. Of these treatment-emergent adverse events, 68 occurred in 34 of 42 (81%) volunteers receiving ASN-1, ASN-2 or ASN100 and the remaining 23 occurred in 9 of 10 (90%) volunteers receiving placebo. All treatment-emergent adverse events were transient, mild or moderate in severity and resolved without intervention. No increase in adverse events was seen with dose escalation. Two mild treatment-emergent adverse events were possibly related to study drug: one headache (200 mg of ASN-1) and one report of fatigue (8,000 mg of ASN100). No infusion-related or hypersensitivity reactions were observed for ASN-1, ASN-2 or ASN100. All volunteers completed all study assessments. Anti-drug antibody responses after

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dosing were measured out to 10 months following dosing and no generation of anti-drug antibodies was observed in any volunteer tested.

The pharmacokinetic data supported single-dose administration of ASN100 based on a greater than three-week half-life for both ASN-1 and ASN-2 administered alone or in combination as ASN100. Furthermore, as depicted in the figure below, in a sample of six patients dosed with 3,600 mg of ASN100, both ASN-1 and ASN-2 were detected in lung ELF out to 30 days after dosing. These concentrations were well above those required to neutralize cytotoxins *in vitro* and *in vivo* studies as supported by pharmacokinetic and pharmacodynamic modeling. To our knowledge, ASN100 is the first mAb product candidate to be measured and reported in human lung ELF, an important and well-recognized measure for dose selection in traditional anti-infective drug development, supporting potential efficacy of ASN100 in the target indication.



Our approach to dose selection for ASN100 was based on tolerability and serum and ELF pharmacokinetics in healthy volunteers, as well as response in animal models of *S. aureus* pneumonia. These data all informed a pharmacokinetic and pharmacodynamics model that supported the ASN100 Phase 2 dose of 3,600 mg, or approximately 40 mg/kg (20 mg/kg of each of ASN-1 and ASN-2). This dose is two times the highest dose needed to protect 100% of animals in the most challenging *in vivo* studies, has been well tolerated in healthy volunteers and we believe it is adequate to address the potential variability in patient lung physiology and *S. aureus* cytotoxin levels.

### **Preclinical Studies**

We tested ASN100 in preclinical efficacy studies against a variety of common and highly virulent *S. aureus* strains known to produce high levels of cytotoxins, including antibiotic-resistant strains. We also conducted investigational new drug application, or IND, enabling pharmacology and toxicology studies and the results, combined with the results of our preclinical efficacy studies, support the potential use of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. The results of these preclinical studies are summarized below.

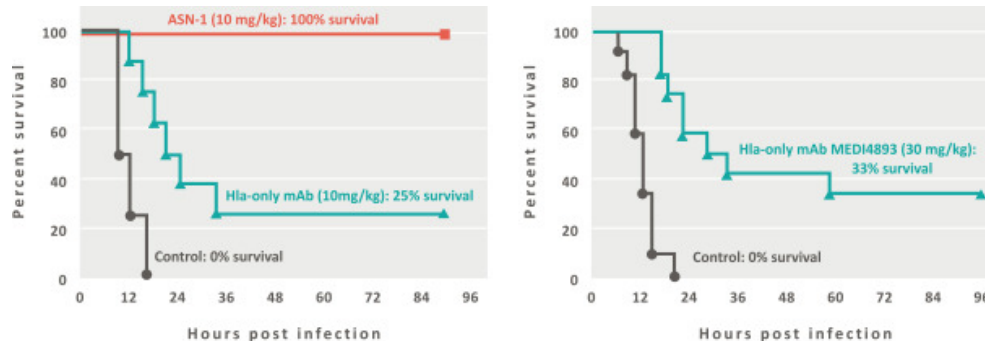
### **Preclinical Efficacy Studies**

*In Vivo Studies.* The activity of ASN-1 was demonstrated across a variety of animal models and strains of *S. aureus*, including the previously established and clinically predictive rabbit model of lethal *S. aureus* pneumonia. In this model, study drug was dosed 24 hours prior to the introduction of a large inoculum of live *S. aureus* directly into the lung. Published results from this model using a prevalent and virulent methicillin-resistant *S. aureus*, or MRSA, strain are shown in the figure on the left below. All of the rabbits treated with 10 mg/kg of ASN-1 survived, while only 25% of rabbits treated with 10 mg/kg of a comparator mAb that targets only H1a survived and no rabbits treated with a control mAb survived. In a separately published study of

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MEDI4893, a mAb that targets only Hla, in this same model with the same MRSA strain, only 33% of rabbits survived when dosed with 30 mg/kg of MEDI4893, as shown in the figure on the right below.

### **Efficacy of ASN-1 and Comparator mAbs in Lethal *S. aureus* Pneumonia Model**



Consistent with these data, in independently conducted studies of ASN100 in this same model against four additional *S. aureus* strains, we observed 100% survival during the relevant time period for this acute pneumonia model, for all rabbits receiving 20 mg/kg of ASN100 (10 mg/kg of each of ASN-1 and ASN-2).

In addition to prevention models, the activity of ASN100 alone and in combination with antibiotics was also studied in an animal model of pneumonia treatment. In this model, ASN100 exhibited activity when administered alone and exhibited notable potentiation of antibiotics' effects at sub-therapeutic doses across three antibiotic classes.

Overall, the data from our *in vivo* studies of ASN100 suggest that neutralizing bacterial cytotoxins prevents *S. aureus* pneumonia, highlight the importance of broad neutralization of the six cytotoxins critical to *S. aureus* pneumonia pathogenesis and support the use of ASN100 in patients receiving concomitant antibiotics.

**In Vitro Studies.** Results from *in vitro* experiments across a wide variety of *S. aureus* strains demonstrated that ASN100 consistently neutralized the six targeted *S. aureus* cytotoxins thereby protecting both human lung epithelial cells from destruction by Hla and human phagocytes from destruction by the five leukocidins critical to *S. aureus* pneumonia pathogenesis. *In vitro* experiments also demonstrated that a 1:1 ratio of ASN-1 and ASN-2, the two mAbs comprising ASN100, was optimal to consistently neutralize all five of the leukocidins and protect human phagocytes across a wide variety of *S. aureus* strains. ASN-1 was also tested in a human tracheobronchial epithelial tissue culture model to assess the role of Hla neutralization in preventing lung tissue damage, demonstrating complete protection of lung epithelial tissue from cytotoxin damage in this model.

#### **Non-Clinical Safety Studies**

We conducted *in vivo* toxicology studies of ASN100 in rats. No clinical observations, no body weight changes and no macroscopic or microscopic effects that were considered related to study treatment were seen when ASN100 was administered at doses of 300 mg/kg and 600 mg/kg. Based on these results, we determined a no-observed-effect level of ASN100 of 600 mg/kg, which is approximately 10-fold higher than the dose being studied in our ongoing Phase 2 clinical trial of ASN100. Additionally, an *in vitro* study of ASN-1, ASN-2 and ASN100 demonstrated no human tissue cross-reactivity, as we expected given that ASN-1 and ASN-2 specifically target bacterial cytotoxins.

#### **Commercial Rationale and Strategy**

We believe there is a significant commercial opportunity for ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. If ASN100 is approved, we expect to focus our initial

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commercial efforts in the United States and potentially Europe, which we believe represent the largest market opportunities for ASN100. In other markets, we plan to evaluate the merits of entering into commercialization agreements with partners who have local market expertise and capabilities.

We plan to deploy a highly targeted sales force to promote ASN100 to ICU healthcare professionals. The ICU is a contained setting within most hospitals and the burden of VAP is borne entirely by this unit. Unlike antibiotics, which typically target a broad patient population and can be used by many physician specialties, ASN100 targets a contained patient population within the ICU. We therefore believe that ASN100 uptake will not be limited by traditional restrictive hospital antibiotic usage policies. We also believe that a single-dose administration of ASN100 has the potential to be readily and easily integrated into and improve the effectiveness of current inefficient and inadequate preventive approaches.

Hospitalizations involving mechanical ventilations represent approximately 12% of all hospital costs in the United States. Moreover, in their published guidelines, the IDSA and the ATS estimate incremental cost associated with VAP infections to be approximately \$40,000 per patient in the United States. We believe that the potential advantages of ASN100, including superior clinical outcomes and measurable health-economic benefits, will drive significant physician demand. We also believe that pricing for a preventive therapy could be supported by the estimated cost savings associated with preventing one case of *S. aureus* pneumonia combined with a number needed to treat, or NNT, analysis, which is an analysis that quantifies the number of patients needed to be treated with a therapeutic in order to prevent one case of disease.

We believe that the current hospital reimbursement environment in the United States and Europe will also support our commercialization efforts for ASN100. In addition to seeking to control costs, hospitals are facing increasing pressure to improve quality of care metrics. For example, one of the largest payors in the United States, Medicare, has increased the use of financial incentives to improve quality of care across many metrics as well as the use of penalties for suboptimal performance, placing individual hospitals at risk of losing millions of dollars in reimbursement per year. These quality measures include, but are not limited to, the ability of a hospital to prevent hospital-acquired infections and reduce readmissions. With *S. aureus* pneumonia infections in mechanically ventilated patients being associated with an almost two-fold increase in readmission rates, we believe that ASN100 has the potential to offer significant health-economic benefits to hospitals in this area of need.

### ***Additional Indications and Markets***

*S. aureus* is a leading cause of many serious infections and is responsible for approximately 45% of skin infections, 45% of pneumonias and 20% of bloodstream infections treated in U.S. hospitals. Each year, over two million antibiotic prescriptions are written for the more than 1.7 million hospital-treated patients in the United States with confirmed *S. aureus* infections. Clinical consequences can be severe with, for example, reported mortality of approximately 40% in MRSA bloodstream infections. *S. aureus* cytotoxins often play a key role in these infections. We believe the unique attributes of ASN100 could be applied to additional indications to expand the potential use of ASN100 to prevent or treat other serious *S. aureus* infections in patients at high risk of infection.

Due to the need for improved treatment outcomes for *S. aureus* pneumonia and preclinical evidence of ASN100's potentiation of antibiotic effects, the first indication that we plan to pursue for ASN100 beyond prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients is treatment of *S. aureus* pneumonia. Approximately 250,000 patients per year are treated in U.S. hospitals for *S. aureus* pneumonia infections, with an associated mortality rate of up to 50% in certain patient populations. At the sites for our ongoing Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients, we plan to collect exploratory data on the safety and efficacy of ASN100 for the treatment of *S. aureus* pneumonia in mechanically ventilated patients who do not meet the enrollment criteria for the trial due to having already developed pneumonia. We anticipate the results of this analysis will be available in the second half of 2018.

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Other potential indications we are currently considering include: *S. aureus* pulmonary exacerbations in patients with cystic fibrosis, *S. aureus* bloodstream infections, *S. aureus* infections in high-risk surgical patients and certain serious complicated skin and skin structure infections caused by *S. aureus*. We anticipate that the data from our current ASN100 development program, including the results of the Phase 2 clinical trial, will continue to inform the development of ASN100 in these or other indications.

### **Our RSV Program: ASN500**

Our ASN500 program, comprised of mAbs targeting RSV for which we have observed high potency in preclinical *in vitro* and *in vivo* models, is currently in its lead-optimization phase. 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. We expect to advance this mAb, once selected, into Phase 1 clinical trials in 2019. In the near term, we plan to advance this program entirely with funding from the Gates Foundation.

RSV is a highly contagious virus that infects nearly every child at least once by the age of two and is a major cause of hospitalization due to respiratory infection in young children and elderly and immunocompromised patients. RSV infections can lead to serious respiratory complications, such as croup, pneumonia and bronchiolitis, as well as, in extreme cases, death. In the United States, an estimated 2.1 million children under the age of five with RSV infection require medical attention each year, and of these, approximately 60,000 are hospitalized. In the elderly and high-risk adult populations in the United States, RSV infection accounts for an estimated 180,000 hospitalizations and 14,000 deaths per year. Prophylaxis for RSV infection with an approved mAb product is used, but only to a limited extent, in the United States and in some other middle-to-high income countries in a narrow population of extremely premature infants or in those with congenital heart disease. This product's high cost and requirement for monthly dosing limit its use in resource-constrained settings. As such, there remains a need for novel, cost-effective approaches to the management of RSV infection in multiple large patient populations.

### **Our Gram-Negative Programs: ASN300 and ASN200**

Gram-negative bacteria are responsible for some of the most lethal hospital-acquired infections, such as bloodstream infections and pneumonia. Due to increasing antibiotic resistance, there are few remaining effective treatment options for these serious infections, necessitating new approaches. Our Gram-negative programs, ASN300 for *Klebsiella pneumoniae* and ASN200 for *Escherichia coli*, apply a precise and multi-modal mAb approach against novel targets to allow for potential use in both preventive and treatment settings, with a goal of providing safe and effective alternatives to small molecule antibiotics, particularly against multi-drug resistant strains. We have selected lead development candidates for our ASN300 and ASN200 programs based on data generated in *in vitro* assays, *in vivo* infection models, manufacturability assessments and toxicology studies. In these studies, we have observed, among other things, activity of these product candidates in *in vivo* models of infection prevention and, with respect to ASN200, potentiation of antibiotic effect in *in vitro* assays. We are currently conducting preclinical studies to further characterize the mechanisms of action of these product candidates and discover biomarkers that may help identify high-risk patient populations to support future clinical development. We are currently seeking external funding to further the preclinical and future potential clinical development of these programs.

### **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.



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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 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 ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our products, if approved, will 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.

### **ASN100**

There are currently no therapies approved for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. We are aware of two mAb products targeting *S. aureus* cytotoxin in clinical development, MedImmune's MEDI4893 and Aridis Pharmaceuticals' AR301, each of which targets only the cytotoxin Hla and is in Phase 2 clinical development. ASN100 may also compete with mAb products that may be developed to target *S. aureus* through different mechanisms of action, including XBiotech's 514G3, which targets *S. aureus* surface Protein A and is in Phase 2 clinical development, and Genentech's RG7861, which is comprised of a *S. aureus* bacterial-surface-targeting mAb attached to an antibiotic and is in Phase 1 clinical development.

### **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.

### **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 product candidates. If our 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 expect to explore commercialization of ASN100 and potentially other 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.

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### **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.

We utilized a single contract manufacturer to produce ASN100 drug product for our completed Phase 1 clinical trial and our ongoing Phase 2 clinical trial. We are currently in the process of transitioning to a new contract manufacturer of ASN100 drug product for our planned Phase 3 clinical trial and we have transferred to this new contract manufacturer the manufacturing technology utilized at our prior contract manufacturer. While we believe that this new contract manufacturer is capable of producing sufficient quantities of drug product to support our planned Phase 3 clinical trial, we also believe that there are a number of alternative third-party manufacturers that have similar capabilities that would be capable of providing sufficient quantities of drug product for the planned trial. However, should our new contract manufacturer not be able to provide sufficient quantities of drug product for our planned Phase 3 trial, we would be required to seek another contract manufacturer to provide this drug product, likely resulting in a delay in such Phase 3 trial.

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

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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 September 30, 2017, 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 one issued European patent, one pending patent application in the United States and nine pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Mexico 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 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 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 applications 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 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 a 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 in this sixth family will expire in April 2036. The seventh family consists of a pending PCT application with composition of matter claims covering a specified combination of antibodies. 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. Each family includes one U.S. provisional patent application with composition of matter claims covering antibodies with specified antibody sequences. We expect that any patents that issue from applications that claim priority to these provisional patent applications and are filed within one year following the applicable provisional application filing date, 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 one pending PCT application with composition of matter claims covering antibodies directed against a specified target. 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

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family will expire in November 2035. The third solely owned family consists of one pending PCT application with composition of matter claims covering antibodies with specified antibody sequences. We expect that any patents that issue in this third solely owned family will expire in October 2036. The co-owned families each consist of one pending PCT application with composition of matter claims covering antibodies with specified antibody sequences. We expect that any patents that issue in these co-owned families 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 pending patent applications in the United States, two pending patent applications in Europe and 11 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Mexico, New Zealand, Russia and South Africa. 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 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 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.

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[Table of Contents](#)**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, Adimab and Arsanis 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.

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Under the Adimab Collaboration Agreement, as of September 30, 2017, 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 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.

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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 and License Agreement in our ASN500 monoclonal antibody program.

Under the Adimab Option Agreement, Adimab has provided to us certain proprietary antibodies against respiratory syncytial virus, or 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

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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 September 30, 2017, we had incurred costs paid or payable to Adimab of approximately \$70,000 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 Arsanis) 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 grant agreement with the Gates Foundation (which is 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 agreement 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



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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***

***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 have 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 have 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 have 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.

***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

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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 have 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 charity default, or in the event of any other specified triggering event. A charity 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 have 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.

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In addition to the licenses described above, we have 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 charity 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.

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 have 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 have 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 charity default (as described above). If we do not cure the charity 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 charity 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.

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### **Government Regulation and Product Licensure**

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, 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 approval of the BLA and licensure 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.

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***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. 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 the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with FDA certain regulatory requirements 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

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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. This group provides authorization for 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.

**Human Clinical Trials in Support of a BLA.** Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated or at risk of the disease to be prevented, 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.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may 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

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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, currently exceeding \$2.4 million, and the sponsor of an approved BLA is also subject to an annual prescription drug program fee, currently \$304,162. 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, an exception from the establishment fee when the establishment does not engage in manufacturing the product during a particular fiscal year, and an exception from the product fee for a product that is the same as another product approved under an abbreviated pathway.

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 74<sup>th</sup> 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

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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 ten 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.



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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 ten 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

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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 PHS Act 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

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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 marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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

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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, 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.

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.

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.

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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. Specifically, those circumstances apply if a subsequent product with the same biologic for the same condition is shown to be clinically superior to the approved product. In this context, clinically superior means that the drug provides a significant therapeutic advantage over and above the already approved product in terms of greater efficacy, greater safety or by providing a major contribution to patient care.

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 June 2017, the FDA has approved five 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.

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### ***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.

***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

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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 Committee for Medicinal Products for Human Use, or 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.

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**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



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**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.

### **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 be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.

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- 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 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.

### ***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

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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

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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.

With the new Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the ACA. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law, however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing 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.

Further legislative changes to or regulatory changes under the ACA remain possible in the 115<sup>th</sup> U.S. Congress and under the Trump Administration. Congress has focused on additional legislative changes, including in particular repeal and replacement of certain provisions of the ACA. To those ends, on May 4, 2017, the U.S. House of Representatives passed the American Health Care Act, or AHCA. On the other hand, the Senate has considered but not passed the AHCA and other legislative proposals leading to new healthcare reform legislation. In addition, while the Trump Administration has threatened to allow the ACA to implode, a bipartisan group of legislators is working to address certain problems with the ACA. Accordingly, it remains to be seen whether new legislation modifying the ACA is enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare.

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

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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 September 30, 2017, we had 39 full-time employees, including a total of 16 employees with M.D., Pharm.D. or Ph.D. degrees. Of these full-time employees, 29 employees are engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

### **Facilities**

Our principal facilities consist of office and laboratory space. We occupy approximately 7,800 square feet of office space in Waltham, Massachusetts under a lease that currently expires in January 2019, approximately 1,500 square meters of office and laboratory space in Vienna, Austria under a lease that currently expires in April 2021 and approximately 25 square meters of laboratory space in Vienna, Austria under a lease with no fixed expiration date that is cancelable by either party upon six months' prior written notice. We believe that our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

### **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, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

### **Scientific and Clinical Advisory Boards**

We have established a scientific advisory board and a clinical advisory board and we regularly seek advice and input from these leading scientists and physicians on matters related to our research and development programs. The members of our advisory boards consist of experts across a range of key disciplines relevant to our programs. Our advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. All of our advisors are affiliated with other entities and devote only a small portion of their time to us.

The members of our advisory boards are generally compensated for their services in cash, at a fixed hourly or daily rate. In addition, our board of directors has agreed on a case-by-case basis to award certain members of our scientific advisory board with grants of cash, restricted stock or stock options in connection with the commencement of their service. In the case of restricted stock or stock options, such awards typically vest over four years, with 25% of the shares underlying the award vesting on the first anniversary of the grant date and an additional 1/48th of the original number of shares underlying the award vesting monthly thereafter.

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The current members of our scientific advisory board are:

<u>Name</u>	<u>Positions</u>
Paul G. Ambrose, Pharm.D.	President of the Institute for Clinical Pharmacodynamics, New York, USA; Honorary Research Fellow in Infectious Diseases at the University of Oxford, UK; and Adjunct Associate Research Professor at the University at Buffalo, New York
Birgitta Henriques-Normark, M.D., Ph.D.	Professor in Medical Microbial Pathogenesis in the Department of Microbiology, Tumor and Cell Biology at the Karolinska Institutet
Rick Malley, M.D..	Kenneth McIntosh Chair in Pediatric Infectious Diseases at Children's Hospital Boston and Associate Professor of Pediatrics at Harvard Medical School
Howard Mayer, M.D..	Senior Vice President and Head of Global Clinical Development at Shire Pharmaceuticals
Steven M. Opal, M.D.	Professor of Medicine in the Infectious Disease Division at The Warren Alpert Medical School of Brown University and Chief of Infectious Disease Division at Memorial Hospital of Rhode Island
Claire Poyart, M.D., Ph.D.	Professor of Medical Microbiology, University Paris Descartes; Head of the Laboratory of Bacteriology of Cochin Hospital; and Head of the National Reference Centre for Streptococci in France
Antoni Torres, M.D., Ph.D.	Head, Respiratory Intensive Care Unit, Department of Pneumology and Respiratory Allergy at the Clinical Institute of the Thorax, Hospital Clinic of Barcelona and Professor of Medicine at the University of Barcelona
Richard Wunderink, M.D.	Professor of Medicine in the Pulmonary and Critical Care Division of Northwestern University's Feinberg School of Medicine and Medical Director of the Medical Intensive Care Unit, Northwestern Memorial Hospital

The current members of our clinical advisory board are:

<u>Name</u>	<u>Positions</u>
Marin Kollef, M.D., FACP, FCCP (Chairman)	Professor of Medicine at the Washington University School of Medicine and Director of the Medical Intensive Care Unit and Respiratory Care Services at Barnes-Jewish Hospital in St. Louis, Missouri
Paul G. Ambrose, Pharm.D.	President of the Institute for Clinical Pharmacodynamics, New York, USA; Honorary Research Fellow in Infectious Diseases at the University of Oxford, UK; and Adjunct Associate Research Professor at the University at Buffalo, New York
Philip S. Barie, M.D.	Professor of Surgery at Weill Cornell Medical College; attending surgeon at New York-Presbyterian/Weill Cornell Medical Center; and Chief, Preston A. Wade (Red) Acute Care Surgery Service, New York-Presbyterian Hospital, Weill Cornell Medical Center

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<u>Name</u>	<u>Positions</u>
Helen W. Boucher, M.D.	Director of the Infectious Diseases Fellowship Program and Ventricular Assist Device and Cardiac Transplant Infectious Diseases Program at Tufts Medical Center; attending physician in the Division of Geographic Medicine and Infectious Diseases at Tufts Medical Center; and Associate Professor of Medicine at Tufts University School of Medicine
Jean Chastre, M.D. Ralph Corey, M.D.	Consulting Professor, Medical ICU, Hospital Pitié-Salpêtrière, Paris Professor of Medicine, Infectious Disease and Pathology of the Department of Medicine at Duke University; Gary Hock Professor of Global Health; and Vice-Chairman of the Department of Medicine at Duke University
Vance Fowler, M.D.	Professor of Medicine and Professor in Molecular Genetics and Microbiology at Duke University
Bruno Francois, M.D.	Specialist, Intensive Care Medicine at University Hospital of Limoges, France and Head of the Limoges Clinical Investigational Center
Howard Mayer, M.D.	Senior Vice President and Head of Global Clinical Development at Shire Pharmaceuticals
Vandana Menon, M.D., Ph.D., M.P.H.	Vice President, Better Outcomes Corporation and Adjunct Associate Professor, Tufts-New England Medical Center
Debra Poutsiaika, M.D., Ph.D.	Associate Professor of Medicine, Tufts University School of Medicine and Attending Physician, Division of Geographic Medicine and Infectious Diseases, Tufts Medical Center
George Sakoulas, M.D.	Associate Adjunct Professor, Division of Host-Microbe Systems and Therapeutics, Center for Immunity, Infection and Inflammation, at the University of California San Diego School of Medicine
Joseph Solomkin, M.D.	Professor of Surgery (Emeritus), University of Cincinnati College of Medicine and the CEO of OASIS Global
George Talbot, M.D.	Member and Immediate past Co-Chair of the ABSSI/CABP and HABP/VABP Project Teams at the Biomarkers Consortium of the Foundation of the National Institutes of Health and a Principal at Talbot Advisors, LLC
Antoni Torres, M.D., Ph.D.	Head, Respiratory Intensive Care Unit, Department of Pneumology and Respiratory Allergy at the Clinical Institute of the Thorax, Hospital Clinic of Barcelona and Professor of Medicine at the University of Barcelona

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## MANAGEMENT

### Executive Officers and Directors

The following table sets forth the name, age as of September 30, 2017 and position of each of our executive officers and directors.

Name	Age	Position
<b>Executive Officers</b>		
René Russo, Pharm.D., BCPS	42	President and Chief Executive Officer, Director
Eszter Nagy, M.D., Ph.D.	51	Co-Founder, Chief Scientific Officer, Managing Director of Arsanis Biosciences GmbH
Michael Gray, M.B.A., C.P.A.	46	Chief Operating Officer and Chief Financial Officer
Chris Stevens, M.D.	58	Chief Medical Officer
David Mantus, Ph.D.	54	Chief Development Officer
<b>Non-Employee Directors</b>		
Tillman U. Gerngross, Ph.D. <sup>(2)(3)</sup>	53	Co-Founder, Chairman of the Board of Directors
William Clark, M.B.A. <sup>(1)</sup>	49	Director
Carl Gordon, Ph.D., C.F.A.	52	Director
David McGirr, M.B.A. <sup>(1)</sup>	63	Director
Terrance McGuire <sup>(3)</sup>	61	Director
Claudio Nessi, Ph.D., M.B.A. <sup>(1)</sup>	48	Director
Michael Ross, Ph.D. <sup>(2)</sup>	68	Director
Amy Schulman, J.D. <sup>(2)(3)(4)</sup>	56	Director

<sup>(1)</sup> Member of the Audit Committee.

<sup>(2)</sup> Member of the Compensation Committee.

<sup>(3)</sup> Member of the Nominating and Corporate Governance Committee.

<sup>(4)</sup> Lead independent director.

### Executive Officers

**René Russo, Pharm.D., BCPS.** Dr. Russo has served as a member of our board of directors and as our President and Chief Executive Officer since April 2016. Dr. Russo served 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 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.

**Eszter Nagy, M.D., Ph.D.** Dr. Nagy co-founded Arsanis in 2010 and built a multi-disciplinary research and preclinical team in Vienna. Dr. Nagy has served as our Chief Scientific Officer and Managing Director of our wholly owned subsidiary, Arsanis Biosciences GmbH, since October 2011. Dr. Nagy also served on our Board of Directors from January 2011 until November 2017. From August 2013 to December 2015, Dr. Nagy served as our President. From January 1999 to September 2010, Dr. Nagy served in various roles during her 12 years at Intercell AG (now Valneva SE), most recently as its Senior Vice President of Global Research. Dr. Nagy co-founded EveliQure



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Biotechnologies (Vienna) in 2012, and was on the Board of Directors of WittyCell, S.A.S (now part of Abivax, SE), both of which are vaccine development companies. Prior to joining the biotechnology industry, Dr. Nagy spent 10 years in academic research, including as an Associate Professor at the University Medical School of Pécs and a Visiting Scientist in the Department of Cancer Genetics at the Roswell Park Cancer Institute. Dr. Nagy received her M.D. and Ph.D. from the University Medical School of Pécs, Hungary, and was a Postdoctoral Fellow at Dartmouth Medical School.

**Michael Gray, M.B.A., C.P.A.** Mr. Gray has served as our Chief Financial Officer since March 2016 and as our Chief Operating Officer since September 2017. Mr. Gray also served 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.

**Chris Stevens, M.D.** Dr. Stevens has served as our Chief Medical Officer since June 2016. Prior to joining us, Dr. Stevens served as a consultant for over 30 companies, from 2004 to 2016, where he assisted in all stages of drug development across the United States and in Europe. Dr. Stevens served key clients during this time, including Cubist Pharmaceuticals, Inc., Dyax, Inc. and Millennium/Takeda, all biotechnology companies. Previously, he served as Senior Vice President of Clinical Development at Alnara Pharmaceuticals from 2009 to 2011 through its acquisition by Eli Lilly and also previously held medical director roles at Circe Biomedical and Altus Pharmaceuticals. Additionally, Dr. Stevens spent 10 years as a clinical and research gastroenterologist at Beth Israel Deaconess Medical Center in Boston and as an Assistant Professor of Medicine at Harvard Medical School, during which he authored more than 30 peer-reviewed publications. Dr. Stevens received his B.A. in Chemistry from the University of North Carolina at Chapel Hill and his M.D. from the University of Miami.

**David Mantus, Ph.D.** Dr. Mantus has served as our Chief Development Officer since May 2016, and as our Executive Vice President, Regulatory, Clinical Operations and Manufacturing from October 2015 until May 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.

### **Non-Employee 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

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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 Life Sciences Advisors, 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.

**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 Genocoea Biosciences, Inc., or Genocoea, a publicly traded biopharmaceutical company, a position he has held since February 2011. He also served as Genocoea's Chief Business Officer from August 2010 to February 2011. Prior to joining Genocoea, 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 Genocoea, 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.

**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 1998. 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.

**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 Insmid 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 Roka Bioscience, Inc., a publicly traded molecular diagnostics company where he has served since December 2013. Mr. McGirr received a B.Sc. in Civil Engineering from the University of Glasgow and received

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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 boards of directors of Acceleron Pharma, Inc., a publicly traded biopharmaceutical company, where he has served since 2005, and Pulmatrix, Inc., a publicly traded biopharmaceutical company, where he has served since May 2016. From January 2008 to July 2014, Mr. McGuire served on the board of directors of Trevena, Inc., a publicly traded biopharmaceutical company. 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 35 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 since 2016, where he has served as a Partner since 2004 and served as an Investment Director from 2001 until 2004. Also, Dr. Nessi has served as Managing Director of Omega Funds since November 2016. Dr. Nessi held other board positions at Axoyan AG from April 2002 to November 2003, 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. In addition to Arsanis, Dr. Nessi is also currently serving on the Board of Directors of the private biotechnology companies Avitide, Inc., GenKyoTex SA and Anaconda Biomed. 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 Life Sciences since 2002 where he also served as a Venture Partner from 2001 until 2002. Prior to joining SV Life Sciences, 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

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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 Partners, 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.

**Amy Schulman, J.D.** Ms. Schulman has served as a member of our board of directors since February 2015. Since July 2014, she has served as Venture Partner at Polaris Partners' Boston office, and she served as CEO of Arisia 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, both Polaris-backed companies. 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 Composition and Election of Directors**

#### ***Board Composition***

Effective upon the closing of this offering, our board of directors will have nine members. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal.

Our directors were elected to and currently serve on the board of directors pursuant to a stockholders' agreement among us and certain of our stockholders. This agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

Our certificate of incorporation and bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our certificate of incorporation and bylaws will also provide that our directors may be removed only for cause by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our certificate of incorporation and bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be William Clark, David McGirr and Claudio Nessi, and their term will expire at the annual meeting of stockholders to be held in 2018;
- the class II directors will be René Russo, Michael Ross and Amy Schulman, and their term will expire at the annual meeting of stockholders to be held in 2019; and
- the class III directors will be Tillman U. Gerngross, Carl Gordon and Terrance McGuire, and their term will expire at the annual meeting of stockholders to be held in 2020.

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Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See “Description of Capital Stock—Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions.”

### ***Director Independence***

The NASDAQ Stock Market LLC, or NASDAQ, Marketplace Rules, or the NASDAQ Listing Rules, require 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 Securities Exchange Act of 1934, as amended, or 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 the NASDAQ Listing Rules, a director will only qualify as an “independent director” if, in the opinion of the listed company’s 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 August and September 2017, 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, with the exception of René Russo, Eszter Nagy and Tillman U. Gerngross, is an “independent director” as defined under the NASDAQ Listing Rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Dr. Russo is not an independent director under these rules because she is our President and Chief Executive Officer. Dr. Nagy was not an independent director under these rules because she is our Chief Scientific Officer. Dr. Nagy resigned from our board of directors immediately prior to the effective time of the registration statement of which this prospectus is a part. Dr. Gerngross is not an independent director under these rules because of his service as Chief Executive Officer of Adimab, LLC, a company with which we have a commercial relationship.

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

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board.

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### ***Audit Committee***

The members of our audit committee are William Clark, Carl Gordon and David McGirr. Mr. McGirr is the chair of the audit committee. Our audit committee's responsibilities will 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 that 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 internal audit function;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm 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 Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that David McGirr is an "audit committee financial expert" as defined in applicable SEC rules. We believe that the composition of our audit committee will meet the requirements for independence under current NASDAQ and SEC rules and regulations. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements, in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

### ***Compensation Committee***

The members of our compensation committee are Tillman U. Gerngross, Michael Ross and Amy Schulman. Ms. Schulman is the chair of the compensation committee. Our compensation committee's responsibilities will include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an 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 then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

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Our board of directors has determined that Dr. Ross and Ms. Schulman are independent within the meaning of Rule 10C-1 under the Exchange Act. We expect to satisfy the member independence requirements for the compensation committee prior to the end of the transition period provided under current NASDAQ and SEC rules and regulations for companies completing their initial public offering.

### ***Nominating and Corporate Governance Committee***

The members of our nominating and corporate governance committee are Tillman U. Gerngross, Terrance McGuire and Amy Schulman. Mr. McGuire is the chair of the nominating and corporate governance committee. Our nominating and corporate governance committee's responsibilities will include:

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

We expect to satisfy the member independence requirements for the nominating and corporate governance committee prior to the end of the transition period provided under current NASDAQ rules and regulations for companies completing their initial public offering.

### **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

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

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the code on our website, [www.arsanis.com](http://www.arsanis.com). In addition, we intend to post on our website all disclosures that are required by law or NASDAQ stock market listing standards concerning any amendments to, or waivers from, any provision of the code.

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### EXECUTIVE COMPENSATION

The following discussion relates to the compensation of our President and Chief Executive Officer, René Russo, our Chief Operating Officer and Chief Financial Officer, Michael Gray, and our Chief Medical Officer, Chris Stevens, for fiscal year 2016. These three individuals are collectively referred to in this prospectus as our named executive officers.

In preparing to become a public company, we have begun a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. We have begun, and expect to continue in the coming months, to evaluate the need for revisions to our executive compensation program to ensure that our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company.

#### Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2016.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (S)</u>	<u>Bonus (S)<sup>(1)</sup></u>	<u>Option Awards (S)<sup>(2)</sup></u>	<u>All Other Compensation (S)</u>	<u>Total (S)</u>
René Russo, Pharm.D., BCPS <i>President and Chief Executive Officer</i>	2016	380,000	116,519	292,318	—	788,837
Michael Gray, M.B.A., C.P.A. <i>Chief Operating Officer and Chief Financial Officer</i>	2016	292,460	181,890 <sup>(3)</sup>	312,897	—	787,247
Chris Stevens, M.D. <i>Chief Medical Officer</i>	2016	221,768	153,221 <sup>(4)</sup>	162,814	176,853 <sup>(5)</sup>	714,656

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

<sup>(2)</sup> 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 13 to our consolidated financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards.

<sup>(3)</sup> Includes a \$100,000 sign-on bonus paid to Mr. Gray in connection with his hire in 2016.

<sup>(4)</sup> Includes a \$100,000 sign-on bonus paid to Dr. Stevens in connection with his hire in 2016.

<sup>(5)</sup> Consists of fees paid to Dr. Stevens for services that he provided to us as a consultant in 2016 prior to his hire.

#### Narrative to Summary Compensation Table

**Base Salary.** In 2016, we paid Dr. Russo an annualized base salary of \$380,000. In 2016, we paid Mr. Gray an annualized base salary of \$350,000, which was pro rated to reflect the number of days he served with our company following his hire in March 2016. In 2016, we paid Dr. Stevens an annualized base salary of \$380,000, which was pro rated to reflect the number of days he served with our company following his hire in June 2016. 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. 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 and Mr. Gray to \$450,000 and \$400,000, respectively, in each case subject to and effective upon the closing of this offering and, in the case of Mr. Gray’s increase, to be retroactive to September 27, 2017.

**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



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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 2016, based upon our overall performance, we granted to Dr. Russo an option to purchase 47,757 shares of our common stock. In 2016, we granted to Mr. Gray an option to purchase 51,274 shares of our common stock and to Dr. Stevens an option to purchase 26,369 shares of our common stock, in each case in connection with the commencement of his employment.

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 this offering, the award of stock options to our executive officers has been 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 1/48<sup>th</sup> 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 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.

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 this offering will be equal to the fair market value of shares of our common stock on the date of grant, which will be determined by reference to the closing market price of our common stock on the date of grant.

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**Outstanding Equity Awards**

The following table sets forth information regarding all outstanding stock options held by each of our named executive officers as of December 31, 2016.

<u>Name</u>	<u>Option Awards</u>				
	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Equity Incentive Plan Awards; Number of Securities Underlying Unexercised Unearned Options (#)</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
René Russo, Pharm.D., BCPS	28,647	52,242 <sup>(1)</sup>	—	\$ 8.20	7/21/2025
Michael Gray, M.B.A., C.P.A.	—	47,757 <sup>(2)</sup>	—	\$ 9.39	7/20/2026
Chris Stevens, M.D.	—	51,274 <sup>(3)</sup>	—	\$ 9.39	7/20/2026
	—	26,369 <sup>(4)</sup>	—	\$ 9.39	7/20/2026

<sup>(1)</sup> Dr. Russo's option to purchase 80,889 shares of common stock vests over four years, with 25% of the shares underlying the option vested on July 16, 2016 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

<sup>(2)</sup> Dr. Russo's option to purchase 47,757 shares of common stock vests over four years, with 25% of the shares underlying the option vested on April 28, 2017 and 2.0833% of the shares vesting monthly thereafter, subject to continued service.

<sup>(3)</sup> Mr. Gray's option to purchase 51,274 shares of common stock 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.

<sup>(4)</sup> Dr. Stevens' option to purchase 26,369 shares of common stock 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.

**Employment Agreements**
***Letter Agreement with Dr. Russo***

In connection with our initial hiring of Dr. Russo as our Chief Development Officer, we entered into a letter agreement with her dated July 12, 2015. Under the letter agreement, Dr. Russo is an at will employee, and her employment with us can be terminated by her or us at any time and for any reason. The letter agreement provides that Dr. Russo is entitled to a base salary of \$380,000 during her employment with us and that she is eligible, at our sole discretion, to earn an annual bonus of up to 35% of her base salary. Dr. Russo's letter agreement also provided that she was entitled to the grant of an option to purchase an amount of shares of our common stock equal to 3.5% of our fully diluted outstanding share count, with an exercise price equal to the fair market value of a share of our common stock on the grant date, subject to a four-year vesting schedule, which option was granted in July 2015.

Under the letter agreement, Dr. Russo is entitled, subject to her execution and nonrevocation of a release of claims in our favor, in the event of the termination of her employment by us without cause or by her for good reason, each as defined in her letter agreement with us, to (i) continue receiving her then-current annual base salary for a period of nine months following the date her employment with us is terminated, and (ii) continue receiving an amount equal to COBRA premiums for health benefit coverage on the same terms as were applicable to her prior to her termination for a period of nine months following the date that her employment with us is terminated, or earlier, if she becomes eligible to enroll in a health benefit plan with a new employer.

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In addition, the letter agreement provides that in the event Dr. Russo's employment with us terminates by reason of her death or disability, Dr. Russo is entitled to a pro rata annual bonus for the year in which such termination occurred based on her target bonus and the number of days served during the year. In addition, in the event that Dr. Russo's employment is terminated by us without cause or by Dr. Russo with good reason, each as defined in the letter agreement, within 12 months following a change of control, or as determined by our board of directors to have been specifically related to such change of control and without cause within three months prior to a change of control, Dr. Russo will be entitled under the letter agreement to (i) continue receiving her then-current annual base salary for a period of 12 months following the date her employment with us is terminated, (ii) continue receiving an amount equal to COBRA premiums for health benefit coverage on the same terms as were applicable to her prior to her termination for a period of 12 months following the date her employment with us is terminated, or earlier, if she becomes eligible to enroll in a health benefit plan with a new employer and (iii) the automatic vesting and exercisability of any unvested stock options and other equity awards then held by her on the date her employment with us is terminated, which options will remain exercisable for the time period set forth in the applicable grant agreement.

### ***Amended and Restated Letter Agreement with Dr. Russo***

In October 2017, we entered into an amended and restated letter agreement with Dr. Russo that will become effective upon the closing of this offering and will supersede and replace our existing letter agreement with Dr. Russo. The terms of the amended and restated letter agreement are substantially similar to those of our existing letter agreement with Dr. Russo, except that under the amended and restated letter agreement Dr. Russo will:

- be entitled to a base salary of \$450,000;
- be eligible, at our sole discretion, to earn an annual bonus of up to 55% of her base salary;
- upon a termination of her employment by us without cause or by her for good reason, be entitled to severance consisting of (i) 12 months continuation of base salary, (ii) a lump sum payment equal to the annual bonus she would have received had she remained employed through the end of the year, pro rated based on the number of days served during the year, and (iii) up to 12 months of COBRA premiums;
- upon a termination of her employment by us without cause or by her for good reason within 18 months following a change of control of our company, be entitled to severance consisting of (i) 18 months of base salary plus 1.5 times her target annual bonus for the year of termination, payable over 18 months following termination, (ii) up to 18 months of COBRA premiums and (iii) full acceleration of vesting of all equity awards held by Dr. Russo; and
- upon a change of control of our company, be entitled to full acceleration of vesting of all equity awards granted to Dr. Russo prior to the closing of this offering.

### ***Letter Agreement with Mr. Gray***

In connection with our initial hiring of Mr. Gray as our Chief Financial Officer and Chief Business Officer, we entered into a letter agreement with him dated January 15, 2016. Under the letter agreement, Mr. Gray is an at will employee, and his employment with us can be terminated by him or us at any time and for any reason. The letter agreement provides that Mr. Gray is entitled to a base salary of \$350,000 during his employment with us and that he is eligible, at our sole discretion, to earn an annual bonus of up to 35% of his base salary. Mr. Gray's letter agreement also provided that he was entitled to the grant of an option to purchase 32,962 shares of our common stock. Following a review of executive compensation in June 2016, our compensation committee approved the grant of an option to purchase 51,274 shares of our common stock to Mr. Gray in lieu of the option contemplated by his letter agreement. The option has an exercise price equal to the fair market value of a share of our common stock on the grant date, is subject to a four-year vesting schedule and was granted in July 2016.

Under the letter agreement, Mr. Gray is entitled, subject to his execution and nonrevocation of a release of claims in our favor, in the event of the termination of his employment by us without cause or by his for good reason, each as defined in his letter agreement with us, to (i) continue receiving his then-current annual base

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salary for a period of three months following the date his employment with us is terminated, and (ii) continue receiving an amount equal to COBRA premiums for health benefit coverage on the same terms as were applicable to him prior to his termination for a period of three months following the date that his employment with us is terminated, or earlier, if he becomes eligible to enroll in a health benefit plan with a new employer.

In addition, the letter agreement provides that in the event Mr. Gray's employment with us terminates by reason of his death or disability, Mr. Gray is entitled to a pro rata annual bonus for the year in which such termination occurred based on his target bonus and the number of days served during the year. In addition, in the event that Mr. Gray's employment is terminated by us without cause or by Mr. Gray with good reason, each as defined in the letter agreement, within 12 months following a change of control, or as determined by our board of directors to have been specifically related to such change of control and without cause within three months prior to a change of control, Mr. Gray will be entitled under the letter agreement to (i) continue receiving his then-current annual base salary for a period of four months following the date his employment with us is terminated, (ii) continue receiving an amount equal to COBRA premiums for health benefit coverage on the same terms as were applicable to him prior to his termination for a period of four months following the date his employment with us is terminated, or earlier, if he becomes eligible to enroll in a health benefit plan with a new employer and (iii) the automatic vesting and exercisability of any unvested stock options and other equity awards then held by him on the date his employment with us is terminated, which options will remain exercisable for the time period set forth in the applicable grant agreement.

### ***Amended and Restated Letter Agreement with Mr. Gray***

In October 2017, we entered into an amended and restated letter agreement with Mr. Gray that will become effective upon the closing of this offering and will supersede and replace our existing letter agreement with Mr. Gray. The terms of the amended and restated letter agreement are substantially similar to those of our existing letter agreement with Mr. Gray, except that under the amended and restated letter agreement Mr. Gray will:

- be entitled to a base salary of \$400,000;
- be eligible, at our sole discretion, to earn an annual bonus of up to 40% of his base salary;
- upon a termination of his employment by us without cause or by him for good reason, be entitled to severance consisting of (i) 12 months continuation of base salary, (ii) a lump sum payment equal to the annual bonus he would have received had he remained employed through the end of the year, pro rated based on the number of days served during the year, and (iii) up to 12 months of COBRA premiums;
- upon a termination of his employment by us without cause or by him for good reason within 18 months following a change of control of our company, be entitled to severance consisting of (i) 18 months of base salary plus 1.5 times his target annual bonus for the year of termination, payable over 18 months following termination, (ii) up to 12 months of COBRA premiums and (iii) full acceleration of vesting of all equity awards held by Mr. Gray; and
- upon a change of control of our company, be entitled to full acceleration of vesting of all equity awards granted to Mr. Gray prior to the closing of this offering.

### ***Letter Agreement with Dr. Stevens***

In connection with our initial hiring of Dr. Stevens as our Chief Medical Officer, we entered into a letter agreement with him dated April 28, 2016. Under the letter agreement, Dr. Stevens is an at will employee, and his employment with us can be terminated by him or us at any time and for any reason. The letter agreement provides that Dr. Stevens is entitled to a base salary of \$380,000 during his employment with us and that he is eligible, at our sole discretion, to earn an annual bonus of up to 30% of his base salary. Dr. Stevens' letter agreement also provided that he was entitled to the grant of an option to purchase 26,369 shares of our common stock, with an exercise price equal to the fair market value of a share of our common stock on the grant date, subject to a four-year vesting schedule, which option was granted in July 2016.

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Under the letter agreement, Dr. Stevens is entitled, subject to his execution and nonrevocation of a release of claims in our favor, in the event of the termination of his employment by us without cause or by his for good reason, each as defined in his letter agreement with us, to (i) continue receiving his then-current annual base salary for a period of three months following the date his employment with us is terminated, and (ii) continue receiving an amount equal to COBRA premiums for health benefit coverage on the same terms as were applicable to him prior to his termination for a period of three months following the date that his employment with us is terminated, or earlier, if he becomes eligible to enroll in a health benefit plan with a new employer.

In addition, the letter agreement provides that in the event Dr. Stevens' employment with us terminates by reason of his death or disability, Dr. Stevens is entitled to a pro rata annual bonus for the year in which such termination occurred based on his target bonus and the number of days served during the year. In addition, in the event that Dr. Stevens' employment is terminated by us without cause or by Dr. Stevens with good reason, each as defined in the letter agreement, within 12 months following a change of control, or as determined by our board of directors to have been specifically related to such change of control and without cause within three months prior to a change of control, Dr. Stevens will be entitled under the letter agreement to (i) continue receiving his then-current annual base salary for a period of four months following the date his employment with us is terminated, (ii) continue receiving an amount equal to COBRA premiums for health benefit coverage on the same terms as were applicable to him prior to his termination for a period of four months following the date his employment with us is terminated, or earlier, if he becomes eligible to enroll in a health benefit plan with a new employer and (iii) the automatic vesting and exercisability of any unvested stock options and other equity awards then held by him on the date his employment with us is terminated, which options will remain exercisable for the time period set forth in the applicable grant agreement.

### ***Amended and Restated Letter Agreement with Dr. Stevens***

In October 2017, we entered into an amended and restated letter agreement with Dr. Stevens that will become effective upon the closing of this offering and will supersede and replace our existing letter agreement with Dr. Stevens. The terms of the amended and restated letter agreement are substantially similar to those of our existing letter agreement with Dr. Stevens, except that under the amended and restated letter agreement Dr. Stevens will:

- upon a termination of his employment by us without cause or by him for good reason, be entitled to severance consisting of (i) 12 months continuation of base salary, (ii) a lump sum payment equal to the annual bonus he would have received had he remained employed through the end of the year, pro rated based on the number of days served during the year, and (iii) up to 12 months of COBRA premiums; and
- upon a termination of his employment by us without cause or by him for good reason within 12 months following a change of control of our company, be entitled to severance consisting of (i) 12 months of base salary plus his target annual bonus for the year of termination, payable over 12 months following termination, (ii) up to 12 months of COBRA premiums and (iii) full acceleration of vesting of all equity awards held by Dr. Stevens.

### ***Employee Non-Competition, Non-Solicitation, Confidentiality and Assignment of Inventions 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 us any prior inventions that such executive officer incorporates into inventions assigned to us under this agreement.

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[Table of Contents](#)**Stock Option and Other Compensation Plans**

In this section we describe our 2010 Special Stock Incentive Plan, as amended to date, or the 2010 Plan; our 2011 Stock Incentive Plan, as amended to date, or the 2011 Plan; our 2017 Equity Incentive Plan, or the 2017 Plan; and our 2017 Employee Stock Purchase Plan, or the 2017 ESPP. Prior to this offering, we granted awards to eligible participants under the 2010 Plan and the 2011 Plan. Following the closing of this offering, we expect to grant awards to eligible participants under the 2017 Plan and the 2017 ESPP.

**2010 Plan**

The 2010 Plan was initially approved by our board of directors and stockholders in August 2010 and was subsequently amended in 2012, 2013 and 2016. The 2010 Plan provides for the grant of incentive stock options, non-qualified options, shares, restricted or otherwise, of our common stock and other stock-based awards. We refer to awards granted under the 2010 Plan as stock rights. Our employees, directors and consultants are eligible to receive stock rights under the 2010 Plan; however incentive stock options may only be granted to our employees. As of December 31, 2016, a maximum of 585,994 shares of our common stock, or the equivalent of such number after our board of directors makes any adjustments upon any change in capitalization or corporate transaction, were authorized for issuance under the 2010 Plan.

The type of stock right granted under the 2010 Plan and the terms of such stock right are set forth in the applicable stock right award agreement.

Pursuant to the 2010 Plan, our board of directors (or a committee to which our board delegates its authority) administers the 2010 Plan. Subject to the provisions of the 2010 Plan, our board of directors is authorized to:

- interpret the provisions of the 2010 Plan and all stock rights and make all rules and determinations that it deems necessary or advisable for the administration of the 2010 Plan;
- determine which employees, directors and consultants will be granted stock rights;
- determine the number of shares of our common stock for which a stock right will be granted;
- specify the terms and conditions upon which a stock right may be granted;
- correct any defect, supply any omission or reconcile any inconsistency in the plan or any grant agreement to the extent it deems expedient to carry the plan into effect; and
- modify grant agreement terms for participants of any specified jurisdiction as it deems necessary or appropriate to facilitate the 2010 Plan or to recognize any differences in tax or other laws applicable to us, to any of our affiliates or to participants.

**Effect of certain changes in capitalization.** If our shares of common stock are subdivided or combined into a greater or smaller number of shares, if we issue shares of common stock as a stock dividend, or if we make any distribution of additional, new or different shares or securities of ours or any distribution of non-cash assets with respect to our shares of common stock, then, subject to the terms of the 2010 Plan, our board of directors shall proportionately and appropriately adjust:

- the number of shares of our common stock available for issuance under the 2010 Plan;
- the number of shares of our common stock deliverable upon the exercise of an option or acceptance of a stock grant; and
- the exercise or purchase price per share.

**Effect of certain corporate transactions.** In the event that we are consolidated with or acquired by another entity in a merger, consolidation or sale of all or substantially all of our assets (other than a transaction to merely change the state of incorporation), which we refer to as corporate transactions, our board of directors, or the

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board of directors of any entity assuming our obligations under the 2010 Plan, may, in its discretion, take one of the following actions pursuant to the 2010 Plan as to outstanding options, subject to the terms of the 2010 Plan:

- provide for the continuation of the outstanding options by equitably substituting for the shares of our common stock then underlying such options either with securities of any successor or acquiring entity or the consideration payable with respect to the outstanding shares of our common stock in connection with the corporate transaction;
- accelerate the time at which participants in the 2010 Plan may exercise outstanding options granted under the plan so that options are fully exercisable from and after a date prior to the date that the corporate transaction is consummated;
- provide by written notice to the participants that the outstanding options will terminate unless exercised (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction) within a specified period following the date of the notice; or
- terminate each outstanding option in exchange for a cash payment equal to the consideration payable upon consummation of the corporate transaction to a holder of the number of shares of our common stock into which such option would have been exercisable (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction), minus the aggregate exercise price of such option.

In taking any of the above actions with respect to stock rights, our board of directors will not be obligated to treat all stock rights, all stock rights held by a participant or all stock rights of the same type, identically.

As of September 30, 2017, options to purchase 107,089 shares of common stock were outstanding under the 2010 Plan, at a weighted average exercise price of \$1.85 per share, and options to purchase 8,936 shares of our common stock had been exercised under the 2010 Plan.

Our board of directors may amend or terminate the 2010 Plan, provided that if stockholder approval is not obtained within 12 months after any amendment to the 2010 Plan increasing the number of shares authorized under the plan or changing the class of person eligible to receive incentive stock options under the plan, no options granted pursuant to such amendment will be deemed to be incentive stock options and no incentive stock options may be issued pursuant to such amendment thereafter. Any modification or amendment of the 2010 Plan that adversely affects a participant's rights will require such participant's consent.

No further awards will be made under the 2010 Plan; however, awards outstanding under the 2010 Plan will continue to be governed by their existing terms.

### **2011 Plan**

The 2011 Plan was initially approved in February 2011 and was subsequently amended in 2013, 2014, 2015 and 2016. The 2011 Plan provides for the grant of incentive stock options, non-qualified options, shares, restricted or otherwise, of our common stock and other stock-based awards. We refer to awards granted under the 2011 Plan as stock rights. Our employees, directors and consultants are eligible to receive stock rights under the 2011 Plan; however incentive stock options may only be granted to our employees. As of September 30, 2017, a maximum of 1,299,038 shares of our common stock, or the equivalent of such number after our board of directors makes any adjustments upon any change in capitalization or corporate transaction, were authorized for issuance under the 2011 Plan.

The type of stock right granted under the 2011 Plan and the terms of such stock right are set forth in the applicable stock right award agreement.

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Pursuant to the 2011 Plan, our board of directors (or a committee to which our board delegates its authority) administers the 2011 Plan. Subject to the provisions of the 2011 Plan, our board of directors is authorized to:

- interpret the provisions of the 2011 Plan and all stock rights and make all rules and determinations that it deems necessary or advisable for the administration of the 2011 Plan;
- determine which employees, directors and consultants will be granted stock rights;
- determine the number of shares of our common stock for which a stock right will be granted;
- specify the terms and conditions upon which a stock right may be granted;
- correct any defect, supply any omission or reconcile any inconsistency in the plan or any grant agreement to the extent it deems expedient to carry the plan into effect; and
- modify grant agreement terms for participants of any specified jurisdiction as it deems necessary or appropriate to facilitate the 2011 Plan or to recognize any differences in tax or other laws applicable to us, to any of our affiliates or to participants.

***Effect of certain changes in capitalization.*** If our shares of common stock are subdivided or combined into a greater or smaller number of shares, if we issue shares of common stock as a stock dividend, or if we make any distribution of additional, new or different shares or securities of ours or any distribution of non-cash assets with respect to our shares of common stock, then, subject to the terms of the 2011 Plan, our board of directors shall proportionately and appropriately adjust:

- the number of shares of our common stock available for issuance under the 2011 Plan;
- the number of shares of our common stock deliverable upon the exercise of an option or acceptance of a stock grant; and
- the exercise or purchase price per share.

***Effect of certain corporate transactions.*** In the event that we are consolidated with or acquired by another entity in a merger, consolidation or sale of all or substantially all of our assets (other than a transaction to merely change the state of incorporation), which we refer to as corporate transactions, our board of directors, or the board of directors of any entity assuming our obligations under the 2011 Plan, may, in its discretion, take one of the following actions pursuant to the 2011 Plan as to outstanding options, subject to the terms of the 2011 Plan:

- provide for the continuation of the outstanding options by equitably substituting for the shares of our common stock then underlying such options either with securities of any successor or acquiring entity or the consideration payable with respect to the outstanding shares of our common stock in connection with the corporate transaction;
- accelerate the time at which participants in the 2011 Plan may exercise outstanding options granted under the plan so that options are fully exercisable from and after a date prior to the date that the corporate transaction is consummated;
- provide by written notice to the participants that the outstanding options will terminate unless exercised (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction) within a specified period following the date of the notice; or
- terminate each outstanding option in exchange for a cash payment equal to the consideration payable upon consummation of the corporate transaction to a holder of the number of shares of our common stock into which such option would have been exercisable (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction), minus the aggregate exercise price of such option.

In taking any of the above actions with respect to stock rights, our board of directors will not be obligated to treat all stock rights, all stock rights held by a participant or all stock rights of the same type, identically.



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As of September 30, 2017, options to purchase 1,090,031 shares of common stock were outstanding under the 2011 Plan, at a weighted average exercise price of \$5.97 per share, and options to purchase zero shares of our common stock had been exercised under the 2011 Plan.

Our board of directors may amend or terminate the 2011 Plan, provided that if stockholder approval is not obtained within 12 months after any amendment to the 2011 Plan increasing the number of shares authorized under the plan or changing the class of person eligible to receive incentive stock options under the plan, no options granted pursuant to such amendment will be deemed to be incentive stock options and no incentive stock options may be issued pursuant to such amendment thereafter. Any modification or amendment of the 2011 Plan that adversely affects a participant's rights will require such participant's consent.

No further awards will be made under the 2011 Plan; however, awards outstanding under the 2011 Plan will continue to be governed by their existing terms.

### ***2017 Equity Incentive Plan***

Our board of directors has adopted, and our stockholders have approved, the 2017 Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus is a part. The 2017 Plan provides for the grant of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of our common stock reserved for issuance under the 2017 Plan is the sum of: (1) 585,994; plus (2) the number of shares (up to 1,368,918 shares) equal to the sum of the number of shares of our common stock available for issuance under the 2010 Plan and the 2011 Plan immediately prior to the effectiveness of the 2017 Plan and the number of shares of our common stock subject to outstanding awards under the 2010 Plan and 2011 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the lowest 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 such fiscal year and an amount determined by our board of directors.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2017 Plan. Incentive stock options, however, may only be granted to our employees.

Pursuant to the terms of the 2017 Plan, our board of directors (or a committee delegated by our board of directors) will administer the plan and, subject to any limitations in the plan, will select the recipients of awards and determine:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and
- the number of shares of our common stock subject to and the terms of any stock appreciation rights, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to an executive officer to grant awards under the 2017 Plan, the executive officer will have the power to make awards to all of our employees, except executive officers. Our

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board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards (which may include a formula by which the exercise price will be determined), and the maximum number of shares subject to awards that such executive officer may make.

***Effect of certain changes in capitalization.*** Upon the occurrence of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, our board of directors shall equitably adjust:

- the number and class of securities available under the 2017 Plan;
- the share counting rules under the 2017 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to, and the repurchase price per share subject to, each outstanding restricted stock award; and
- the share and per-share related provisions and the purchase price, if any, of each other stock-based award.

***Effect of certain corporate transactions.*** Upon a merger or other reorganization event (as defined in the 2017 Plan), our board of directors may, on such terms as our board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of, or a combination of, the following actions pursuant to the 2017 Plan as to some or all outstanding awards, other than restricted stock awards:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited, and/or vested but unexercised awards will terminate, immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of the notice;
- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and/or
- provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings).

Our board of directors does not need to take the same action with respect to all awards, all awards held by a participant or all awards of the same type.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted stock awards will continue for the benefit of the successor

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company and will, unless our board of directors may otherwise determine, apply to the cash, securities or other property into which shares of our common stock are converted or exchanged pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award or any other agreement between the participant and us.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2017 Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part as the case may be.

No award may be granted under the 2017 Plan on or after the date that is ten years following the effectiveness of the registration statement related to this offering. Our board of directors may amend, suspend or terminate the 2017 Plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

### ***2017 Employee Stock Purchase Plan***

Our board of directors has adopted, and our stockholders have approved, the 2017 ESPP, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus is a part. The 2017 ESPP will be administered by our board of directors or by a committee appointed by our board of directors. The 2017 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 219,748 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2017 ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2019 and continuing until, and including, the fiscal year ending December 31, 2029, equal to the lowest of 512,745 shares of our common stock, 2% of the number of shares of our common stock outstanding on the first day of such fiscal year and an amount determined by our board of directors.

All of our employees or employees of any designated subsidiary, as defined in the 2017 ESPP, are eligible to participate in the 2017 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- such person has been employed by us or by a designated subsidiary for at least six months prior to enrolling in the 2017 ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2017 ESPP.

No employee may purchase shares of our common stock under the 2017 ESPP and any of our other employee stock purchase plans in excess of \$25,000 of the fair market value of our common stock (as of the date of the option grant) in any calendar year. In addition, no employee may purchase shares of our common stock under the 2017 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries.

We expect to make one or more offerings to our eligible employees to purchase stock under the 2017 ESPP beginning at such time as our board of directors may determine. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our common stock at the end of the offering period. Our board of directors or a committee designated by the board of directors may, at their discretion, choose a different period of not more than 12 months for offerings.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2017 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her

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accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the 2017 ESPP, the purchase price shall be determined by our board of directors for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

An employee who is not a participant on the last day of the offering period is not entitled to purchase shares under the 2017 ESPP, and the employee's accumulated payroll deductions will be refunded. An employee's rights under the 2017 ESPP terminate upon voluntary withdrawal from an offering under the 2017 ESPP at any time, or when the employee ceases employment for any reason.

We will be required to make equitable adjustments to the number and class of securities available under the 2017 ESPP, the share limitations under the 2017 ESPP, and the purchase price for an offering period under the 2017 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends.

In connection with a reorganization event, as defined in the 2017 ESPP, our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our common stock under the 2017 ESPP on such terms as our board or committee determines:

- provide that options shall be assumed, or substantially equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board or committee in such notice, which date shall not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event under the terms of which holders of our common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our common stock that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the acquisition price is treated as the fair market value of our common stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2017 ESPP minus (2) the result of multiplying such number of shares by the purchase price; and/or
- provide that, in connection with our liquidation or dissolution, options shall convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2017 ESPP or any portion thereof. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Internal Revenue Code. Further, our board of directors may not make any amendment that would cause the 2017 ESPP to fail to comply with Section 423 of the Internal Revenue Code. The 2017 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

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### **401(k) 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.

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

Our certificate of incorporation, which will become effective upon the closing of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or 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 certificate of incorporation, which will become effective upon the closing of this offering, 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 we intend to enter into new indemnification agreements with all of our directors and executive officers prior to the completion of this offering. 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 of 1933, as amended, or the Securities Act, may be permitted to directors, executive officers or persons controlling us, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1

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plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It also is possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

### Director Compensation

The table below shows all compensation to our non-employee directors during 2016.

Name	Fees Earned or Paid in Cash (S)	Option Awards (S) <sup>(1)</sup>	Total (S)
Tillman U. Gerngross, Ph.D.	67,500	231,974	299,474
Jan Adams, Ph.D. <sup>(2)</sup>	—	—	—
Daniel Burgess <sup>(3)</sup>	21,667	—	21,667
Carl Gordon, Ph.D., C.F.A.	—	—	—
Terrance McGuire	—	—	—
Claudio Nessi, Ph.D., M.B.A.	—	—	—
Michael Ross, Ph.D.	—	—	—
Amy Schulman, J.D.	70,000	—	70,000

<sup>(1)</sup> 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 13 to our consolidated financial statements appearing at the end of this prospectus regarding assumptions underlying the valuation of equity awards. The option reported in this column was granted to Dr. Gerngross in connection with his service as chairman of our board of directors and consisted of an option to purchase 38,675 shares of common stock at an exercise price of \$9.39 per share, subject to vesting as to 25% after one year from the date of grant and the remainder monthly over the following three years, subject to continued service. In addition to the option described above, as of December 31, 2016, Dr. Gerngross held an option to purchase 26,809 shares of common stock at an exercise price of \$1.85 per share that was fully vested, Mr. Burgess held an option to purchase 6,482 shares of common stock at an exercise price of \$8.06 per share that was vested with respect to 3,644 shares and Ms. Schulman held an option to purchase 6,482 shares of common stock at an exercise price of \$8.06 per share that was vested with respect to 3,104 shares. As of December 31, 2016, there were no other stock awards or option awards outstanding and held by our non-employee directors.

<sup>(2)</sup> Dr. Adams resigned from our board of directors on September 27, 2017.

<sup>(3)</sup> Mr. Burgess resigned from our board of directors on September 27, 2017.

Prior to this offering, we paid cash fees to certain of our non-employee directors for their service on our board of directors, however we did not have a formal non-employee director compensation policy. We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings. Dr. Russo, our director who also serves as our President and Chief Executive Officer, does not receive any additional compensation for her service as a director. Dr. Russo is one of our named executive officers and, accordingly, the compensation that we pay to Dr. Russo is discussed under “—Summary Compensation Table” and “—Narrative to Summary Compensation Table.” Dr. Nagy, our Chief Scientific Officer, also served as a member of our board of directors during 2016 and 2017, until her resignation from our board immediately prior to the effective time of the registration statement of which this prospectus is a part. Dr. Nagy did not receive any additional compensation for her service as a director.

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In September 2017, our board of directors approved a director compensation program that became effective on the effective date of the registration statement of which this prospectus forms a part. Under this director compensation program, we will 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, if any, and the chairman of each committee will 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 and no fee shall be payable in respect of any period prior to the completion of this offering. 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:

	<u>Member Annual Fee</u>	<u>Chairman Annual Fee</u>	<u>Lead Independent Director Fee</u>
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 will continue to 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 effective on the effective date of the registration statement of which this prospectus forms a part, each non-employee director will receive under the 2017 Plan, upon (1) the pricing of this offering, with respect to each non-employee director then serving on our board of directors, and (2) upon his or her initial election to our board of directors, with respect to each non-employee director elected to our board of directors after this offering, an option to purchase 7,324 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 (other than directors who are elected on or before this offering, for which the six-month period will not be required) will receive, under the 2017 Plan, an option to purchase 2,929 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 fair market value of our common stock on the date of grant.

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### TRANSACTIONS WITH RELATED PERSONS

Since January 1, 2014, we have engaged in the following transactions with our directors, executive officers and holders of more than 5% of our voting securities, and affiliates of our directors, executive officers and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

#### Series B Convertible Preferred Stock Financing—Second Closing

In May 2015, we issued and sold an aggregate of 966,851 shares of our Series B convertible preferred stock in the second tranche of our Series B convertible preferred stock financing at a price per share of \$7.24 in cash, for an aggregate purchase price of \$7,000,001. The following table sets forth the aggregate number of shares of our Series B convertible preferred stock that we issued and sold to our 5% stockholders and their affiliates in this second tranche and the aggregate purchase price for such shares:

<u>Purchaser<sup>(1)</sup></u>	<u>Shares of Series B Preferred Stock</u>	<u>Cash Purchase Price</u>
Entities affiliated with Polaris Venture Partners	276,243	\$1,999,999
Entities affiliated with SV Life Sciences	276,243	\$1,999,999
OrbiMed Private Investments IV, LP	276,243	\$1,999,999
NeoMed Innovation V, L.P.	138,122	\$1,000,003

<sup>(1)</sup> See “Principal Stockholders” for additional information about shares held by these entities.

#### 2015 Convertible Note Financing

In December 2015, we issued and sold an aggregate of \$4,000,000 in 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 the closing of our Series C convertible preferred stock financing in April 2016. The following table sets forth the aggregate principal amount of notes issued and sold to our 5% stockholders and their affiliates in this transaction and the cash purchase price for such notes:

<u>Purchaser<sup>(1)</sup></u>	<u>Aggregate Principal Amount of 2015 Notes</u>	<u>Cash Purchase Price</u>
Entities affiliated with Polaris Venture Partners	\$ 1,188,237	\$1,188,237
Entities affiliated with SV Life Sciences	\$ 1,188,237	\$1,188,237
OrbiMed Private Investments IV, LP	\$ 1,188,237	\$1,188,237
NeoMed Innovation V, L.P.	\$ 435,289	\$ 435,289

<sup>(1)</sup> See “Principal Stockholders” for additional information about shares held by these entities.

#### Series C Convertible Preferred Stock Financing

In April 2016, we issued and sold an aggregate of 1,031,342 shares of our Series C convertible preferred stock, consisting of (i) 569,946 shares sold for cash at a price per share of \$9.65 for an aggregate cash purchase price of \$5,499,979 and (ii) 461,396 shares issued upon conversion of \$4,007,242 in outstanding principal and interest under the 2015 Notes at a price per share of approximately \$8.69. Additionally, in connection with the Series C convertible preferred stock financing, we issued and sold an aggregate of \$5,500,000 in 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



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accrued under the 2016 Notes was converted into shares of Series D convertible preferred stock in connection with the closing of our Series D convertible preferred stock financing in April 2017. The following table sets forth the aggregate numbers of shares of our Series C convertible preferred stock that we sold to our 5% stockholders and their affiliates in these transactions for cash and cancellation of indebtedness under the 2015 Notes, respectively, the aggregate amount of consideration for such shares, the aggregate principal amount of the 2016 Notes that we issued and sold to our 5% stockholders and their affiliates in these transactions and the cash purchase price for the 2016 Notes:

<u>Purchaser<sup>(1)</sup></u>	<u>Shares of Series C Preferred Stock Issued for Cash</u>	<u>Cash Purchase Price</u>	<u>Shares of Series C Issued upon Conversion of 2015 Notes</u>	<u>Principal Cancelled under 2015 Notes</u>	<u>Interest Cancelled under 2015 Notes</u>	<u>Aggregate Principal Amount of 2016 Notes</u>	<u>Cash Purchase Price for 2016 Notes</u>
Entities affiliated with Polaris Venture Partners	92,350	\$891,178	137,062	\$1,188,237	\$ 2,151	\$891,178	\$891,178
Entities affiliated with SV Life Sciences Fund	92,350	\$891,178	137,062	\$1,188,237	\$ 2,151	\$891,178	\$891,178
OrbiMed Private Investments IV, LP	92,350	\$891,178	137,062	\$1,188,237	\$ 2,151	\$891,178	\$891,178
NeoMed Innovation V, L.P.	33,830	\$326,460	50,210	\$ 435,289	\$ 788	\$326,467	\$326,460

<sup>(1)</sup> See "Principal Stockholders" for additional information about shares held by these entities.

### 2017 Convertible Note Financing

In January 2017, we issued and sold an aggregate of \$4,934,981 in 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 the closing of our Series D convertible preferred stock financing in April 2017. The following table sets forth the aggregate principal amount of notes issued and sold to our 5% stockholders and their affiliates in this transaction and the cash purchase price for such notes:

<u>Purchaser<sup>(1)</sup></u>	<u>Aggregate Principal Amount of 2017 Notes</u>	<u>Cash Purchase Price</u>
Entities affiliated with Polaris Venture Partners	\$ 1,294,943	\$1,294,943
Entities affiliated with SV Life Sciences	\$ 1,294,943	\$1,294,943
OrbiMed Private Investments IV, LP	\$ 1,294,943	\$1,294,943
NeoMed Innovation V, L.P.	\$ 565,147	\$ 565,147
Tillman U. Gerngross, Ph.D.	\$ 250,000	\$ 250,000

<sup>(1)</sup> See "Principal Stockholders" for additional information about shares held by these entities.

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**Series D Convertible Preferred Stock Financing**

In April 2017, we issued and sold an aggregate of 14,220,284 shares of our Series D convertible preferred stock, consisting of (i) 12,323,987 shares sold for an aggregate of \$35,053,178 in cash and conversion of \$4,946,793 in outstanding principal and interest under the 2017 Notes at a price per share of approximately \$3.2457 and (ii) 1,896,297 shares issued upon conversion of \$5,539,344 in outstanding principal and interest under the 2016 Notes at a price per share of approximately \$2.92. The following table sets forth the aggregate numbers of shares of our Series D convertible preferred stock that we sold to our 5% stockholders and their affiliates in these transactions and the aggregate amount of consideration for such shares:

<u>Purchaser<sup>(1)</sup></u>	<u>Shares of Series D Preferred Stock Issued for Cash and upon Conversion of 2017 Notes</u>			<u>Interest Cancelled under 2017 Notes</u>	<u>Shares of Series D Preferred Stock Issued upon Conversion of 2016 Notes</u>		
	<u>Cash Purchase Price</u>	<u>Principal Cancelled under 2017 Notes</u>	<u>Interest Cancelled under 2017 Notes</u>		<u>Principal Cancelled under 2016 Notes</u>	<u>Interest Cancelled Under 2016 Notes</u>	
Bill & Melinda Gates Foundation	2,464,799	\$7,999,998	—	—	—	—	—
Entities affiliated with Polaris Venture Partners	1,924,752	\$4,949,125	\$1,294,943	\$ 3,099	307,259	\$ 891,178	\$ 6,375
Entities affiliated with SV Life Sciences Fund	1,924,750	\$4,949,125	\$1,294,943	\$ 3,099	307,262	\$ 891,178	\$ 6,375
OrbiMed Private Investments IV, LP	1,924,752	\$4,949,125	\$1,294,943	\$ 3,099	307,262	\$ 891,178	\$ 6,375
NeoMed Innovation V, L.P.	839,938	\$2,159,687	\$ 565,147	\$ 1,353	112,559	\$ 326,467	\$ 2,335
Tillman U. Gerngross, Ph.D.	308,099	\$ 749,399	\$ 250,000	\$ 598	—	—	—

<sup>(1)</sup> See “Principal Stockholders” for additional information about shares held by these entities.

In September 2017, we issued and sold an additional 1,540,500 shares of Series D convertible preferred stock to Section 32 Fund I, LP, at a price of \$3.2457 per share, for gross proceeds of \$5.0 million.

**Indications of Interest**

Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering.

**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 provide certain laboratory services and sublet approximately 150 square meters of office and lab space. Tamás Henics, the husband of Eszter Nagy, our Chief Scientific Officer, serves as Chief Scientific Officer at EveliQure.

Payments due to us from EveliQure under the agreement were €75,000 (or \$83,000) and €71,000 (or \$79,000) for the years ended December 31, 2015 and 2016, respectively, and approximately €66,000 (or \$73,000) to date in 2017. These amounts included rental charges as well as amounts attributable to facilities and laboratory services. The agreement remains in effect until terminated and either Arsanis Biosciences GmbH or EveliQure can terminate the agreement at any time on six months’ notice.

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### **Agreements with Adimab, LLC**

We are party to a collaboration agreement with Adimab, LLC, or Adimab, that we entered into in May 2011, which was subsequently amended in February 2013, January 2014, January 2015 and April 2017. 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. We made payments to Adimab pursuant to the license and assignment agreement of \$0.5 million, \$0.2 million and \$0.1 million for the years ended December 31, 2014, 2015 and 2016, respectively. We have not made any payments under this agreement to Adimab to date in 2017.

We are also party to an option and license agreement with Adimab that we entered into in February 2017, pursuant to which we have made payments of \$70,871 to Adimab to date in 2017.

See “Business—Collaboration and License Agreements” for additional information regarding the collaboration agreement and the option and license agreement.

### **Agreements with Bill & Melinda Gates Foundation**

We are party to a grant agreement with the Bill & Melinda Gates Foundation, or the Gates Foundation, that we entered into in February 2017, pursuant to which the Gates Foundation granted us up to \$9.3 million to conduct specified preclinical development activities. We are also party to a letter agreement with the Gates Foundation that we entered into in April 2017 in connection with the purchase by the Gates Foundation of \$8.0 million of our Series D convertible preferred stock. See “Business—Collaboration and License Agreements” for additional information regarding these agreements.

### **Registration Rights**

We are a party to an investors’ rights agreement with the holders of our preferred stock, including our 5% stockholders and their affiliates and entities affiliated with some of our directors. This investors’ rights agreement provides these holders the right, subject to certain conditions, beginning six months following the completion of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing.

See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

### **Stockholders’ Agreement**

We are party to a stockholders’ agreement with the holders of our preferred stock, including our 5% stockholders and their affiliates and entities affiliated with some of our directors, providing, among other things, for specified voting with respect to the election of directors. This agreement will terminate upon the closing of this offering.

### **Indemnification Agreements**

Our certificate of incorporation, which will become effective upon the closing of this offering, provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with our directors, and we intend to enter into new indemnification agreements with all of our directors and executive officers prior to the completion of this offering.

### **Policies and Procedures for Related Person Transactions**

Our board of directors has adopted written 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.

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If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a “related person transaction,” the related person must report the proposed related person transaction to our Chief Financial Officer and the chairman of our audit committee. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, 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 chairman 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 the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person’s interest in the transaction. As appropriate for the circumstances, 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 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.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC’s related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person’s position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of \$200,000 or 5% of the annual gross revenue of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our certificate of incorporation or by-laws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee’s charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to

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consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests.

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The following table sets forth information with respect to the beneficial ownership of our common stock as of September 30, 2017 by:

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

The column entitled “Percentage of Shares Beneficially Owned—Before Offering and Concurrent Private Placement” is based on a total of 7,694,383 shares of our common stock outstanding as of September 30, 2017, assuming the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 7,180,483 shares of our common stock upon the closing of this offering. The column entitled “Percentage of Shares Beneficially Owned—After Offering and Concurrent Private Placement” is based on 13,694,383 shares of our common stock to be outstanding after this offering, including the shares of our common stock that we are selling in this offering and 2,000,000 shares of our common stock that New Enterprise Associates 16, L.P. has agreed to purchase in the concurrent private placement, but not including any additional shares issuable upon exercise of outstanding options or warrants. The table also assumes that all outstanding warrants to purchase shares of our preferred stock become warrants to purchase shares of our common stock upon the closing of this offering.

Beneficial ownership is determined in accordance with the rules and regulations of the Securities and Exchange Commission and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options and warrants that are currently exercisable or exercisable within 60 days after September 30, 2017 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o Arsanis, Inc., 890 Winter Street, Suite 230, Waltham, Massachusetts 02451.

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Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The following table does not reflect any potential purchases by these potential purchasers. If any shares are purchased by our existing principal stockholders, directors or their affiliated entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from those set forth in the following table.

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Before Offering and Concurrent Private Placement</u>	<u>After Offering and Concurrent Private Placement</u>
<b>5% Stockholders:</b>			
Entities affiliated with Polaris Ventures <sup>(1)</sup>	1,368,957	17.79%	10.00%
Entities affiliated with SV Life Sciences <sup>(2)</sup>	1,368,961	17.79%	10.00%
OrbiMed Private Investments IV LP <sup>(3)</sup>	1,368,966	17.79%	10.00%
NeoMed Innovation V L.P. <sup>(4)</sup>	567,639	7.38%	4.15%
Bill & Melinda Gates Foundation <sup>(5)</sup>	722,179	9.39%	5.27%
Section 32 Fund I, LP <sup>(6)</sup>	451,362	5.87%	3.30%
GV 2016, L.P. <sup>(7)</sup>	451,362	5.87%	3.30%
<b>Directors and Named Executive Officers:</b>			
René Russo, Pharm.D., BCPS <sup>(8)</sup>	66,089	*	*
Eszter Nagy, M.D., Ph.D. <sup>(9)</sup>	366,373	4.70%	2.66%
Michael Gray, M.B.A., C.P.A. <sup>(10)</sup>	21,364	*	*
Chris Stevens, M.D. <sup>(11)</sup>	9,339	*	*
Tillman U. Gerngross, Ph.D. <sup>(12)</sup>	242,190	3.13%	1.76%
William Clark, M.B.A.	—	*	*
Carl Gordon, Ph.D., C.F.A. <sup>(13)</sup>	1,368,966	17.79%	10.00%
David McGirr, M.B.A.	—	*	*
Terrance McGuire <sup>(14)</sup>	1,368,957	17.79%	10.00%
Claudio Nessi, Ph.D., M.B.A. <sup>(15)</sup>	567,639	7.38%	4.15%
Michael Ross, Ph.D. <sup>(16)</sup>	1,368,961	17.79%	10.00%
Amy Schulman, J.D. <sup>(17)</sup>	4,591	*	*
All current executive officers and directors as a group (13 persons) <sup>(18)</sup>	5,396,249	67.88%	38.68%

\* Less than one percent

<sup>(1)</sup> Consists of (a) 1,320,962 shares of common stock issuable upon conversion of preferred stock held by Polaris Venture Partners V, L.P., (b) 25,743 shares of common stock issuable upon conversion of preferred stock held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., (c) 9,046 shares of common stock issuable upon conversion of preferred stock held by Polaris Venture Partners Founders' Fund V, L.P. and (d) 13,206 shares of common stock issuable upon conversion of preferred 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

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- 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) Consists of (a) 903,110 shares of common stock issuable upon conversion of preferred stock held by SV Life Sciences Fund V, L.P. (“SVLS V LP”), (b) 19,082 shares of common stock issuable upon conversion of preferred stock held by SV Life Sciences Fund V Strategic Partners, L.P. (“SVLS V SPP”), (c) 431,980 shares of common stock issuable upon conversion of preferred stock held by SV Life Sciences Fund VI, L.P. (“SVLS VI LP”) and (d) 14,789 shares of common stock issuable upon conversion of preferred 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. 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. SVLS V GP, SVLSF V, LLC and each of the individuals comprising the SVLSF V, LLC investment committee may be deemed to share voting, dispositive and investment power over the shares held of record by the SV Life Sciences Funds. Each of SVLS V GP, SVLSF V, LLC and the individual members of the SVLSF V, LLC investment committee disclaim beneficial ownership of the shares owned directly by the SV Life Sciences Funds except to the extent of any pecuniary interest therein. 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. 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. SVLS VI GP, SVLSF VI, LLC and each of the individuals comprising the SVLSF VI, LLC investment committee may 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, SVLSF VI, LLC and the individual members of the SVLSF VI, LLC investment committee disclaim beneficial ownership of the shares owned directly by the SV VI Funds except to the extent of any pecuniary interest therein. The address for the entities is One Boston Place, Suite 3900, 201 Washington Street, Boston, Massachusetts 02108.
- (3) Consists of 1,368,966 shares of common stock issuable upon conversion of preferred stock held by OrbiMed Private Investment VI, LP (“OPI VI”). OrbiMed Capital GP VI LLC (“GP VI”) is the general partner of OPI VI. OrbiMed Advisors LLC (“OrbiMed Advisors”) is the managing member of GP VI. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors. By virtue of such relationships, GP VI, OrbiMed Advisors and Mr. Isaly may be deemed to have voting and investment power with respect to the shares held by OPI VI 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. Each of GP VI, OrbiMed Advisors, Mr. Isaly and Dr. Gordon disclaims beneficial ownership of the shares held by OPI VI, except to the extent of its or his pecuniary interest therein if any. The address of OPI VI is 601 Lexington Avenue, 54th Floor, New York, New York 10022.
- (4) Consists of 567,639 shares of common stock issuable upon conversion of preferred 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.
- (5) Consists of 722,179 shares of common stock issuable upon conversion of preferred stock held by the Bill & Melinda Gates Foundation (the “Foundation”). The address for the Foundation is 1432 Elliot Ave West, Seattle, WA 98102. For purposes of Rule 13d-3 under the Securities Exchange Act of 1934, as amended, 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.
- (6) Consists of 451,362 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Section 32 Fund 1, L.P. Section 32 GP 1, LLC, the general partner of Section 32 Fund 1, LP,



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- may be deemed to have voting and dispositive power over the shares held by Section 32 Fund 1, LP. Investment decisions with respect to the shares held by Section 32 Fund 1, LP are made by the managing member of Section 32 GP 1, LLC, William J. Maris. Mr. Maris disclaims beneficial ownership of all shares held by Section 32 Fund 1, LP except to the extent of his pecuniary interest therein. The address for all entities and individuals affiliated with Section 32 Fund 1, LP is 2071 San Elijo Avenue, Cardiff-by-the-Sea, California 92007.
- <sup>(7)</sup> Consists of 451,362 shares of common stock issuable upon conversion of preferred stock held by GV 2016, L.P. GV 2016 GP, L.P., the general partner of GV 2016, L.P., GV 2016 GP, L.L.C., the general partner of GV 2016 GP, L.P., Alphabet Holdings LLC, the sole member of GV 2016 GP, L.L.C., Google Inc., the sole member of Alphabet Holdings LLC, and Alphabet Inc., the sole stockholder of Google Inc., may be deemed to have sole power to vote or dispose of these shares. The address for GV 2016, L.P., GV 2016 GP, L.P., GV 2016 GP, L.L.C., Alphabet Holdings LLC, Google Inc., and Alphabet Inc. is 1600 Amphitheatre Parkway, Mountain View, CA 94043.
- <sup>(8)</sup> Consists of shares of common stock underlying options held by Dr. Russo that are exercisable as of September 30, 2017 or will become exercisable within 60 days after such date.
- <sup>(9)</sup> Consists of (a) 273,464 shares of common stock owned by Dr. Nagy and (b) 92,909 shares of common stock underlying options held by Dr. Nagy that are exercisable as of September 30, 2017 or will become exercisable within 60 days after such date.
- <sup>(10)</sup> Consists of shares of common stock underlying options held by Mr. Gray that are exercisable as of September 30, 2017 or will become exercisable within 60 days after such date.
- <sup>(11)</sup> Consists of shares of common stock underlying options held by Dr. Stevens that are exercisable as of September 30, 2017 or will become exercisable within 60 days after such date.
- <sup>(12)</sup> Consists of (a) 102,549 shares of common stock owned by Mr. Gerngross, (b) 90,272 shares of common stock issuable upon conversion of preferred stock held by Mr. Gerngross and (c) 49,369 shares of common stock underlying options held by Mr. Gerngross that are exercisable as of September 30, 2017 or will become exercisable within 60 days after such date.
- <sup>(13)</sup> Consists of the shares described in note 3 above.
- <sup>(14)</sup> Consists of the shares described in note 1 above.
- <sup>(15)</sup> Consists of the shares described in note 4 above.
- <sup>(16)</sup> Consists of the shares described in note 2 above.
- <sup>(17)</sup> Consists of shares of common stock underlying options held by Ms. Schulman that are exercisable as of September 30, 2017 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.
- <sup>(18)</sup> Includes 255,441 shares of common stock underlying options that are exercisable as of September 30, 2017 or will become exercisable within 60 days after such date.

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The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We will file copies of these documents with the Securities and Exchange Commission as exhibits to our registration statement of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 200,000,000 shares of our common stock, par value \$0.001 per share, and 10,000,000 shares of our preferred stock, par value \$0.001 per share, all of which preferred stock will be undesignated.

As of September 30, 2017, we had issued and outstanding:

- 513,900 shares of our common stock held by 35 stockholders of record;
- 200,001 shares of our Series A-1 convertible preferred stock held by 7 stockholders of record, convertible into 58,597 shares of our common stock;
- 2,114,538 shares of our Series A-2 convertible preferred stock held by 7 stockholders of record, convertible into 756,687 shares of our common stock;
- 2,762,431 shares of our Series B convertible preferred stock held by 8 stockholders of record, convertible into 1,233,406 shares of our common stock;
- 1,031,342 shares of our Series C convertible preferred stock held by 10 stockholders of record, convertible into 513,934 shares of our common stock; and
- 15,760,784 shares of our Series D convertible preferred stock held by 19 stockholders of record, convertible into 4,617,859 shares of our common stock.

Upon the closing of this offering, all of the outstanding shares of our preferred stock will automatically convert into an aggregate of 7,180,483 shares of our common stock.

**Common Stock**

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no pre-emptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

**Preferred Stock**

Under the terms of our certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

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The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

### **Warrants**

As of September 30, 2017, we had outstanding:

- a warrant to purchase up to an aggregate of 11,013 shares of our Series A-2 convertible preferred stock, at an exercise price of \$4.54 per share, which we refer to as the Series A-2 warrant, and
- a warrant to purchase up to an aggregate of 14,502 shares of our Series B convertible preferred stock, at an exercise price of \$7.24 per share, which we refer to as the Series B warrant.

Upon the closing of this offering:

- the Series A-2 warrant will become exercisable for an aggregate of 3,940 shares of our common stock, at an exercise price of \$12.70 per share and
- the Series B warrant will become exercisable for an aggregate of 6,474 shares of our common stock, at an exercise price of \$16.22 per share.

These warrants provide for adjustments in the event of specified reclassifications, stock dividends, stock splits or other changes in our corporate structure.

### **Options**

As of September 30, 2017, options to purchase an aggregate of 1,197,120 shares of our common stock, at a weighted average exercise price of \$5.61 per share, were outstanding.

### **Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions**

#### *Delaware Law*

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a “business combination” with any “interested stockholder” for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A “business combination” includes, among other things, a merger or consolidation involving us and the “interested stockholder” and the sale of more than 10% of our assets. In general, an “interested stockholder” is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that will own 15% or more of our outstanding voting stock upon the closing of this offering.

#### *Staggered Board; Removal of Directors*

Our certificate of incorporation and our bylaws to be effective upon the closing of the offering divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation

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and our bylaws to be effective upon the closing of the offering provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws to be effective upon the closing of the offering, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our certificate of incorporation to be effective upon the closing of the offering provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

### ***Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations***

Our certificate of incorporation and our bylaws to be effective upon the closing of the offering provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws to be effective upon the closing of the offering also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our bylaws to be effective upon the closing of the offering 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 our 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 our 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 our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

### ***Super-Majority Voting***

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws to be effective upon the closing of the offering may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

### ***Exclusive Forum Selection***

Our certificate of incorporation to be effective upon the closing of the offering provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of our company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any

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provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. Although our certificate of incorporation contains the choice of forum provision described above, it is possible that a court could rule that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

### **Registration Rights**

We have entered into a second amended and restated investors' rights agreement dated as of April 12, 2016, which was amended on April 24, 2017, with holders of our preferred stock. Beginning six months following the closing of this offering, holders of a total of 7,180,483 shares of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, or the Securities Act, under specified circumstances. We refer to the shares with these registration rights as registrable securities. After registration pursuant to these rights, the registrable securities will become freely tradable without restriction under the Securities Act. In addition, in connection with the concurrent private placement to New Enterprise Associates 16, L.P., or NEA, we have granted to NEA the right to require us to register under the Securities Act under specified circumstances the shares sold to NEA in the concurrent private placement, and upon such registration, such shares would become freely tradable without restriction under the Securities Act.

#### ***Demand and Form S-3 Registration Rights***

Beginning 180 days after this offering, subject to specified limitations set forth in the investors' rights agreement, at any time, the holders of at least 25% of the then outstanding registrable securities may demand that we register registrable securities then outstanding under the Securities Act for purposes of a public offering having an aggregate offering price to the public of not less than \$10.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions.

In addition, subject to specified limitations set forth in the investors' rights agreement, at any time after we become eligible to file a registration statement on Form S-3, holders of the registrable securities then outstanding may request that we register their registrable securities on Form S-3 for purposes of a public offering for which the reasonably anticipated aggregate offering price to the public would exceed \$1.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

#### ***Incidental Registration Rights***

If, at any time after the closing of this offering, we propose to register for our own account any of our securities under the Securities Act, the holders of registrable securities will be entitled to notice of the registration and, subject to specified exceptions, have the right to require us to use our reasonable best efforts to register all or a portion of the registrable securities then held by them in that registration.

In the event that any registration in which the holders of registrable securities participate pursuant to our investors' rights agreement is an underwritten public offering, we have agreed to enter into an underwriting agreement in usual and customary form and use our reasonable best efforts to facilitate such offering.

#### ***Expenses***

Pursuant to the investors' rights agreement, we are required to pay all registration expenses, including all registration and filing fees, exchange listing fees, printing expenses, fees and expenses of one counsel selected by the selling stockholders to represent the selling stockholders, state Blue Sky fees and expenses and the expense of any special audits incident to or required by any such registration, but excluding underwriting discounts, selling commissions and the fees and expenses of the selling stockholders' own counsel (other than the counsel selected to represent all selling stockholders).

The investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the

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registration statement attributable to us or any violation or alleged violation whether by action or inaction by us under the Securities Act, the Securities Exchange Act of 1934, as amended, or the Exchange Act, any state securities or Blue Sky law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities or Blue Sky law in connection with such registration statement or the qualification or compliance of the offering, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

**NASDAQ Global Market**

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol "ASNS."

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[Table of Contents](#)**SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Based on the 513,900 shares of our common stock that were outstanding on September 30, 2017, upon the closing of this offering, we will have outstanding 13,694,383 shares of our common stock, after giving effect to the issuance of 4,000,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase 600,000 additional shares of our common stock to cover over-allotments, the issuance and sale by us of 2,000,000 shares of our common stock to New Enterprise Associates 16, L.P. in the concurrent private placement and the conversion of all outstanding shares of our preferred stock into an aggregate of 7,180,483 shares of our common stock upon the closing of this offering. Of these shares, all shares sold in this offering will be freely tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, unless purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining 9,694,383 shares of our common stock will be “restricted securities” under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or 701 under the Securities Act.

**Rule 144**

In general, under Rule 144, beginning 90 days after the date of this prospectus, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 136,943 shares immediately after this offering and the concurrent private placement; and
- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon waiver or expiration of the 180-day lock-up period described below, approximately 9,672,044 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

**Rule 701**

In general, under Rule 701 under the Securities Act, any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other

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written agreement is eligible to resell these shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the various restrictions, including the availability of public information about us, holding period and volume limitations, contained in Rule 144. Subject to the 180-day lock-up period described below, approximately 513,900 shares of our common stock, based on shares outstanding as of September 30, 2017 will be eligible for sale in accordance with Rule 701.

### **Lock-up Agreements**

We, and each of our executive officers and directors and the holders of substantially all of our outstanding stock have agreed that, without the prior written consent of Citigroup Global Markets Inc. and Cowen and Company, LLC, on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus:

- offer, sell, contract to sell, pledge or otherwise dispose of, or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of (whether by actual disposition or effective economic disposition due to cash settlement or otherwise), directly or indirectly, including the filing (or participation in the filing) of a registration statement (other than a registration statement on Form S-8) with the Securities and Exchange Commission with respect to, any shares of our capital stock or any securities convertible into, or exercisable or exchangeable for, such capital stock;
- establish or increase a put equivalent position or liquidate or decrease a call equivalent position with respect to any shares of our capital stock or any securities convertible into or exercisable or exchangeable for such capital stock; or
- publicly announce an intention to effect any of the foregoing.

These agreements are subject to certain exceptions, as described in the section of this prospectus entitled “Underwriting.”

### **Registration Rights**

Beginning six months after the closing of this offering, the holders of an aggregate of 9,180,483 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

### **Stock Options and Form S-8 Registration Statement**

As of September 30, 2017, we had outstanding options to purchase an aggregate of 1,197,120 shares of our common stock, of which options to purchase 321,388 shares were vested. Following this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and reserved for future options and other awards under the 2010 Plan, the 2011 Plan, the 2017 Plan and the 2017 ESPP. See “Executive Compensation—Stock Option and Other Compensation Plans” for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

Certain of our existing principal stockholders, directors and their affiliated entities have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. Shares purchased by certain of these investors would not be able to be resold in the public market immediately following this offering as a result of restrictions under securities laws and lock-up agreements, but would be able to be sold following the expiration of these restrictions as described above. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The foregoing discussion does not reflect any potential purchases by these potential purchasers.



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[Table of Contents](#)**MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS  
FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following is a discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of shares of our common stock acquired in this offering by a non-U.S. holder. For purposes of this discussion, the term “non-U.S. holder” means a beneficial owner (other than a partnership or other pass-through entity) of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons who hold their common stock through partnerships or such other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, or the IRS, will not challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder’s individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- financial institutions;
- brokers or dealers in securities;
- tax-exempt organizations;
- pension plans;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment or who have elected to mark securities to market;
- insurance companies;
- controlled foreign corporations;
- passive foreign investment companies;
- non-U.S. governments; and
- certain U.S. expatriates.

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**THIS DISCUSSION IS FOR INFORMATION ONLY AND IS NOT, AND IS NOT INTENDED TO BE, LEGAL OR TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, LOCAL, ESTATE AND NON-U.S. INCOME AND OTHER TAX CONSIDERATIONS OF ACQUIRING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGES IN APPLICABLE LAWS.**

**Distributions**

As discussed under the heading “Dividend Policy” above, we do not expect to make cash dividends to holders of our common stock in the foreseeable future. If we make distributions in respect of our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, subject to the tax treatment described in this section. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to the non-U.S. holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading “Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock.” Any such distributions will also be subject to the discussions below under the headings “Information Reporting and Backup Withholding” and “FATCA” below.

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements (generally including provision of a properly executed IRS Form W-8ECI (or applicable successor form) certifying that the dividends are effectively connected with the non-U.S. holder’s conduct of a trade or business within the United States). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed in the hands of the non-U.S. holder at the same graduated U.S. federal income tax rates as would apply if such holder were a U.S. person (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is classified as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty and the specific methods available to them to satisfy these requirements.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

**Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock**

Subject to the discussion below under the headings “Information Reporting and Backup Withholding” and “FATCA,” a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on any gain realized upon such non-U.S. holder’s sale, exchange or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed

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base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to U.S. persons, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30% (or a lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) may also apply;

- the non-U.S. holder is a non-resident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the non-U.S. holder recognized in the taxable year of the disposition, if any; or
- we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation" unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "United States real property interests" (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. If we are determined to be a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, then (i) a purchaser of shares of our common stock from a non-U.S. holder generally will withhold 15% of the proceeds payable to such non-U.S. holder and (ii) the non-U.S. holder's net gain derived from the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. The tax treatment described in (ii) of the preceding sentence will also generally apply to the non-U.S. holder's net gain derived from the disposition of shares of our common stock even if our common stock is regularly traded on an established securities market if such holder beneficially owns more than 5% of our outstanding common stock, during the applicable testing period.

### **U.S. Federal Estate Tax**

Shares of our common stock that are owned or treated as owned by an individual who is not a citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death are considered U.S.-situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

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

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders generally will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable IRS Form W-8), or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the heading "Distributions," will generally be exempt from U.S. backup withholding.

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Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

### **FATCA**

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a 30% withholding tax on dividends on, and gross proceeds from the sale or disposition of, our common stock if paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," the foreign entity undertakes certain due diligence, reporting, withholding and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain of its U.S. investors or (iii) the foreign entity is otherwise exempt under FATCA.

Withholding under FATCA generally (1) applies to payments of dividends on our common stock, and (2) will apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**The preceding discussion of material U.S. federal tax considerations is for information only. It is not, and is not intended to be, legal or tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local, estate and non-U.S. income and other tax consequences of acquiring, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.**

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**UNDERWRITING**

Citigroup Global Markets Inc., Cowen and Company, LLC and Piper Jaffray & Co. are acting as joint book-running managers of this offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, the underwriters named below have severally agreed to purchase, and we have agreed to sell to them, the number of shares of our common stock indicated below:

<u>Underwriter</u>	<u>Number of Shares</u>
Citigroup Global Markets Inc.	1,600,000
Cowen and Company, LLC	1,300,000
Piper Jaffray & Co.	<u>1,100,000</u>
Total	<u>4,000,000</u>

The underwriting agreement provides that the obligations of the underwriters to purchase the shares of our common stock included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the shares of our common stock (other than those covered by the over-allotment option described below) if they purchase any of the shares.

Shares of our common stock sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares of our common stock sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed \$0.42 per share. After the initial offering of the shares of our common stock, if all the shares of our common stock are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

Certain of our existing principal stockholders, directors and their affiliated entities, have indicated an interest in purchasing an aggregate of up to approximately 2,000,000 shares of our common stock in this offering at the initial per share public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to any of these potential purchasers, and any of these potential purchasers could determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount and commissions on these shares as they will on any other shares sold to the public in this offering.

If the underwriters sell more shares of our common stock than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 600,000 additional shares of our common stock at the initial public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional shares of our common stock approximately proportionate to that underwriter's initial purchase commitment set forth in the table above. Any shares of our common stock issued or sold under the option will be issued and sold on the same terms and conditions as the other shares of our common stock that are the subject of this offering.

We, our officers and directors and substantially all of our stockholders have agreed that, subject to specified limited exceptions, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc. and Cowen and Company, LLC, offer, sell, contract to sell, pledge or otherwise dispose of, including the filing of a registration statement in respect of, or hedge any shares of our capital stock or any securities convertible into, or exercisable or exchangeable for, our capital stock.

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Citigroup Global Markets Inc. and Cowen and Company, LLC in their sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of officers and directors, shall be with notice.

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for the shares of our common stock was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price will be our results of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management, and currently prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company. We cannot assure you, however, that the price at which the shares of our common stock will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our shares of common stock will develop and continue after this offering.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol "ASNS."

The following table shows the per share and total public offering price, underwriting discounts and commissions that we are to pay to the underwriters and proceeds to us, before expenses, in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option:

	Per share	Total	
		No exercise	Full exercise
Public offering price	\$ 10.00	\$40,000,000	\$46,000,000
Underwriting discounts and commissions paid by us	\$ 0.70	\$ 2,800,000	\$ 3,220,000
Proceeds to us, before expenses	\$ 9.30	\$37,200,000	\$42,780,000

We estimate that expenses payable by us in connection with this offering, exclusive of underwriting discounts and commissions, will be approximately \$3.0 million. We have agreed to reimburse the underwriters for expenses in an amount up to \$30,000 relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters' over-allotment option, and other transactions that would stabilize, maintain or otherwise affect the price of our common stock.

- Short sales involve secondary market sales by the underwriters of a greater number of shares of our common stock than they are required to purchase in this offering:
  - "Covered" short sales are sales of shares of our common stock in an amount up to the number of shares of our common stock represented by the underwriters' over-allotment option.
  - "Naked" short sales are sales of shares of our common stock in an amount in excess of the number of shares of our common stock represented by the underwriters' over-allotment option.
- The underwriters can close out a short position by purchasing additional shares of our common stock, either pursuant to the underwriters' over-allotment option or in the open market.
- To close a naked short position, the underwriters must purchase shares of our common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

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- To close a covered short position, the underwriters must purchase shares of our common stock in the open market or exercise their over-allotment option. In determining the source of shares of our common stock to close the covered short position, the underwriters will consider, among other things, the price of shares of our common stock available for purchase in the open market as compared to the price at which they may purchase shares of our common stock through their over-allotment option.
- As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of our common stock on NASDAQ, as long as such bids do not exceed a specified maximum, to stabilize the price of the shares of our common stock.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the shares. They may also cause the price of the shares of our common stock to be higher than the price that would otherwise prevail in the open market in the absence of these transactions. The underwriters may conduct these transactions on NASDAQ, in the over-the-counter market or otherwise. The underwriters are not required to engage in any of these transactions and may discontinue them at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more of the underwriters or their respective affiliates. The representatives may agree with us to allocate a number of shares of our common stock to underwriters for sale to their online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' or their respective affiliates' websites and any information contained in any other website maintained by any of the underwriters or their respective affiliates is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors in this offering.

### **Concurrent Private Placement**

New Enterprise Associates 16, L.P. has agreed to purchase 2,000,000 shares of our common stock at the initial per share public offering price in a private placement expected to close concurrently with this offering. The underwriters for this offering will serve as placement agents for such concurrent private placement and will receive a placement agent fee that will be a percentage of the total purchase price of the private placement shares equal to the percentage discount the underwriters will receive on shares sold in this offering. The closing of this offering is not conditioned upon the closing of such concurrent private placement.

### **Other Relationships**

The underwriters are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans or credit default swaps) for their own account and for the accounts of their customers and may at

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any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Notice to Prospective Investors in the European Economic Area**

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of shares of our common stock described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares of our common stock shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of our common stock, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

The sellers of the shares of our common stock have not authorized and do not authorize the making of any offer of shares of our common stock through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares of our common stock as contemplated in this prospectus. Accordingly, no purchaser of the shares of our common stock, other than the underwriters, is authorized to make any further offer of the shares of our common stock on behalf of the sellers or the underwriters.

### **Notice to Prospective Investors in the United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a relevant person).

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.



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### **Notice to Prospective Investors in Canada**

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

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

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### **Notice to Prospective Investors in Australia**

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act) in relation to our common stock has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- you confirm and warrant that you are either:
  - a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;
  - a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; a person associated with the company under section 708(12) of the Corporations Act; or
  - a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and
- you warrant and agree that you will not offer any of our common stock for resale in Australia within 12 months of that common stock being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act

### **Notice to Prospective Investors in France**

Neither this prospectus nor any other offering material relating to the shares of our common stock described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The shares of our common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares of our common stock has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the shares of our common stock to the public in France.

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Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1° -or-2° -or 3° of the French Code *monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

The shares of our common stock may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code *monétaire et financier*.

### **Notice to Prospective Investors in Hong Kong**

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

### **Notice to Prospective Investors in Japan**

The shares of our common stock offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The shares of our common stock have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

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Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant party which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares of our common stock and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares of our common stock and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

### **LEGAL MATTERS**

The validity of the shares of common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts. Goodwin Procter LLP, New York, New York is acting as counsel for the underwriters in connection with this offering.

### **EXPERTS**

The financial statements as of December 31, 2016 and 2015 and for each of the two years in the period ended December 31, 2016 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

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You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at <http://www.sec.gov>, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we will file reports, proxy statements and other information with the SEC.

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows present fairly, in all material respects, the financial position of Arsanis, Inc. and its subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses from operations since inception, has an accumulated deficit, and will require additional financing to fund future operations. These circumstances raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
August 10, 2017, except for the effects of the reverse  
stock split described in Note 20 to the consolidated  
financial statements, as to which the date  
is November 6, 2017

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**ARSANIS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(Amounts in thousands, except share and per share amounts)

	<u>December 31,</u>		<u>September 30,</u>	<u>Pro Forma</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>September 30,</u>
			<u>(unaudited)</u>	<u>2017</u>
				<u>(unaudited)</u>
<b>Assets</b>				
Current assets:				
Cash	\$ 6,759	\$ 3,035	\$ 26,254	\$ 26,254
Grant and incentive receivables	1,541	1,345	1,454	1,454
Restricted cash	—	—	5,118	5,118
Prepaid expenses and other current assets	87	1,336	442	442
Total current assets	<u>8,387</u>	<u>5,716</u>	<u>33,268</u>	<u>33,268</u>
Property and equipment, net	760	519	479	479
Restricted cash	338	394	350	350
Deferred offering costs	—	9	2,117	2,117
Other assets	25	966	948	948
Total assets	<u>\$ 9,510</u>	<u>\$ 7,604</u>	<u>\$ 37,162</u>	<u>\$ 37,162</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>				
Current liabilities:				
Accounts payable	\$ 423	\$ 1,645	\$ 4,164	\$ 4,164
Accrued expenses	1,541	2,156	5,716	5,716
Unearned income	430	504	1,065	1,065
Loans payable, net of discount	250	2,299	2,309	2,309
Convertible promissory notes, net of discount	2,240	2,863	—	—
Derivative liability	1,793	2,593	—	—
Total current liabilities	<u>6,677</u>	<u>12,060</u>	<u>13,254</u>	<u>13,254</u>
Loans payable, net of discount and current portion	4,704	10,127	10,209	10,209
Unearned income	2,433	2,054	2,081	2,081
Other long-term liabilities	70	87	49	18
Total liabilities	<u>13,884</u>	<u>24,328</u>	<u>25,593</u>	<u>25,562</u>
Commitments and contingencies (Note 16)				
Redeemable convertible preferred stock (Series A-1, A-2, B, C and D), \$0.001 par value; 5,087,983, 6,711,756 and 21,894,619 shares authorized as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), respectively; 5,076,970, 6,108,312 and 21,869,096 shares issued and outstanding as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), respectively; aggregate liquidation preference of \$39,952 and \$91,107 as of December 31, 2016 and September 30, 2017 (unaudited), respectively; no shares issued or outstanding, pro forma as of September 30, 2017 (unaudited)				
	<u>29,948</u>	<u>39,838</u>	<u>90,821</u>	<u>—</u>
Stockholders' equity (deficit):				
Common stock, \$0.001 par value; 7,500,000, 10,000,000 and 31,000,000 shares authorized as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), respectively; 513,900 shares issued and outstanding as of December 31, 2015 and 2016 and September 30, 2017 (unaudited); 7,694,383 shares issued and outstanding, pro forma as of September 30, 2017 (unaudited)	1	1	1	8
Additional paid-in capital	372	991	1,582	92,427
Accumulated other comprehensive income	718	834	243	243
Accumulated deficit	(35,413)	(58,388)	(81,078)	(81,078)
Total stockholders' equity (deficit)	<u>(34,322)</u>	<u>(56,562)</u>	<u>(79,252)</u>	<u>11,600</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 9,510</u>	<u>\$ 7,604</u>	<u>\$ 37,162</u>	<u>\$ 37,162</u>

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

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**ARSANIS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Amounts in thousands, except share and per share amounts)

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
			(unaudited)	
Operating expenses:				
Research and development	\$ 12,706	\$ 17,831	\$ 13,604	\$ 18,898
General and administrative	2,119	6,515	5,042	5,629
Total operating expenses	<u>14,825</u>	<u>24,346</u>	<u>18,646</u>	<u>24,527</u>
Loss from operations	<u>(14,825)</u>	<u>(24,346)</u>	<u>(18,646)</u>	<u>(24,527)</u>
Other income (expense):				
Grant and incentive income	2,155	2,390	1,829	3,180
Interest expense	(472)	(2,515)	(1,723)	(1,716)
Change in fair value of warrant liability	1	39	11	16
Change in fair value of derivative liability	—	1,388	822	762
Loss on extinguishment of debt	—	(35)	(35)	(462)
Other income (expense), net	<u>(77)</u>	<u>104</u>	<u>88</u>	<u>57</u>
Total other income, net	<u>1,607</u>	<u>1,371</u>	<u>992</u>	<u>1,837</u>
Net loss	<u>(13,218)</u>	<u>(22,975)</u>	<u>(17,654)</u>	<u>(22,690)</u>
Accretion of redeemable convertible preferred stock to redemption value	<u>(19)</u>	<u>(25)</u>	<u>(19)</u>	<u>(36)</u>
Net loss attributable to common stockholders	<u>\$ (13,237)</u>	<u>\$ (23,000)</u>	<u>\$ (17,673)</u>	<u>\$ (22,726)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (26.02)</u>	<u>\$ (44.79)</u>	<u>\$ (34.42)</u>	<u>\$ (44.22)</u>
Weighted average common shares outstanding—basic and diluted	<u>508,659</u>	<u>513,527</u>	<u>513,402</u>	<u>513,900</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		<u>\$ (7.85)</u>		<u>\$ (4.08)</u>
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)		<u>2,931,519</u>		<u>5,568,027</u>

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



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**ARSANIS, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(Amounts in thousands)**

	<u>Year Ended</u> <u>December 31,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
Net loss	\$(13,218)	\$(22,975)	\$(17,654)	\$(22,690)
Other comprehensive income (loss):			<b>(unaudited)</b>	
Foreign currency translation gain (loss)	316	116	(233)	(591)
Comprehensive loss	<u>\$(12,902)</u>	<u>\$(22,859)</u>	<u>\$(17,887)</u>	<u>\$(23,281)</u>

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

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## ARSANIS, INC.

## CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' 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' Deficit
	Shares	Amount	Shares	Amount				
<b>Balances as of December 31, 2014</b>	4,110,119	\$ 22,941	505,128	\$ 1	\$ 250	\$ 402	\$ (22,195)	\$ (21,542)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$12	966,851	6,988	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	316	—	316
Exercise of stock options	—	—	8,936	—	15	—	—	15
Forfeiture of unvested restricted common stock	—	—	(164)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	126	—	—	126
Accretion of redeemable convertible preferred stock to redemption value	—	19	—	—	(19)	—	—	(19)
Net loss	—	—	—	—	—	—	(13,218)	(13,218)
<b>Balances as of December 31, 2015</b>	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	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	116	—	116
Stock-based compensation expense	—	—	—	—	644	—	—	644
Accretion of redeemable convertible preferred stock to redemption value	—	25	—	—	(25)	—	—	(25)
Net loss	—	—	—	—	—	—	(22,975)	(22,975)
<b>Balances as of December 31, 2016</b>	6,108,312	39,838	513,900	1	991	834	(58,388)	(56,562)
Issuances 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	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	(591)	—	(591)
Stock-based compensation expense	—	—	—	—	627	—	—	627
Accretion of redeemable convertible preferred stock to redemption value	—	36	—	—	(36)	—	—	(36)
Net loss	—	—	—	—	—	—	(22,690)	(22,690)
<b>Balances as of September 30, 2017 (unaudited)</b>	21,869,096	\$ 90,821	513,900	\$ 1	\$ 1,582	\$ 243	\$ (81,078)	\$ (79,252)

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

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**ARSANIS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Amounts in thousands)

	<u>Year Ended</u>		<u>Nine Months Ended</u>	
	<u>December 31,</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
	<u>2015</u>	<u>2016</u>	<u>(unaudited)</u>	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (13,218)	\$ (22,975)	\$ (17,654)	\$ (22,690)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	126	644	460	627
Depreciation and amortization expense	389	285	235	148
Non-cash interest expense	394	2,307	1,589	1,575
Non-cash rent expense	47	9	13	(17)
Loss on extinguishment of debt	—	35	35	462
Change in fair value of warrant liability	(1)	(39)	(11)	(16)
Change in fair value of derivative liability	—	(1,388)	(822)	(762)
Changes in operating assets and liabilities:				
Grant and incentive receivables	(56)	152	(646)	57
Prepaid expenses and other current assets	(31)	(1,278)	(945)	940
Other assets	—	(941)	(975)	18
Accounts payable	77	1,264	290	2,342
Accrued expenses	758	521	91	2,063
Unearned income	699	(235)	(137)	289
Net cash used in operating activities	<u>(10,816)</u>	<u>(21,639)</u>	<u>(18,477)</u>	<u>(14,964)</u>
<b>Cash flows from investing activities:</b>				
Purchases of property and equipment	(170)	(73)	(72)	(59)
Changes in restricted cash	(77)	(65)	(66)	(5,042)
Net cash used in investing activities	<u>(247)</u>	<u>(138)</u>	<u>(138)</u>	<u>(5,101)</u>
<b>Cash flows from financing activities:</b>				
Proceeds from issuance of redeemable convertible preferred stock	7,000	5,500	5,500	40,053
Proceeds from issuance of loans payable	—	7,000	7,000	—
Proceeds from issuance of convertible promissory notes	4,000	5,500	5,500	4,935
Proceeds from issuance of loans under funding agreements	1,527	514	292	685
Exercise of stock options	16	—	—	—
Repayments of loans payable	(1,000)	(250)	(250)	(1,750)
Payments of issuance costs of convertible promissory notes	(26)	—	—	(17)
Payments of issuance costs of redeemable convertible preferred stock	(12)	(87)	(86)	(197)
Payments of issuance costs of loans payable	—	(30)	(30)	—
Payments of initial public offering costs	—	—	—	(795)
Net cash provided by financing activities	<u>11,505</u>	<u>18,147</u>	<u>17,926</u>	<u>42,914</u>
<b>Effect of exchange rate changes on cash</b>	<u>(122)</u>	<u>(94)</u>	<u>(18)</u>	<u>370</u>
<b>Net increase (decrease) in cash</b>	320	(3,724)	(707)	23,219
Cash at beginning of period	6,439	6,759	6,759	3,035
Cash at end of period	<u>\$ 6,759</u>	<u>\$ 3,035</u>	<u>\$ 6,052</u>	<u>\$ 26,254</u>
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid for interest	\$ 81	\$ 291	\$ 197	\$ 211
Cash paid for taxes	\$ 29	\$ 4	\$ 4	\$ 3
<b>Supplemental disclosure of non-cash investing and financing activities:</b>				
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 23	\$ 2	\$ —	\$ —
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ —	\$ —	\$ 1,322
Issuance of redeemable convertible preferred stock upon extinguishment of convertible promissory notes	\$ —	\$ 4,452	\$ 4,452	\$ 11,102
Derivative liability in connection with issuance of convertible promissory notes	\$ 1,793	\$ 3,929	\$ 3,929	\$ 403
Extinguishment of convertible promissory notes	\$ —	\$ 2,677	\$ 2,667	\$ 8,405
Extinguishment of derivative liability in connection with extinguishment of convertible promissory notes	\$ —	\$ 1,741	\$ 1,741	\$ 2,234
Issuance of warrants in connection with issuance of loans payable	\$ —	\$ 60	\$ 60	\$ —
Accretion of redeemable convertible preferred stock to redemption value	\$ 19	\$ 25	\$ 19	\$ 36

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

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**1. Nature of the Business and Basis of Presentation**

Arsanis, Inc. (the “Company”) is a clinical-stage biopharmaceutical company focused on applying monoclonal antibody immunotherapies to address serious infectious diseases. The Company believes that its monoclonal antibodies (“mAbs”) offer a novel approach to address serious infectious diseases. Unlike antibiotics that propagate resistance, disrupt both disease-causing and beneficial bacteria and have adverse off-target effects, mAbs have the ability to precisely bind only to the intended target, thereby avoiding these undesired consequences. The Company’s lead product candidate, ASN100, is a first-in-class mAb therapeutic in Phase 2 clinical development for the prevention of *Staphylococcus aureus* pneumonia in high-risk, mechanically ventilated patients, a potentially life-threatening and costly infection for which there are no approved preventive therapies. In addition to ASN100, the Company’s preclinical pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus (“RSV”).

Arsanis was incorporated under the laws of the State of Delaware and is headquartered in Waltham, Massachusetts, with European research and preclinical development operations headquartered in Vienna, Austria.

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.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and include the accounts of the Company and its wholly owned subsidiary, Arsanis Biosciences GmbH, after elimination of all significant intercompany accounts and transactions.

**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 that the consolidated financial statements are issued.

Through September 30, 2017, the Company has funded its operations primarily with proceeds from the sale of preferred and common stock, borrowings under convertible promissory notes, borrowings under a loan and security agreement, grant and loan proceeds from funding agreements with Österreichische Forschungsförderungsgesellschaft mbH (“FFG”), proceeds from a research and development incentive program provided by the Austrian government and proceeds from a grant agreement with the Bill & Melinda Gates Foundation (the “Gates Foundation”). The Company has incurred recurring losses since its inception, including net losses of \$13.2 million and \$23.0 million for the years ended December 31, 2015 and 2016, respectively, and \$22.7 million for the nine months ended September 30, 2017 (unaudited). In addition, as of December 31, 2016 and September 30, 2017 (unaudited), the Company had an accumulated deficit of \$58.4 million and \$81.1 million, respectively. The Company expects to continue to generate operating losses for the foreseeable future. As of August 10, 2017, the issuance date of the annual consolidated financial statements for the year ended

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December 31, 2016, the Company expected that its cash of \$2.3 million as of March 31, 2017 (unaudited), together with the \$35.1 million of gross cash proceeds received from the Company's sale of Series D redeemable convertible preferred stock in April 2017 (see Note 11), would be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through April 30, 2018.

As of October 20, 2017, the issuance date of the interim financial statements for the nine months ended September 30, 2017, the Company expects that its cash of \$26.3 million as of September 30, 2017 (unaudited) will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through June 30, 2018. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. In the event the Company does not complete an initial public offering, the Company expects to seek additional funding through private equity financings, debt financings, or other capital sources, including collaborations with other companies, government contracts or other strategic transactions. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

If the Company is unable to obtain funding, the Company will 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. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

**2. Summary of Significant Accounting Policies*****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, stock options, warrants and derivative instruments. 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.

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[Table of Contents](#)**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS*****Unaudited Interim Financial Information***

The accompanying consolidated balance sheet as of September 30, 2017, the consolidated statements of operations, of comprehensive loss and of cash flows for the nine months ended September 30, 2016 and 2017, and the consolidated statement of redeemable convertible preferred stock and stockholders' deficit for the nine months ended September 30, 2017 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2017 and the results of its operations and its cash flows for the nine months ended September 30, 2016 and 2017. The financial data and other information disclosed in these notes related to the nine months ended September 30, 2016 and 2017 are also unaudited. The results for the nine months ended September 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, any other interim periods, or any future year or period.

***Unaudited Pro Forma Information***

The accompanying unaudited pro forma consolidated balance sheet as of September 30, 2017 has been prepared to give effect, upon the closing of a qualified IPO, to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into 7,180,483 shares of common stock and all outstanding warrants to purchase shares of redeemable convertible preferred stock as of September 30, 2017 becoming warrants to purchase shares of common stock as if the Company's proposed IPO had occurred on September 30, 2017.

In the accompanying consolidated statements of operations, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2016 and the nine months ended September 30, 2017 have been prepared to give effect, upon the closing of a qualified IPO, to the automatic conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock and all outstanding warrants to purchase shares of redeemable convertible preferred stock as of September 30, 2017 becoming warrants to purchase shares of common stock as if the proposed IPO had occurred on the later of January 1, 2016 or the issuance date of the redeemable convertible preferred stock or the warrants.

***Foreign Currency and Currency Translation***

The functional currency for the Company's wholly owned foreign subsidiary, 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 stockholder's deficit as a component of accumulated other comprehensive income (loss). 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.

***Restricted Cash***

In March 2017, the Company received a payment of \$1.6 million under a grant agreement with the Gates Foundation (see Note 7). As of September 30, 2017 (unaudited), \$0.4 million of the payment received from the Gates Foundation was classified as restricted cash (current) in the consolidated balance sheet due to restrictions on the use of the funds imposed by the agreement. Such funds received from the Gates Foundation are no longer classified as restricted cash once the Company incurs qualifying expenses under the grant agreement and the restrictions no longer apply.

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**ARSANIS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In April 2017, the Company entered into a letter agreement with the Gates Foundation (see Note 7). In connection with the letter agreement, the Gates Foundation purchased \$8.0 million of shares of the Company's Series D redeemable convertible preferred stock and the Company committed to use the proceeds 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. As of September 30, 2017 (unaudited), \$4.7 million of the proceeds received from the Gates Foundation for the purchase of shares was classified as restricted cash (current) in the consolidated balance sheet due to restrictions on the use of the funds imposed by the agreement. Such funds received from the Gates Foundation are no longer classified as restricted cash once the Company incurs qualifying expenses under the letter agreement and the restrictions no longer apply.

The Company maintains a letter of credit for the benefit of the landlords in connection with the Company's office leases (see Note 16) and another letter of credit in connection with the Company's corporate credit cards. As of December 31, 2015 and 2016 and September 30, 2017 (unaudited), restricted cash (non-current) consisted of \$0.1 million, \$0.1 million and \$0, respectively, held in connection with the Company's corporate credit cards and \$0.3 million, \$0.3 million and \$0.4 million, respectively, held for the benefit of the landlords in connection with the Company's office leases.

***Concentrations of Credit Risk***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. 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.

***Deferred Offering Costs***

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations. The Company recorded deferred offering costs of \$0, \$9,000 and \$2.1 million as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), respectively.

***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 respective assets. As of December 31, 2015 and 2016 and September 30, 2017 (unaudited), 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 respective assets as follows:

	<u>Estimated Useful Life</u>
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

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[Table of Contents](#)**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 recorded 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 Company's warrant liability and derivative liability are carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note 3). In April 2017, in connection with the Company's issuance and sale of Series D redeemable convertible preferred stock, the derivative liability was extinguished. The carrying values of 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 loan and security agreement with Silicon Valley Bank approximates its fair value because the debt bears interest at a market rate. The carrying value of the loans received under the funding agreements with FFG approximates their fair value because the Company records imputed interest expense based on rates that approximate market rates of interest as of December 31, 2016 and September 30, 2017 (unaudited). The carrying value of the Company's convertible promissory notes approximated their fair value due to the short term of the notes. In April 2017, in connection with the Company's issuance and sale of Series D redeemable convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes was automatically converted into shares of Series D redeemable convertible preferred stock (see Notes 9 and 11).



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[Table of Contents](#)**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS*****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.

***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 agreement with the Gates Foundation (see Note 7) 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 agreement 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***

Research and development costs are expensed as incurred. 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

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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. The Company historically has been a private company and lacks 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.

***Warrant Liability***

The Company classifies warrants for the purchase of shares of its redeemable convertible preferred stock (see Note 10) as a liability on its consolidated balance sheets (included in other long-term liabilities) as these warrants are free-standing financial instruments that may require the Company to transfer assets upon exercise.

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The warrant liability was initially recorded at fair value upon the date of the warrant issuance and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the consolidated statement of operations. Changes in the fair value of the warrant liability will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

The Company utilizes the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value these warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying redeemable convertible preferred stock issuable upon exercise of the warrant, remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying redeemable convertible preferred stock.

***Derivative Liability***

The Company's outstanding convertible promissory notes (see Note 9) contained a contingent put option and a conversion feature, each of which met the definition of a derivative instrument. The Company classified these instruments as a liability on its consolidated balance sheets because the contingent put option provided for the accelerated repayment of the notes at a substantial premium upon the occurrence of specified events and the conversion feature was not clearly and closely related to its host instrument and met the definition of a derivative. The derivative liability was initially recorded at fair value upon issuance of the convertible promissory notes and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability were recognized as a component of other income (expense), net in the consolidated statement of operations. In April 2017, in connection with the Company's issuance and sale of Series D redeemable convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes was automatically converted into shares of Series D redeemable convertible preferred stock and the derivative liability was extinguished (see Notes 9 and 11).

***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 years ended December 31, 2015 and 2016, comprehensive loss included \$0.3 million and \$0.1 million, respectively, of foreign currency translation gain adjustments. For the nine months ended September 30, 2016 and 2017 (unaudited), comprehensive loss included \$0.2 million and \$0.6 million, respectively, of foreign currency translation loss adjustments.

***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.

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 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) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. 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, outstanding stock options, warrants to purchase shares of redeemable convertible preferred stock, unvested restricted stock, convertible promissory notes and redeemable convertible preferred stock are considered potential dilutive common shares.

The Company's redeemable convertible preferred stock contractually entitle the holders of such shares to participate in dividends but contractually do 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 March 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. Certain of these changes are required to be applied retrospectively, while other changes are required to be applied prospectively. The Company early adopted ASU 2016-09 effective January 1, 2016, and its adoption of ASU 2016-09 had no material impact on the Company's financial position, results of operations or cash flows.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires deferred tax liabilities and assets to be classified as non-current in the consolidated balance sheet. ASU 2015-17 is required to be adopted for annual periods beginning after

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 15, 2016, including interim periods within those fiscal years. The amendment may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company early adopted this guidance retrospectively to all periods presented, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"), which requires that debt issuance costs related to a debt liability be presented in the balance sheet as a direct reduction in the carrying amount of that debt liability. The amendments in ASU 2015-03 are effective for the annual periods ending after December 15, 2015. The Company adopted the standard retrospectively to all periods presented on the required effective date of January 1, 2016, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In November 2014, the FASB issued ASU No. 2014-16, *Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* ("ASU 2014-16"). The guidance requires an entity to determine the nature of the host contract by considering all stated and implied substantive terms and features of the hybrid financial instrument, weighing each term and feature on the basis of the relevant facts and circumstances (commonly referred to as the whole-instrument approach). The Company adopted the standard retrospectively to all periods presented on the required effective date of January 1, 2016, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40) ("ASU 2014-15"). The amendments in this update explicitly require a company's management to assess an entity's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The new standard is effective in the first annual period ending after December 15, 2016. The Company adopted ASU 2014-15 as of the required effective date of December 31, 2016. This guidance relates to footnote disclosure only (see Note 1), and its adoption had no impact on the Company's financial position, results of operations or cash flows.

**Recently Issued Accounting Pronouncements**

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*. 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 is currently evaluating the impact that the adoption of ASU 2017-11 will have on its consolidated financial statements.

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 standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-09 will have on its consolidated financial statements.

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## ARSANIS, INC.

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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 standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2017-01 will have on its consolidated financial statements.

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 standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-18 will have on its consolidated financial statements.

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 standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2016-16 will have on its consolidated financial statements.

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 standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2016-15 will have on its consolidated financial statements.

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. Early adoption is permitted. In September 2017, the FASB issued ASU No. 2017-13, *Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842)*, which provides additional clarification and implementation guidance related to ASU 2016-02 and has the same effective date and transition requirements as ASU 2016-02. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”), which supersedes existing revenue recognition guidance under GAAP. 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. The Company expects that these judgments and estimates will 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 August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delays the effective date of ASU 2014-09 such that the standard is effective for public entities for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption of the standard is permitted for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. 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 Licensing*, 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. In December 2016, the FASB issued ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers* (“ASU 2016-20”), which amends narrow aspects of the guidance in ASU 2014-09. ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2016-20 have the same effective dates and transition requirements as ASU 2014-09. In September 2017, the FASB issued ASU No. 2017-13, *Revenue Recognition (Topic 605), Revenue from Contracts with Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842)*, which provides additional clarification and implementation guidance related to ASU 2014-09 and has the same effective date and transition requirements as ASU 2014-09. The adoption of these standards is not expected to have an impact on the Company’s financial position, results of operations or cash flows as the Company does not currently have any revenue-generating arrangements.

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**3. Fair Value of Financial Assets and Liabilities**

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	\$ —	\$ —	\$ 26	\$ 26
Derivative liability	—	—	1,793	1,793
	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,819</u>	<u>\$1,819</u>

	Fair Value Measurements as of December 31, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	\$ —	\$ —	\$ 47	\$ 47
Derivative liability	—	—	2,593	2,593
	<u>\$ —</u>	<u>\$ —</u>	<u>\$2,640</u>	<u>\$2,640</u>

	Fair Value Measurements as of September 30, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	\$ —	\$ —	\$ 31	\$ 31
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 31</u>	<u>\$ 31</u>

During the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), there were no transfers between Level 1, Level 2 and Level 3.

*Valuation of Warrant Liability*

The warrant liability in the table above is composed of the fair value of warrants to purchase shares of Series A-2 redeemable convertible preferred stock (the "Series A-2 preferred stock") and Series B redeemable convertible preferred stock (the "Series B preferred stock") that were issued to the lender in connection with the Company's 2012 Loan Agreement, as amended (see Note 10). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The Company used the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the preferred stock warrants. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying shares of Series A-2 and Series B preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The Company determined the fair value per share of the underlying



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preferred stock by taking into consideration the most recent sales of its preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future.

*Valuation of Derivative Liability*

The fair value of the derivative liability recognized in connection with the Company's convertible promissory notes (see Note 9) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method ("PWERM"), which considered as inputs the type, timing and probability of occurrence of a change-of-control event, the future equity financing and cash settlement of the convertible promissory notes; the potential amount of the payment under each of these potential settlement scenarios; and the risk-adjusted discount rate reflecting the expected risk profile for each of the potential settlement scenarios.

In April 2017, in connection with the Company's issuance and sale of Series D redeemable convertible preferred stock (the "Series D preferred stock"), all of the outstanding principal and accrued interest under the convertible promissory notes was automatically converted into shares of Series D preferred stock and the derivative liability was extinguished (see Notes 9 and 11).

The following table provides a roll forward of the aggregate fair values of the Company's warrant liability and derivative liability, for which fair value is determined using Level 3 inputs (in thousands):

	<b>Warrant Liability</b>	<b>Derivative Liability</b>
Balance as of December 31, 2014	\$ 27	\$ —
Initial fair value of derivative liability in connection with 2015 Notes	—	1,793
Change in fair value	(1)	—
Balance as of December 31, 2015	26	1,793
Initial fair value of warrant liability in connection with First Amendment to the 2012 Loan Agreement	60	—
Extinguishment of derivative liability in connection with extinguishment of 2015 Notes	—	(1,741)
Initial fair value of derivative liability in connection with 2016 Notes	—	3,929
Change in fair value	(39)	(1,388)
Balance as of December 31, 2016	47	2,593
Initial fair value of derivative liability in connection with 2017 Notes	—	403
Change in fair value	(16)	(762)
Extinguishment of derivative liability in connection with extinguishment of 2016 and 2017 Notes	—	(2,234)
Balance as of September 30, 2017 (unaudited)	<u>\$ 31</u>	<u>\$ —</u>

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**ARSANIS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**4. Prepaid Expenses and Other Current Assets**

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

	<u>December 31,</u>		<u>September 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
Prepaid clinical trial costs	\$—	\$1,246	\$ 188
Other	87	90	254
	<u>\$ 87</u>	<u>\$1,336</u>	<u>\$ 442</u>

**5. Property and Equipment, Net**

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

	<u>December 31,</u>		<u>September 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
Laboratory and office equipment	\$ 1,522	\$ 1,489	\$ 1,724
Furniture and fixtures	376	374	416
Leasehold improvements	240	265	292
Computer equipment and software	169	166	186
	<u>2,307</u>	<u>2,294</u>	<u>2,618</u>
Less: Accumulated depreciation and amortization	<u>(1,547)</u>	<u>(1,775)</u>	<u>(2,139)</u>
	<u>\$ 760</u>	<u>\$ 519</u>	<u>\$ 479</u>

Depreciation and amortization expense for the years ended December 31, 2015 and 2016 and for the nine months ended September 30, 2016 and 2017 (unaudited) was \$0.4 million, \$0.3 million, \$0.2 million and \$0.1 million, respectively.

**6. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<u>December 31,</u>		<u>September 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
Accrued clinical trial costs	\$ 2	\$ 481	\$ 1,882
Accrued compensation and benefits	949	1,295	1,601
Accrued professional fees	227	51	1,807
Other	363	329	426
	<u>\$1,541</u>	<u>\$2,156</u>	<u>\$ 5,716</u>

**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) (the “Adimab Collaboration Agreement”). Under the Adimab Collaboration Agreement, the

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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

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), the Company recognized research and development expense of \$0.2 million, \$8,000, \$8,000 and \$0, 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 (see Note 17) (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. If the Company materially breaches these diligence obligations, Adimab will have the right to terminate the Adimab Option Agreement.

If the Company exercises its option under the Adimab Option Agreement, the Company 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 Arsanis) 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.

In February 2017, the Company entered into a grant agreement with the Gates Foundation pursuant to which 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. 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 agreement 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

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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 nine months ended September 30, 2017 (unaudited), the Company recognized research and development expense of \$0.1 million in connection with the Adimab Option Agreement, which consisted of reimbursement for services performed by Adimab.

***Gates Foundation Grant Agreement***

In February 2017, the Company entered into a grant agreement with the Gates Foundation, a related party (see Note 17), 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

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the agreement (see Note 2). Such funds received from the Gates Foundation are no longer classified as restricted cash once the Company incurs qualifying expenses under the grant agreement and the restrictions no longer apply.

During the nine months ended September 30, 2017 (unaudited), the Company recognized grant income of \$1.2 million under the grant agreement with the Gates Foundation upon incurring qualifying expenses. As of September 30, 2017 (unaudited), unearned income under the grant agreement with the Gates Foundation was \$0.4 million.

***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 preferred stock for proceeds of \$8.0 million and the Company committed to use the proceeds 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 classified as restricted cash (current) in the consolidated balance sheet due to restrictions on the use of funds imposed by the agreement (see Note 2). Such funds received from the Gates Foundation are no longer classified as restricted cash once the Company incurs qualifying expenses under the letter agreement and the restrictions no longer apply.

During the nine months ended September 30, 2017 (unaudited), the Company incurred qualifying expenses of \$3.3 million 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.

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[Table of Contents](#)**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS***FFG Grants*

For grants under the funding agreements with FFG, the Company recognized grant income of \$0.7 million and \$0.6 million during the years ended December 31, 2015 and 2016, respectively, and \$0.4 million during each of the nine months ended September 30, 2016 and 2017 (unaudited). As of December 31, 2015 and 2016 and September 30, 2017 (unaudited), the Company recorded grant receivables from FFG of \$0.4 million, \$36,000 and \$0.3 million, respectively, for qualifying expenses incurred that were reimbursable under the funding agreements. As of December 31, 2015 and 2016 and September 30, 2017 (unaudited), there were no amounts recorded as unearned income in connection with the FFG Grants.

*FFG Loans*

Loans under the funding agreements with FFG (see Note 8) 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 \$0.3 million and \$0.4 million during the years ended December 31, 2015 and 2016, respectively, and \$0.3 million and \$0.4 million during the nine months ended September 30, 2016 and 2017 (unaudited), 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 \$0.4 million, \$0.5 million and \$0.7 million as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), respectively, and unearned income (non-current) related to such benefit was \$2.4 million, \$2.1 million and \$2.1 million as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), 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 10%, 12% and 12% for the years ended December 31, 2015 and 2016 and for the year ending December 31, 2017, 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 \$1.2 million and \$1.4 million during the years ended December 31, 2015 and 2016, respectively, and of \$1.1 million during each of the nine months ended September 30, 2016 and 2017 (unaudited), in connection with the Austrian research and development incentive program. As of December 31, 2015 and 2016 and September 30, 2017 (unaudited), the Company recorded receivables for amounts due under the program of \$1.1 million, \$1.3 million and \$1.2 million, respectively, which amounts were included in grant and incentive receivables in the consolidated balance sheet.

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**8. Loans Payable**

The aggregate principal amount of debt outstanding as of December 31, 2015 and 2016 and September 30, 2017 (unaudited) consisted of the following (in thousands):

	<u>December 31,</u>		<u>September 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
Term loans under 2012 Loan Agreement	\$ 250	\$ 7,000	\$ 5,250
FFG loans	<u>7,567</u>	<u>8,047</u>	<u>10,047</u>
	<u>\$7,817</u>	<u>\$15,047</u>	<u>\$ 15,297</u>

Current and non-current debt obligations reflected in the consolidated balance sheets as of December 31, 2015 and 2016 and September 30, 2017 (unaudited) consisted of the following (in thousands):

	<u>December 31,</u>		<u>September 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
Current liabilities:			(unaudited)
Term loans under 2012 Loan Agreement	\$ 250	\$ 2,333	\$ 2,333
FFG loans	—	—	—
Unamortized debt discount	—	(34)	(24)
Loans payable, net of discount	<u>250</u>	<u>2,299</u>	<u>2,309</u>
Non-current liabilities:			
Term loans under 2012 Loan Agreement	—	4,667	2,917
FFG loans	7,567	8,047	10,047
Unamortized debt discount	(2,863)	(2,587)	(2,755)
Loans payable, net of discount and current portion	<u>4,704</u>	<u>10,127</u>	<u>10,209</u>
Total loans payable, net of discount	<u>\$ 4,954</u>	<u>\$12,426</u>	<u>\$ 12,518</u>

**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”), which provided for a term loan of up to \$0.5 million (the “2012 Term Loan A Advance”) on the closing date and additional term loans in the aggregate of \$2.0 million (the “2012 Term Loan B Advance”). The Company borrowed the full \$2.5 million available under the agreement in two separate tranches: \$0.5 million under the 2012 Term Loan A Advance, which was borrowed in December 2012, and \$2.0 million under the 2012 Term Loan B Advance, which was borrowed in February 2013. Borrowings under the 2012 Term Loan A Advance and 2012 Term Loan B Advance (collectively, the “2012 Term Loan Advance”) bore interest at a rate per annum equal to greater of 3.25% and The Wall Street Journal prime rate; provided, however, that in an event of default, as defined in the 2012 Loan Agreement, the interest rate applicable to borrowings under the 2012 Loan Agreement would be increased by 4.0%.

The 2012 Loan Agreement required monthly payments of principal and interest, beginning on October 1, 2013 through March 1, 2016 (the “Maturity Date”), when all unpaid principal and interest became due and payable. The 2012 Loan Agreement also provided that the Company could voluntarily prepay all (but not less



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than all) of the outstanding principal at any time. A final payment of 4.0% multiplied by the principal amount of the borrowings under the 2012 Term Loan A Advance and 2012 Term Loan B Advance was due upon the earlier to occur of the Maturity Date or prepayment of such borrowings.

In connection with the 2012 Loan Agreement, on December 7, 2012, the Company issued to SVB a warrant for the purchase of Series A-2 preferred stock, which warrant became exercisable as to 2,202 shares of Series A-2 preferred stock on December 12, 2012 in connection with the 2012 Term Loan A Advance and as to 8,811 shares of Series A-2 preferred stock on February 25, 2013 in connection with the 2012 Term Loan B Advance (see Note 10). On the dates the warrant became exercisable, the Company recorded a debt discount and a warrant liability in the Company's consolidated balance sheet equal to the fair value of the portions of the warrant on the dates they became exercisable.

On February 29, 2016, in connection with an amendment to the 2012 Loan Agreement, the Company repaid all remaining principal and accrued interest outstanding under the 2012 Term Loan A Advance and 2012 Term Loan B Advance.

*First Amendment*

On February 19, 2016, the Company entered into the First Amendment to the 2012 Loan Agreement (the "First Amendment"). The First Amendment provided for an additional borrowing of \$3.5 million ("2016 Term Loan A Advance"), with a requirement that a portion of the proceeds be used to pay in full, all amounts then outstanding, under the 2012 Term Loan A Advance and the 2012 Term Loan B Advance.

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 (collectively the "2016 Term Loan B Advance"), 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 under the 2016 Term Loan A Advance, which was borrowed on February 29, 2016, and \$3.5 million under the 2016 Term Loan B Advance, which was borrowed on August 23, 2016. Following these borrowings in February and August 2016, no additional amounts were available to be borrowed under the 2012 Loan Agreement. Borrowings under the 2016 Term Loan A Advance and 2016 Term Loan B Advance (collectively, the "2016 Term Loan Advance") bear 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 First Amendment will be increased by 4.0%. As of December 31, 2016 and September 30, 2017 (unaudited), the interest rate applicable to borrowings under the 2016 Term Loan Advance was 3.50% and 4.0%, respectively.

The Company is required to make equal monthly payments of principal as well as accrued interest beginning January 1, 2017 through December 1, 2019 (the "First Amendment Maturity Date"), when all unpaid principal and interest become due and payable. The First Amendment also provided that the Company could 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 ranges from 0% to 2% of the outstanding principal if paid prior to the First Amendment Maturity Date. The Company has not accrued for this prepayment fee as it does not intend to prepay the outstanding balance. A final payment of 5.0% multiplied by the principal amount of the borrowings under the 2016 Term Loan Advance is due upon the earlier to occur of the First Amendment Maturity Date or prepayment of all outstanding principal. In connection with the First Amendment, the Company paid an arrangement fee of \$20,000 to SVB and incurred legal costs of \$7,000, both of which were recorded as a debt discount. The debt discount is reflected as a reduction of the carrying value of the loan payable on the Company's consolidated

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balance sheet and is being amortized to interest expense over the term of the loan using the effective interest method.

In connection with the First Amendment, on February 29, 2016, the Company repaid all remaining principal and accrued interest outstanding under the 2012 Term Loan A Advance and 2012 Term Loan B Advance, totaling \$0.1 million, and paid a final payment of \$0.1 million. The Company accounted for the repayment of amounts due under the 2012 Term Loan A Advance and 2012 Term Loan B Advance in connection with the First Amendment to the 2012 Loan Agreement as an extinguishment of the 2012 Term Loan A Advance and 2012 Term Loan B Advance and as a new debt issuance, which did not result in an impact to the Company's statement of operations as there was no unamortized debt discount at the time of extinguishment.

Borrowings under the 2012 Loan Agreement are collateralized by a pledge of 65% of the outstanding capital stock of the Company's subsidiary in Austria. The 2012 Loan Agreement contains affirmative and negative covenants but does not contain any financial covenants.

In connection with the First Amendment to the 2012 Loan Agreement, on February 19, 2016, the Company issued to SVB a warrant for the purchase of Series B preferred stock, which warrant became exercisable as to 7,251 shares of Series B preferred stock on February 29, 2016 in connection with 2016 Term Loan A Advance and as to 7,251 shares of Series B preferred stock on August 23, 2016 in connection with the 2016 Term Loan B Advance. On the dates that the warrant became exercisable, the Company recorded a debt discount and a warrant liability in the Company's consolidated balance sheet equal to the fair value of the portions of the warrant on the dates they became exercisable. The debt discount is being amortized to interest expense using the effective interest method over the term of the loan.

The Company recognized interest expense under the 2012 Loan Agreement, as amended, of \$49,000 and \$0.3 million during the years ended December 31, 2015 and 2016, respectively, and \$0.2 million and \$0.3 million during the nine months ended September 30, 2016 and 2017 (unaudited), respectively, including interest expense related to the amortization of the debt discount of \$26,000 and \$0.1 million during the years ended December 31, 2015 and 2016, respectively, and \$0.1 million during each of the nine months ended September 30, 2016 and 2017 (unaudited). As of December 31, 2015 and 2016 and September 30, 2017 (unaudited), the unamortized debt discount was \$0, \$0.1 million and \$35,000, respectively.

During the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2017 (unaudited), the Company made aggregate principal payments in connection with the 2012 Loan Agreement of \$1.0 million, \$0.3 million and \$1.8 million, respectively.

***FFG Loans***

In connection with the funding agreements with FFG (see Note 7), 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 \$7.6 million, \$8.0 million and \$10.0 million as of December 31, 2015 and 2016 and September 30, 2017 (unaudited), respectively. Amounts due under the FFG loans bear interest at rates ranging from 0.75% to 2.0% per annum and mature 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, 2015 and 2016 and September 30, 2017 (unaudited), the unamortized debt discount related to FFG loans was \$2.9 million, \$2.6 million and \$2.7 million, respectively.

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**ARSANIS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The Company recognized interest expense of \$0.4 million and \$0.5 million during the years ended December 31, 2015 and 2016, respectively, and of \$0.4 million and \$0.5 million during each of the nine months ended September 30, 2016 and 2017 (unaudited) respectively, related to the FFG loans, which included interest expense related to the amortization of debt discount of \$0.3 million and \$0.4 million during the years ended December 31, 2015 and 2016, respectively, and of \$0.3 million and \$0.4 million during the nine months ended September 30, 2016 and 2017 (unaudited), respectively. There were no principal payments due or paid under the FFG loans during the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2017 (unaudited).

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 contain no affirmative, negative or financial covenants and are not secured by any of the Company's assets.

As of December 31, 2016, the aggregate minimum future principal payments due in connection with the 2012 Loan Agreement, as amended, and the FFG loans are summarized as follows (in thousands):

<u>Year Ending December 31,</u>	
2017	\$ 2,333
2018	2,333
2019	2,334
2020	4,423
2021	—
Thereafter	<u>3,624</u>
	<u>\$15,047</u>

**9. Convertible Promissory Notes**

At each balance sheet date, convertible promissory notes, net of discount, consisted of the following (in thousands):

	<u>December 31,</u>	
	<u>2015</u>	<u>2016</u>
Principal	\$ 4,000	\$ 5,500
Accrued interest	1	27
Unamortized discount	(1,736)	(2,664)
Unamortized deferred issuance costs	(25)	—
Convertible promissory notes, net of discount	<u>\$ 2,240</u>	<u>\$ 2,863</u>

There were no convertible promissory notes outstanding as of September 30, 2017 (unaudited).

*2015 Notes*

On December 16, 2015, the Company issued convertible promissory notes (the "2015 Notes") in the aggregate principal amount of \$4.0 million. The 2015 Notes bore interest at a rate of 0.56% per annum, were unsecured and were due and payable, including accrued interest, on December 16, 2016. In the event of a qualified sale of preferred stock to one or more institutional investors resulting in gross proceeds to the Company

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of at least \$5.0 million, all principal and accrued and unpaid interest under the 2015 Notes was automatically convertible into a number of shares of the Company's preferred stock issued in such a financing equal to the outstanding principal and accrued but unpaid interest under the 2015 Notes, divided by the price per share of the preferred stock sold in the financing, multiplied by 0.90. In addition, in the event of a dissolution, liquidation, winding-up or change-of-control event, the 2015 Notes contained a put option whereby the Company was required to pay to the holder of the 2015 Notes an amount equal to the greater of (i) the principal amount then outstanding under the 2015 Notes, plus any accrued but unpaid interest, multiplied by 1.10 and (ii) such amount that would be received if all outstanding principal and interest under 2015 Notes had converted into shares of the Company's Series B preferred stock at the Series B Original Issue Price (see Note 11).

The Company concluded that the conversion feature in the event of a qualified financing and the put option each met the definition of embedded derivative that was required to be accounted for as a separate unit of accounting. The Company recorded the combined issuance-date fair value of the derivative liabilities of \$1.8 million as a debt discount and as a derivative liability in the Company's consolidated balance sheet.

In connection with the 2015 Notes, the Company paid legal costs of \$26,000 which were capitalized and recorded as debt discount and amortized using the effective interest method over the term of the loan. The Company recognized interest expense of \$0.1 million, \$0.4 million and \$0.4 million, including amortization of debt discount of \$0.1 million, \$0.4 million and \$0.4 million during the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 (unaudited), respectively, in connection with the 2015 Notes. As of December 31, 2015, the unamortized debt discount on the 2015 Notes was \$1.8 million.

In April 2016, in connection with the Company's issuance and sale of Series C redeemable convertible preferred stock (the "Series C preferred stock"), all of the outstanding principal and accrued interest then-outstanding under the 2015 Notes, totaling \$4.0 million, was converted into 461,396 shares of Series C preferred stock at a price equal to 90% of the \$9.65 per share price paid by investors in the Series C financing.

The Company accounted for the conversion of the 2015 Notes as a debt extinguishment and recognized a loss on extinguishment of debt of \$35,000 within other income (expense), net in the consolidated statement of operations. The loss on extinguishment was calculated as the difference between (i) the fair value of the 461,396 shares of Series C preferred stock issued to settle the 2015 Notes of \$4.5 million and (ii) the carrying value of the 2015 Notes, net of the unamortized debt discount, of \$2.7 million plus the then-current fair value of derivative liability associated with the 2015 Notes at the time of the extinguishment of \$1.7 million.

*2016 Notes*

On April 12, 2016, the Company issued convertible promissory notes (the "2016 Notes") in the aggregate principal amount of \$5.5 million. The 2016 Notes bore interest at a rate of 0.70% per annum, were unsecured and were due and payable, including accrued interest, on October 12, 2017. In the event of a qualified sale of preferred stock to one or more institutional investors resulting in gross proceeds to the Company of at least \$20.0 million, all principal and accrued and unpaid interest under the 2016 Notes was automatically convertible into a number of shares of the Company's preferred stock issued in such a financing equal to the outstanding principal and accrued but unpaid interest under the 2016 Notes, divided by the price per share of the preferred stock sold in the financing, multiplied by 0.90. In addition, in the event of a dissolution, liquidation, winding-up or change-of-control event, the 2016 Notes contained a put option whereby the Company was required to pay to the holder of 2016 Notes an amount equal to the greater of (i) the principal amount then outstanding under the 2016 Notes plus any accrued but unpaid interest, multiplied by 1.10 and (ii) such amount that would be received if all outstanding principal and interest under 2016 Notes had converted into shares of the Company's Series C preferred stock at the Series C

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Original Issue Price (see Note 11). In addition, in the event that (i) any principal or interest under any of the 2016 Notes remained outstanding on October 12, 2017 (the maturity date); (ii) any amount under the 2016 Notes was to be prepaid; or (iii) any amount under any of the 2016 Notes became due and payable in connection with an event of default, as defined, the 2016 Notes were convertible at the option of the holder into a number of shares of the Company's Series C preferred stock equal to the quotient of the outstanding principal amount all accrued and unpaid interest under the 2016 Notes divided by the Series C Original Issue Price (see Note 11).

The Company concluded that both the conversion feature in the event of a qualified financing and the put option met the definition of embedded derivatives that were required to be accounted for as a separate unit of accounting. The Company recorded the combined issuance-date fair value of the derivative liabilities of \$3.9 million as a debt discount and as a derivative liability in the consolidated balance sheet.

The Company recognized interest expense of \$1.3 million, \$0.7 million and \$0.9 million, including amortization of debt discount of \$1.3 million, \$0.7 million and \$0.9 million during the year ended December 31, 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), respectively, in connection with the 2016 Notes. As of December 31, 2016, the unamortized debt discount on the 2016 Notes was \$2.7 million. There were no debt issuance costs associated with the 2016 Notes.

In April 2017, 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, 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, the per share price paid in cash by investors in the Series D preferred stock financing.

The Company accounted for the conversion of the 2016 Notes as a debt extinguishment and recognized a loss on extinguishment of debt of \$0.3 million within other income (expense), net in the consolidated statement of operations. As of the date of conversion, the unamortized discount on the 2016 Notes was \$1.8 million. The loss on extinguishment was calculated as the difference between (i) the fair value of the 1,896,297 shares of Series D preferred stock issued to settle the 2016 Notes of \$6.2 million and (ii) the carrying value of the 2016 Notes, net of the unamortized debt discount, of \$3.7 million plus the then-current fair value of derivative liability associated with the 2016 Notes at the time of the extinguishment of \$2.1 million.

*2017 Notes*

On January 17, 2017, the Company issued convertible promissory notes (the "2017 Notes") in the aggregate principal amount of \$4.9 million. The 2017 Notes bore interest at a rate of 0.96% per annum, were unsecured and were due and payable, including accrued interest, on October 12, 2017. In the event of a qualified sale of preferred stock to one or more institutional investors resulting in gross proceeds to the Company of at least \$20.0 million, all principal and accrued and unpaid interest under the 2017 Notes was automatically convertible into a number of shares of the Company's preferred stock issued in such a financing equal to the outstanding principal and accrued but unpaid interest under the 2017 Notes, divided by the price per share of the preferred stock sold in the financing. In addition, in the event of a dissolution, liquidation, winding-up or change-of-control event, the 2017 Notes contained a put option whereby the Company was required to pay to the holder of 2017 Notes an amount equal to the greater of (i) the principal amount then outstanding under the 2017 Notes plus any accrued but unpaid interest, multiplied by 1.10 and (ii) such amount that would be received if all outstanding principal and interest under 2017 Notes had converted into shares of the Company's Series C preferred stock at the Series C Original Issue Price (see Note 11). In addition, in the event that (i) any principal or interest under any of the 2017 Notes remained outstanding on October 12, 2017 (the maturity date); (ii) any amount under the 2017 Notes was to be prepaid; or (iii) any amount under any of the 2017 Notes became due and payable in

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connection with an event of default, as defined, the 2017 Notes were convertible at the option of the holder into a number of shares of the Company's Series C preferred stock equal to the quotient of the outstanding principal amount and all accrued and unpaid interest under the 2017 Notes divided by the Series C Original Issue Price (see Note 11).

The Company concluded that the put option met the definition of an embedded derivative that was required to be accounted for as a separate unit of accounting. The Company recorded the issuance-date fair value of the derivative liability of \$0.4 million as a debt discount and as a derivative liability in the consolidated balance sheet.

In connection with the 2017 Notes, the Company paid legal costs of \$17,000, which were capitalized and recorded as debt discount and amortized using the effective interest method over the term of the loan. The Company recognized interest expense of \$0.2 million, including amortization of debt discount of \$0.1 million, during the nine months ended September 30, 2017 (unaudited) in connection with the 2017 Notes.

In April 2017, in connection with the Company's issuance and sale of Series D preferred stock, all of the outstanding principal and accrued interest 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, the per share price paid in cash by investors in the Series D preferred stock financing.

The Company accounted for the conversion of the 2017 Notes as a debt extinguishment and recognized a loss on extinguishment of debt of \$0.1 million within other income (expense), net in the consolidated statement of operations. As of the date of conversion, the unamortized debt discount on the 2017 Notes was \$0.3 million. The loss on extinguishment was calculated as the difference between (i) the fair value of the 1,524,107 shares of Series D preferred stock issued to settle the 2017 Notes of \$4.9 million and (ii) the carrying value of the 2017 Notes, net of the unamortized debt discount, of \$4.7 million plus the then-current fair value of derivative liability associated with the 2017 Notes at the time of the extinguishment of \$0.2 million.

The terms of the 2015 Notes, 2016 Notes and 2017 Notes provided that (i) all outstanding principal and interest was due and payable in cash upon an event of default, as defined in the agreements; (ii) amounts outstanding under the notes were not pre-payable without the written consent of the holders of more than 50% of the outstanding principal of the notes; and (iii) indebtedness under the notes was subordinate to any indebtedness under other venture debt entered into by the Company. There were no financial or negative covenants associated with the convertible promissory notes.

**10. Preferred Stock Warrants**

As of each balance sheet date, outstanding warrants to purchase shares of redeemable convertible preferred stock consisted of the following:

<b>December 31, 2015</b>					
<u>Date Exercisable</u>	<u>Number of Shares Issuable</u>	<u>Exercise Price</u>	<u>Exercisable for</u>	<u>Classification</u>	<u>Expiration</u>
December 12, 2012	2,202	\$ 4.54	Series A-2	Liability	December 6, 2022
February 25, 2013	8,811	\$ 4.54	Series A-2	Liability	December 6, 2022
	<u>11,013</u>				

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December 31, 2016					
<u>Date Exercisable</u>	<u>Number of Shares Issuable</u>	<u>Exercise Price</u>	<u>Exercisable for</u>	<u>Classification</u>	<u>Expiration</u>
December 12, 2012	2,202	\$ 4.54	Series A-2	Liability	December 6, 2022
February 25, 2013	8,811	\$ 4.54	Series A-2	Liability	December 6, 2022
February 29, 2016	7,251	\$ 7.24	Series B	Liability	February 18, 2026
August 23, 2016	7,251	\$ 7.24	Series B	Liability	February 18, 2026
	<u>25,515</u>				
September 30, 2017 (unaudited)					
<u>Date Exercisable</u>	<u>Number of Shares Issuable</u>	<u>Exercise Price</u>	<u>Exercisable for</u>	<u>Classification</u>	<u>Expiration</u>
December 12, 2012	2,202	\$ 4.54	Series A-2	Liability	December 6, 2022
February 25, 2013	8,811	\$ 4.54	Series A-2	Liability	December 6, 2022
February 29, 2016	7,251	\$ 7.24	Series B	Liability	February 18, 2026
August 23, 2016	7,251	\$ 7.24	Series B	Liability	February 18, 2026
	<u>25,515</u>				

In connection with the 2012 Loan Agreement, on December 7, 2012, the Company issued to SVB a warrant for the purchase of Series A-2 preferred stock, which warrant became exercisable as to 2,202 shares of Series A-2 preferred stock on December 12, 2012 in connection with the 2012 Term Loan A Advance and as to 8,811 shares of Series A-2 preferred stock on February 25, 2013 in connection with the 2012 Term Loan B Advance. The warrant is exercisable at a price of \$4.54 per share and expires on December 6, 2022.

The Company classifies the warrant as a liability on its consolidated balance sheet (included in other long-term liabilities) as the warrant is a free-standing financial instrument that may require the Company to transfer assets upon exercise. The liability associated with each portion of the warrant that became exercisable was recorded at fair value on the dates they became exercisable and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the Company's consolidated statement of operations. Changes in the fair value of the warrant liability will continue to be recognized until the warrant is exercised, expires or qualifies for equity classification. On the dates the warrant became exercisable, the fair value of the portion of the warrant to purchase 2,202 shares of Series A-2 preferred stock that became exercisable in connection with the 2012 Term Loan A Advance and the fair value of the portion of the warrant to purchase 8,811 shares of Series A-2 preferred stock that became exercisable in connection with the 2012 Term Loan B Advance were determined to be \$7,000 and \$26,000, respectively. The Company remeasured the liability associated with the warrant as of December 31, 2015 and 2016 and September 30, 2017 (unaudited) and determined that the fair value of the warrant liability was \$26,000, \$12,000 and \$8,000, respectively. The Company recognized a gain (loss) of \$1,000, \$14,000, \$0 and \$4,000 within other income (expense), net in the consolidated statements of operations for the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), respectively, related to the change in fair value of the warrant.

In connection with the First Amendment to the 2012 Loan Agreement, on February 19, 2016, the Company issued to SVB a warrant for the purchase of Series B preferred stock, which warrant became exercisable as to 7,251 shares of Series B preferred stock on February 29, 2016 in connection with 2016 Term Loan A Advance and as to 7,251 shares of Series B preferred stock on August 23, 2016 in connection with the 2016 Term Loan B Advance. The warrant is exercisable at a price of \$7.24 per share and expires on February 18, 2026.

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The Company classifies the warrant as a liability on its consolidated balance sheet (included in other long-term liabilities) as the warrant is a free-standing financial instrument that may require the Company to transfer assets upon exercise. The liability associated with each portion of the warrant that became exercisable was recorded at fair value on the dates they became exercisable and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the Company's consolidated statement of operations. Changes in the fair value of the warrant liability will continue to be recognized until the warrant is exercised, expires or qualifies for equity classification. On the dates the warrant became exercisable, the fair value of the portion of the warrant to purchase 7,251 shares of Series B preferred stock that became exercisable in connection with 2016 Term Loan A Advance and the fair value of the portion of the warrant to purchase 7,251 shares of Series B preferred stock that became exercisable in connection with the 2016 Term Loan B Advance were determined to be \$35,000 and \$25,000, respectively. The Company remeasured the liability associated with the warrant as of December 31, 2016 and September 30, 2017 (unaudited) and determined that the fair value of the warrant liability was \$35,000 and \$23,000, respectively. The Company recognized a gain of \$25,000, \$11,000 and \$12,000 within other income (expense), net in the consolidated statements of operations for the year ended December 31, 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), respectively, related to the change in fair value of the warrant.

**11. Redeemable Convertible Preferred Stock**

As of December 31, 2016 and September 30, 2017 (unaudited), the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 6,711,756 shares and 21,894,619 shares, respectively, of \$0.001 par value preferred stock. The redeemable convertible preferred stock is classified outside of stockholders' equity (deficit) because the shares contain certain redemption features that are not solely within the control of the Company.

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 and the Series C 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.

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.

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.

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 (see Note 9).

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 (see Note 9).



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## ARSANIS, INC.

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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 (unaudited), 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.

As of each balance sheet date, Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2015				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 preferred stock	200,001	200,001	\$ 394	\$ 400	58,597
Series A-2 preferred stock	2,125,551	2,114,538	9,599	9,600	619,551
Series B preferred stock	2,762,431	2,762,431	19,955	20,000	809,379
	<u>5,087,983</u>	<u>5,076,970</u>	<u>\$29,948</u>	<u>\$ 30,000</u>	<u>1,487,527</u>
	December 31, 2016				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 preferred stock	200,001	200,001	\$ 395	\$ 400	58,597
Series A-2 preferred stock	2,125,551	2,114,538	9,599	9,600	619,551
Series B preferred stock	2,776,934	2,762,431	19,966	20,000	809,379
Series C preferred stock	1,609,270	1,031,342	9,878	9,952	302,177
	<u>6,711,756</u>	<u>6,108,312</u>	<u>\$39,838</u>	<u>\$ 39,952</u>	<u>1,789,704</u>
	September 30, 2017 (unaudited)				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 preferred stock	200,001	200,001	\$ 396	\$ 400	58,597
Series A-2 preferred stock	2,125,551	2,114,538	9,599	9,600	756,687
Series B preferred stock	2,776,933	2,762,431	19,971	20,000	1,233,406
Series C preferred stock	1,031,342	1,031,342	9,890	9,952	513,934
Series D preferred stock	15,760,792	15,760,784	50,965	51,155	4,617,859
	<u>21,894,619</u>	<u>21,869,096</u>	<u>\$90,821</u>	<u>\$ 91,107</u>	<u>7,180,483</u>

The holders of the Preferred Stock have the following rights and preferences:

*Voting Rights*

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to the stockholders for a vote and are entitled to the number of votes equal to the number of

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whole shares of common stock into which such holders of Preferred Stock could convert on the record date of for determination of stockholders entitled to vote. In addition, the holders of Preferred Stock, voting as a single class, are entitled to elect five directors of the Company. The holders of Preferred Stock, together with the holders of common stock and voting as a single class, are entitled to elect the remaining directors of the Company by vote of a majority of such shares.

*Dividends*

The holders of the Preferred Stock are entitled to receive noncumulative dividends when, as and if declared by the board of directors. The Company may not pay any dividends on shares of common stock of the Company unless the holders of Preferred Stock then outstanding simultaneously receive dividends at the same rate and same time as dividends are paid with respect to common stock. Through December 31, 2016 and September 30, 2017 (unaudited), no cash dividends have been declared or paid.

*Liquidation Rights*

In the event of any voluntary or involuntary liquidation event, dissolution, winding up of the Company or Deemed Liquidation Event (as defined below), each holder of the then outstanding Series D preferred stock will be entitled to receive, prior and in preference to any distributions to the holders of Series C, Series B, Series A-1 and Series A-2 preferred stock and common stock, an amount equal to the greater of (i) the Original Issue Price (as defined below), plus any declared but unpaid dividends thereon, or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After the payment of all preferential amounts to the holders of Series D preferred stock, each holder of the then outstanding Series C preferred stock will be entitled to receive, prior and in preference to any distributions to the holders of Series B, Series A-1 and Series A-2 preferred stock and common stock, an amount equal to the greater of (i) the Original Issue Price (as defined below), plus any declared but unpaid dividends thereon, or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After the payment of all preferential amounts to the holders of Series C preferred stock, each holder of the then outstanding Series B preferred stock will be entitled to receive, prior and in preference to any distributions to the holders of Series A-1 and Series A-2 preferred stock and common stock, an amount equal to the greater of (i) the Original Issue Price (as defined below), plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After the payment of all preferential amounts to the holders of Series B preferred stock, each holder of the then outstanding Series A-1 and Series A-2 preferred stock will be entitled to receive, prior and in preference to any distributions to the holders of common stock, an amount equal to the greater of (i) the Original Issue Price (as defined below), plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event.

After payments have been made in full to the holders of Preferred Stock, then, to the extent available, the remaining amounts will be distributed among the holders of the shares of common stock, pro rata based on the number of shares held by each holder.

The majority of the holders of Preferred Stock, voting together as a single class, may deem a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the

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outstanding shares of the surviving or acquiring corporation), sale, transfer or exclusive license of substantially all of the assets of the Company to be a Deemed Liquidation Event.

The Original Issue Price is \$2.00 per share for Series A-1, \$4.54 per share for Series A-2, \$7.24 per share for Series B, \$9.65 per share for Series C and \$3.2457 per share for Series D preferred stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock.

*Conversion*

Each share of Preferred Stock is convertible into common stock, at any time, at the option of the holder, and without the payment of additional consideration, at the applicable conversion ratio then in effect for each series of Preferred Stock and subject to adjustment in accordance with anti-dilution provisions. In addition, each share of Preferred Stock will be automatically converted into common stock at the applicable conversion ratio then in effect for each series of Preferred Stock upon the earlier of (i) the closing of a firm commitment underwritten public offering of its common stock with gross proceeds to the Company of at least \$30.0 million, or (ii) a date specified by vote or written consent of the holders of a 75% majority of the outstanding Preferred Stock on an as-converted to common stock basis.

The conversion ratio of each series of Preferred Stock is determined by dividing the Original Issue Price of each series of preferred stock by the Conversion Price of each series. As of December 31, 2016, the Conversion Price was \$6.8260 per share for Series A-1, \$15.4950 per share for Series A-2, \$24.7101 per share for Series B and \$32.9355 per share for Series C preferred stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock.

In connection with the Company's issuance and sale of Series D preferred stock in April 2017, in accordance with the terms of the Company's certificate of incorporation, as amended and restated, the Conversion Prices for Series A-2 preferred stock, Series B preferred stock and Series C preferred stock were adjusted. The Company assessed whether a beneficial conversion feature should be recognized upon such adjustment and concluded that no beneficial conversion feature existed at that time because the adjusted conversion prices continued to be higher than the fair values of the Company's common stock as of the original issuance dates of the Company's Series A-2 preferred stock, Series B preferred stock and Series C preferred stock. As of September 30, 2017 (unaudited), the Conversion Price was \$6.8260 per share for Series A-1, \$12.6868 per share for Series A-2, \$16.2152 per share for Series B, \$19.3650 per share for Series C and \$11.0776 per share for Series D preferred stock, in each case subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock.

*Redemption*

At the written election of at least a majority of the holders of Preferred Stock, voting together as a single class, the shares of Preferred Stock outstanding are redeemable, at any time on or after April 24, 2022, in three equal installments commencing at least 90 days after the required vote, in an amount equal to the Original Issue Price per share of each series of Preferred Stock plus any declared but unpaid dividends thereon.

**12. Common Stock**

As of December 31, 2016 and September 30, 2017 (unaudited), the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 10,000,000 shares and 31,000,000 shares,

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respectively, of \$0.001 par value common stock. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above.

Each share of common stock entitles the holder to one vote, together with the holders of Preferred Stock, on all matters submitted to the stockholders for a vote. The holders of Preferred Stock, voting as a single class, are entitled to elect five directors of the Company. The holders of common stock, together with the holders of Preferred Stock and voting as a single class, are entitled to elect the remaining directors of the Company by vote of a majority of such shares. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Preferred Stock. Through December 31, 2016 and September 30, 2017 (unaudited), no cash dividends have been declared or paid.

As of December 31, 2016 and September 30, 2017 (unaudited), the Company had reserved 2,382,016 shares and 8,562,028 shares, respectively, of common stock for the conversion of outstanding shares of Preferred Stock (see Note 11), the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2010 Special Stock Incentive Plan and 2011 Equity Incentive Plan (see Note 13) and the exercise of outstanding warrants to purchase shares of Preferred Stock (see Note 10), assuming all warrants to purchase shares of Preferred Stock became warrants to purchase shares of common stock at the applicable conversion ratio.

**13. Stock-Based Compensation*****2011 Stock Incentive Plan***

The Company's 2011 Stock Incentive Plan, as amended (the "2011 Plan"), provides for the Company to issue restricted stock awards, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees including officers and directors who are also employees. Restricted stock awards and non-statutory stock options may be granted to employees, members of the board of directors, outside advisors and consultants of the Company.

The total number of common shares that may be issued under the 2011 Plan was 512,745 shares as of December 31, 2016, of which 33,740 shares remained available for future grant as of December 31, 2016. In April 2017, the Company effected an increase in the total number of shares of the Company's common stock reserved for issuance under the 2011 Plan from 512,745 shares to 1,299,038 shares, of which 171,817 shares remained available for future grant as of September 30, 2017 (unaudited).

Shares that are expired, terminated, surrendered or canceled under the 2011 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.

***2010 Special Stock Incentive Plan***

The Company's 2010 Special Stock Incentive Plan (the "Special Plan") provides for the Company to issue restricted stock awards or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Restricted stock awards and non-statutory stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company.

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The total number of common shares that may be issued under the Special Plan was 585,994 shares as of December 31, 2016 and September 30, 2017 (unaudited), of which 2,194 shares remained available for future grant as of December 31, 2016 and September 30, 2017 (unaudited).

Shares that are expired, terminated, surrendered or canceled under the Special 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.

The 2011 Plan and the Special Plan are 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 (or 110% of fair value in the case of an award granted to employees who hold more than 10% of the total combined voting power of all classes of stock at the time of grant) and the term of stock options may not be greater than five years for an incentive stock option granted to a 10% stockholder and greater than ten years for all other options granted. Stock options awarded under both plans expire 10 years after the grant date, unless the board of directors sets a shorter term. Vesting periods for both plans 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 under both plans typically vest over four years. Non-statutory options granted to employees, officers, members of the board of directors, advisors, and consultants of the Company under both plans typically vest over three or four years.

During the years ended December 31, 2015 and 2016, the Company granted options to purchase 102,195 shares and 316,916 shares, respectively, of common stock to employees and directors. During the nine months ended September 30, 2016 and 2017 (unaudited), the Company granted options to purchase 316,916 shares and 657,882 shares, respectively, of common stock to employees and directors. The Company recorded stock-based compensation expense for options granted to employees and directors of \$0.1 million and \$0.6 million during the years ended December 31, 2015 and 2016, respectively, and of \$0.4 million and \$0.6 million during nine months ended September 30, 2016 and 2017 (unaudited), respectively.

During the years ended December 31, 2015 and 2016, the Company granted options to purchase 2,343 shares and 4,686 shares, respectively, of common stock to non-employees. During the nine months ended September 30, 2016 and 2017 (unaudited), the Company granted options to purchase 4,686 shares and 0 shares, respectively, of common stock to non-employees. The Company recorded stock-based compensation expense for options granted to non-employees of \$16,000 and \$15,000 during the years ended December 31, 2015 and 2016, respectively, and of \$11,000 and \$6,000 during nine months ended September 30, 2016 and 2017 (unaudited), respectively.

***Stock Option Valuation***

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors were as follows, presented on a weighted average basis:

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
			(unaudited)	
Risk-free interest rate	1.81%	1.26%	1.26%	1.91%
Expected term (in years)	5.98	5.80	5.80	6.08
Expected volatility	75.3%	75.3%	75.3%	76.2%
Expected dividend yield	0%	0%	0%	0%

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## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The assumptions that the Company used to determine the grant-date fair value of stock options granted to non-employees were as follows, presented on a weighted average basis:

	Year Ended December 31,		Nine Months Ended September 30,	
	2015	2016	2016	2017
			(unaudited)	
Risk-free interest rate	1.95%	2.08%	2.08%	*
Expected term (in years)	8.55	8.82	8.82	*
Expected volatility	77.3%	77.8%	77.8%	*
Expected dividend yield	0%	0%	0%	*

\* Not applicable as no stock options were granted to non-employees during the nine months ended September 30, 2017.

**Stock Options**

The following table summarizes the Company's stock option activity since December 31, 2015 (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, 2015	231,576	\$ 5.10	8.34	\$ 720
Granted	321,602	9.31		
Exercised	—	—		
Forfeited	(4,275)	3.86		
Outstanding as of December 31, 2016	548,903	\$ 7.58	8.62	\$ 1,000
Granted	657,882	4.00		
Exercised	—	—		
Forfeited	(9,665)	9.11		
Outstanding as of September 30, 2017 (unaudited)	1,197,120	\$ 5.61	8.88	\$ 236
Options exercisable as of December 31, 2016	216,556	\$ 5.23	7.53	\$ 903
Options exercisable as of September 30, 2017 (unaudited)	321,388	\$ 6.49	7.36	\$ 236
Options unvested as of December 31, 2016	332,347	\$ 9.10	9.34	\$ 97
Options unvested as of September 30, 2017 (unaudited)	875,732	\$ 5.27	9.44	\$ —

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, 2015 and 2016 was \$5.40 and \$6.02, respectively. The weighted average grant-date fair value per share of stock options granted during the nine months ended September 30, 2016 and 2017 (unaudited) was \$6.02 and \$2.69, respectively.

The total fair value of options vested during the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited) was \$43,000, \$0.5 million, \$0.4 million and \$0.6 million, respectively.

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**ARSANIS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
***Restricted Common Stock***

The Company has granted restricted common stock with time-based vesting conditions. The exercise price of the restricted stock awards are 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 since December 31, 2015:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested restricted common stock as of December 31, 2015	1,458	\$ 0.14
Issued	—	—
Vested	<u>(1,458)</u>	0.14
Unvested restricted common stock as of December 31, 2016	<u>—</u>	\$ —

All shares of restricted common stock were vested as of December 31, 2016. The total fair value of restricted common stock vested during the years ended December 31, 2015 and 2016 was \$21,000 and \$1,000, respectively. The total fair value of restricted common stock vested during the nine months ended September 30, 2016 (unaudited) was \$1,000.

***Stock-Based Compensation***

Stock-based compensation expense was classified in the consolidated statements of operations as follows (in thousands):

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
Research and development expenses	\$ 43	\$294	\$ 229	\$ 225
General and administrative expenses	83	350	231	402
	<u>\$126</u>	<u>\$644</u>	<u>\$ 460</u>	<u>\$ 627</u>

As of December 31, 2016 and September 30, 2017 (unaudited), total unrecognized compensation cost related to the unvested stock-based awards was \$1.8 million and \$2.9 million, respectively, which is expected to be recognized over weighted average periods of 2.84 and 2.92 years, respectively.

**14. Income Taxes**

During the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), 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.

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Loss before the provision for income taxes for the years ended December 31, 2015 and 2016 consisted of the following (in thousands):

	Year Ended December 31,	
	2015	2016
United States	\$ (2,261)	\$(12,969)
Foreign (Austria)	(10,957)	(10,006)
	<u>\$ (13,218)</u>	<u>\$(22,975)</u>

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,	
	2015	2016
U.S. federal statutory income tax rate	(35.0)%	(35.0)%
State income taxes, net of federal benefit	(0.9)	(2.8)
Foreign rate differential	7.1	3.2
Research and development tax credits	(0.3)	(1.0)
Nondeductible expenses	0.2	0.7
Uncertain tax position reserves	0.1	0.5
Stock-based compensation	0.1	0.3
Change in deferred tax asset valuation allowance	28.7	34.1
Effective income tax rate	<u>— %</u>	<u>— %</u>

Net deferred tax assets as of December 31, 2015 and 2016 consisted of the following (in thousands):

	December 31,	
	2015	2016
Net operating loss carryforwards	\$ 9,243	\$ 13,134
Research and development tax credit carryforwards	42	264
Start-up costs	879	3,917
Accrued expenses and other	203	689
Total deferred tax assets	<u>10,367</u>	<u>18,004</u>
Valuation allowance	(10,367)	(18,004)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2016, the Company had U.S. federal and state net operating loss carryforwards of \$8.3 million and \$4.4 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2030 and 2035, respectively. In addition, as of December 31, 2016, the Company had foreign net operating loss carryforwards of \$40.1 million, which do not expire. As of December 31, 2016, the Company also had U.S. federal and state research and development tax credit carryforwards of \$0.2 million and \$0.1 million, respectively, which begin to expire in 2031 and 2035, respectively. As of December 31, 2016, uncertain tax position reserves recorded were \$0.1 million for U.S. federal research and development tax credits and \$0.1 million for state research and development tax credits.



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During the nine months ended September 30, 2017 (unaudited), gross deferred tax assets increased by approximately \$8.1 million due to the operating loss incurred by the Company during that period.

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, 2015 and 2016 and September 30, 2017 (unaudited). 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, 2015 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,	
	2015	2016
Valuation allowance at beginning of year	\$ (6,577)	\$(10,367)
Increases recorded to income tax provision	(3,790)	(7,637)
Valuation allowance at end of year	<u>\$(10,367)</u>	<u>\$(18,004)</u>

Changes in unrecognized tax benefits consisted of the following (in thousands):

	Year Ended December 31,	
	2015	2016
Unrecognized tax benefits at beginning of year	\$ 2	\$ 21
Increases for tax positions taken in current year	19	105
Unrecognized tax benefits at end of year	<u>\$ 21</u>	<u>\$ 126</u>

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The Company's U.S. federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2013 through December 31, 2015. 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.

**15. Net Loss per Share and Unaudited Pro Forma 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):

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
			(unaudited)	
Numerator:				
Net loss	\$ (13,218)	\$ (22,975)	\$ (17,654)	\$ (22,690)
Accretion of redeemable convertible preferred stock to redemption value	(19)	(25)	(19)	(36)
Net loss attributable to common stockholders	<u>\$ (13,237)</u>	<u>\$ (23,000)</u>	<u>\$ (17,673)</u>	<u>\$ (22,726)</u>
Denominator:				
Weighted average common shares outstanding—basic and diluted	<u>508,659</u>	<u>513,527</u>	<u>513,402</u>	<u>513,900</u>
Net loss per share attributable to common stockholders— basic and diluted	<u>\$ (26.02)</u>	<u>\$ (44.79)</u>	<u>\$ (34.42)</u>	<u>\$ (44.22)</u>

The Company's potentially dilutive securities, which include stock options, warrants to purchase shares of Preferred 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:

	<u>Year Ended December 31,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
			(unaudited)	
Options to purchase common stock	231,576	548,903	548,903	1,197,120
Restricted common stock	1,458	—	—	—
Redeemable convertible preferred stock (as converted to common stock)	1,487,527	1,789,704	1,789,704	7,180,483
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	<u>3,226</u>	<u>7,475</u>	<u>7,475</u>	<u>10,414</u>
	<u>1,723,787</u>	<u>2,346,082</u>	<u>2,346,082</u>	<u>8,388,017</u>

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**ARSANIS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
***Unaudited Pro Forma Net Loss per Share Attributable to Common Stockholders***

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2016 and the nine months ended September 30, 2017 have been prepared to give effect to adjustments arising upon the closing of a qualified initial public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders does not include the effects of the accretion of Preferred Stock to redemption value or the change in fair value of the warrant liability because the calculation gives effect to the automatic conversion of shares of Preferred Stock outstanding as of September 30, 2017 into common stock and all warrants to purchase shares of Preferred Stock outstanding as of September 30, 2017 becoming warrants to purchase shares of common stock as if the proposed initial public offering had occurred on the later of January 1, 2016 or the issuance date of the Preferred Stock or the warrants.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2016 and the nine months ended September 30, 2017 have been prepared to give effect, upon a qualified initial public offering, to the automatic conversion of all outstanding shares of Preferred Stock into shares of common stock as if the proposed initial public offering had occurred on the later of January 1, 2016 or the issuance date of the Preferred Stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	<u>Year Ended December 31, 2016</u>	<u>Nine Months Ended September 30, 2017</u>
	(unaudited)	
Numerator:		
Net loss attributable to common stockholders	\$ (23,000)	\$ (22,726)
Accretion of redeemable convertible preferred stock to redemption value	25	36
Change in fair value of warrant liability	(39)	(16)
Pro forma net loss attributable to common stockholders	<u>\$ (23,014)</u>	<u>\$ (22,706)</u>
Denominator:		
Weighted average common shares outstanding—basic and diluted	513,527	513,900
Pro forma adjustment to reflect assumed automatic conversion of redeemable convertible preferred stock into common stock upon the closing of the proposed initial public offering	<u>2,417,992</u>	<u>5,054,127</u>
Pro forma weighted average common shares outstanding—basic and diluted	<u>2,931,519</u>	<u>5,568,027</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted	<u>\$ (7.85)</u>	<u>\$ (4.08)</u>

**16. Commitments and Contingencies**
***Lease Agreements***

In November 2010, the Company entered into a lease agreement for office, laboratory, parking and storage space, which expires on April 30, 2021. The Company has the option to extend the lease agreement for an

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**ARSANIS, INC.**

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additional year. Monthly lease payments, inclusive of base rent, ancillary charges and the respective value added tax to be paid on the base rent and the ancillary charges inclusive of non-rent shared tenant occupancy costs, total \$45,000. Monthly lease payments include base rent charges of \$38,000.

In July 2015, the Company entered into a lease agreement for an animal-use facility. 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. Monthly lease payments, inclusive of the base rent and the respective value added tax to be paid on the base rent, total \$37,000. Monthly lease payments include base rent charges of \$31,000.

In November 2015, the Company entered into a lease agreement for office and laboratory space, which expires on January 31, 2019. Monthly lease payments, inclusive of non-rent shared tenant occupancy costs, total \$26,000. Monthly lease payments include base rent charges of \$26,000, which are subject to a 2.6% increase in the second year of the lease and a 2.5% increase in the third year of the lease.

The Company recognizes rent expense on a straight-line basis over the respective lease period and has recorded deferred rent for rent expense incurred but not yet paid.

The Company recorded rent expense of \$1.0 million, \$1.2 million, \$0.9 million and \$0.9 million during the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), respectively.

The following table summarizes the future minimum lease payments due under operating leases as of December 31, 2016 (in thousands):

<u>Year Ending December 31,</u>	
2017	\$ 947
2018	768
2019	478
2020	452
2021	<u>151</u>
	<u>\$2,796</u>

***License Agreements***

The Company entered into a license agreement with Adimab under which it is obligated to make contingent and non-contingent payments (see Note 7).

***Manufacturing Commitments***

In July 2016, the Company entered into an agreement with a contract manufacturing organization to provide clinical trial materials. As of December 31, 2016 and September 30, 2017 (unaudited), the Company had committed to minimum payments under this agreement totaling \$3.2 million and \$0 million, respectively.

***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,

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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, 2015 or 2016 or September 30, 2017 (unaudited).

***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 (see Note 7). 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 year ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), the Company made payments to Adimab of \$0.2 million, \$0.1 million, \$0.1 million and \$0, respectively, under the Adimab Collaboration Agreement. During the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), the Company recognized research and development expense of \$0.2 million, \$8,000, \$8,000 and \$0, respectively, in connection with the Adimab Collaboration Agreement. As of December 31, 2015, amounts due to Adimab totaled \$0.1 million. As of December 31, 2016 and September 30, 2017 (unaudited), no amounts were due to Adimab under the Adimab Collaboration Agreement.

In February 2017, the Company entered into the Adimab Option Agreement with Adimab (see Note 7). During the nine months ended September 30, 2017 (unaudited), the Company made payments to Adimab of \$0.1 million and recognized \$0.1 million of research and development expense under the Adimab Option Agreement. As of September 30, 2017 (unaudited), the Company owed \$0 to Adimab under the Adimab Option Agreement.

***Agreements with the Gates Foundation***

In February 2017, the Company entered into a grant agreement with the Gates Foundation (see Note 7). In April 2017, the Company entered into a letter agreement with the Gates Foundation (see Note 7). In connection with the letter agreement, the Gates Foundation purchased \$8.0 million of shares of the Company's Series D preferred stock and the Gates Foundation became a principal stockholder of the Company. In March 2017, the Company received a payment of \$1.6 million from the Gates Foundation under the grant agreement. During the nine months ended September 30, 2017 (unaudited), the Company recognized grant income of \$1.2 million under the grant agreement upon incurring qualifying expenses. As of September 30, 2017 (unaudited), unearned income under the grant agreement was \$0.4 million.

The Company classified the proceeds received from the Gates Foundation in connection with the Company's sale and issuance of Series D preferred stock and the grant agreement as restricted cash (current) in

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the consolidated balance sheet due to restrictions on the use of funds imposed by the agreements (see Note 2). During the nine months ended September 30, 2017 (unaudited), the Company incurred qualifying expenses of \$3.3 million under the letter agreement with the Gates Foundation.

***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 provides certain laboratory services and sublets office and lab space to EveliQure. Tamas Henics, the husband of Eszter Nagy, the Company's Chief Scientific Officer and a member of its board of directors, serves as Chief Scientific Officer at EveliQure. During the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), the Company received payments from EveliQure under the agreement of less than \$0.1 million in each period. During the years ended December 31, 2015 and 2016 and the nine months ended September 30, 2016 and 2017 (unaudited), the Company recognized other income under the agreement of less than \$0.1 million in each period. As of December 31, 2015, no amounts were due from EveliQure. As of December 31, 2016 and September 30, 2017 (unaudited), amounts due from EveliQure each totaled less than \$0.1 million.

**18. Benefit Plans**

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 year ended December 31, 2015 and 2016 and the nine months ended September 30, 2017 (unaudited).

**19. Geographic Information**

The Company's property and equipment, net by location was as follows (in thousands):

	<b>December 31,</b>		<b>September 30,</b>
	<b>2015</b>	<b>2016</b>	<b>2017</b>
United States	\$ 57	\$ 68	\$ 43
Austria	703	451	436
Total property and equipment, net	<u>\$760</u>	<u>\$519</u>	<u>\$ 479</u>

**20. Subsequent Events**

For its consolidated financial statements as of December 31, 2016 and for the year then ended, the Company evaluated subsequent events through August 10, 2017, the date on which those financial statements were issued, and, with respect to the reverse stock split described below, through November 6, 2017.

***Sale of 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.

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The rights and preferences of the Series D preferred stock are similar to all other series of the Company's Preferred Stock, except that, in the event of any voluntary or involuntary liquidation event, dissolution, winding up of the Company or Deemed Liquidation Event, holders of then outstanding Series D preferred stock have priority and preference to all other classes of Preferred Stock and common stock. The Original Issue Price and Conversion Price of the Series D preferred stock are \$3.2457 and \$11.0776, respectively, per share.

In April 2017, in connection with the Company's sale of Series D preferred stock, the Company amended its certificate of incorporation, as amended and restated, to increase the total number of authorized shares of all classes of capital stock to 52,894,619 shares, consisting of 21,894,619 shares of preferred stock and 31,000,000 shares of common stock.

Because the price per share of the Series D preferred stock was lower than the Conversion Price of the Company's Series A-2, Series B and Series C preferred stock, in accordance with the Company's certificate of incorporation, as amended and restated, the Conversion Price of each of these series was adjusted to \$12.6868 per share for Series A-2, \$16.2152 per share for Series B and \$19.3650 per share for Series C preferred stock. The Conversion Price for Series A-1 preferred stock was not adjusted.

***Conversion of 2016 and 2017 Notes in Connection with Series D Preferred Stock Financing***

In April 2017, 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, 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, the per share price paid in cash by investors in the Series D preferred stock financing (see Note 9).

In April 2017, in connection with the Company's issuance and sale of Series D preferred stock, all of the outstanding principal and accrued interest 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, the per share price paid in cash by investors in the Series D preferred stock financing (see Note 9).

***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 \$8.0 million of shares of the Company's Series D preferred stock and the Company committed to use the proceeds 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.

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[Table of Contents](#)**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS*****Increase in Shares Available for Issuance and Grant of Stock Options under the 2011 Plan***

In April 2017, the Company effected an increase in the total number of shares of the Company's common stock reserved for issuance under the 2011 Plan from 512,745 shares to 1,299,038 shares.

In June 2017, the Company granted options to purchase 657,882 shares of common stock, at an exercise price of \$4.00 per share, to employees as compensation for future services to the Company.

***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 Preferred Stock (see Note 11). 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.

**21. Subsequent Events (Unaudited)**

For its interim consolidated financial statements as of September 30, 2017 and for the nine months then ended, the Company evaluated subsequent events through October 20, 2017, the date on which those financial statements were issued, and, with respect to the reverse stock split described above, through November 6, 2017.



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**4,000,000 Shares**



**Common Stock**

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**PROSPECTUS**

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**Citigroup**

**Cowen**

**Piper Jaffray**

**November 15, 2017**

Until December 10, 2017 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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