

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM S-1  
REGISTRATION STATEMENT**

UNDER  
THE SECURITIES ACT OF 1933

**ARSANIS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

2836  
(Primary Standard Industrial  
Classification Code Number)  
890 Winter Street, Suite 230  
Waltham, MA 02451  
(781) 819-5704

27-3181608  
(I.R.S. Employer  
Identification Number)

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

René Russo, Pharm.D., BCPS  
President and Chief Executive Officer  
Arsanis, Inc.  
890 Winter Street, Suite 230  
Waltham, MA 02451  
(781) 819-5704

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**Approximate date of commencement of proposed sale to public:**  
As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.   
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common stock, par value \$0.001 per share	\$	\$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price. Includes the offering price of additional shares of common stock that the underwriters have the option to purchase to cover over-allotments, if any.

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

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

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2017

PRELIMINARY PROSPECTUS

Shares



Common Stock

This is an initial public offering of common stock by Arsanis, Inc. We are selling \_\_\_\_\_ shares of common stock. The estimated initial public offering price is between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

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

We have applied to list our common stock 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	\$ _____	\$ _____
Underwriting discounts and commissions <sup>(1)</sup>	\$ _____	\$ _____
Proceeds to Arsanis, before expenses	\$ _____	\$ _____

<sup>(1)</sup> We refer you to "Underwriting" beginning on page 178 for additional information regarding underwriter compensation.

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

**Citigroup**

**Cowen**

**Piper Jaffray**

\_\_\_\_\_, 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.

**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					<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;
- 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 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 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

superiority to placebo. 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 a third party 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.

### **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, efficacy of these product candidates in *in vivo* models of infection prevention and, with respect to ASN200, potentiation of antibiotic efficacy 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 June 30, 2017, we had an accumulated deficit of \$69.5 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.

- 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, six 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.

### **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.

### **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.



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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.

**THE OFFERING**

Common stock offered	shares (approximately % (or % 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)
Common stock to be outstanding immediately following this offering	shares
Over-allotment option	shares
Use of proceeds	We estimate that the net proceeds from this offering will be \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase up to additional shares of common stock to cover over-allotments, if any), based on an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, 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.
Proposed NASDAQ Global Market symbol	"ASNS"

The number of shares of our common stock to be outstanding after this offering is based on 1,754,035 shares of our common stock outstanding as of September 1, 2017, and excludes:

- 4,086,027 shares of common stock issuable upon exercise of stock options outstanding as of September 1, 2017, at a weighted average exercise price of \$1.64 per share;
- 586,093 shares of common stock available for future issuance under our 2011 Stock Incentive Plan, as amended, and 7,465 shares of common stock available for future issuance under our 2010 Special Stock Incentive Plan, as amended, in each case as of September 1, 2017;
- additional shares of our common stock that will become available under our 2017 Stock Incentive Plan in connection with this offering;
- additional shares of our common stock that will become available under our 2017 Employee Stock Purchase Plan in connection with this offering; and
- 35,549 shares of common stock issuable following the closing of this offering upon the exercise of warrants outstanding as of September 1, 2017, at a weighted average exercise price of \$4.36 per share.

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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 24,507,086 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 35,549 shares of common stock upon the closing of this offering; and
- 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.

## 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 six months ended June 30, 2016 and 2017 and the consolidated balance sheet data as of June 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,		Six Months Ended June 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	\$ 6,165	\$ 8,297
General and administrative	2,119	6,515	3,092	3,174
Total operating expenses	<u>14,825</u>	<u>24,346</u>	<u>9,257</u>	<u>11,471</u>
Loss from operations	<u>(14,825)</u>	<u>(24,346)</u>	<u>(9,257)</u>	<u>(11,471)</u>
Other income (expense):				
Grant and incentive income	2,155	2,390	1,260	1,562
Interest expense	(472)	(2,515)	(1,065)	(1,463)
Change in fair value of warrant liability	1	39	6	11
Change in fair value of derivative liability	—	1,388	380	762
Loss on extinguishment of debt	—	(35)	(35)	(462)
Other income (expense), net	<u>(77)</u>	<u>104</u>	<u>51</u>	<u>(29)</u>
Total other income, net	<u>1,607</u>	<u>1,371</u>	<u>597</u>	<u>381</u>
Net loss	<u>(13,218)</u>	<u>(22,975)</u>	<u>(8,660)</u>	<u>(11,090)</u>
Accretion of redeemable convertible preferred stock to redemption value	<u>(19)</u>	<u>(25)</u>	<u>(12)</u>	<u>(20)</u>
Net loss attributable to common stockholders	<u><u>\$(13,237)</u></u>	<u><u>\$(23,000)</u></u>	<u><u>\$(8,672)</u></u>	<u><u>\$(11,110)</u></u>
Net loss per share attributable to common stockholders—basic and diluted <sup>(1)</sup>	<u><u>\$ (7.62)</u></u>	<u><u>\$ (13.12)</u></u>	<u><u>\$ (4.95)</u></u>	<u><u>\$ (6.33)</u></u>
Weighted average common shares outstanding—basic and diluted <sup>(1)</sup>	<u>1,736</u>	<u>1,753</u>	<u>1,751</u>	<u>1,754</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) <sup>(1)</sup>		<u><u>\$ (2.30)</u></u>		<u><u>\$ (0.70)</u></u>
Pro forma weighted average common shares outstanding—basic and diluted (unaudited) <sup>(1)</sup>		<u>10,005</u>		<u>15,843</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.

	As of June 30, 2017		Pro Forma
	Actual	Pro Forma <sup>(2)</sup>	As Adjusted <sup>(3)</sup>
(in thousands)			
<b>Consolidated Balance Sheet Data:</b>			
Cash	\$ 24,143	\$ 29,143	\$
Working capital <sup>(1)</sup>	28,954	33,954	
Total assets	39,518	44,518	
Loan payable, net of discount, including current portion	12,694	12,694	
Warrant liability	36	—	
Redeemable convertible preferred stock	85,805	—	
Total stockholders' equity (deficit)	(67,697)	23,144	

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

<sup>(2)</sup> The pro forma balance sheet data give effect to:

- our issuance and sale in September 2017 of an aggregate of 1,540,500 shares of Series D convertible preferred stock for gross proceeds of \$5.0 million;
- the automatic conversion of all outstanding shares of our preferred stock, including the shares of Series D convertible preferred stock that we issued and sold in September 2017, into an aggregate of 24,507,086 shares of common stock upon closing of this offering; and
- all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 35,549 shares of our common stock upon closing of this offering.

<sup>(3)</sup> The pro forma as adjusted balance sheet data give further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity by \$ \_\_\_\_\_ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. This pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should consider carefully the risks described below, together with the other information contained in this 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 \$11.1 million for the six months ended June 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 June 30, 2017, we had an accumulated deficit of \$69.5 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 through , 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, 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 September 20, 2017 issuance date of our interim financial statements for the six months ended June 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.

***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 \$5.8 million as of June 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 \$9.7 million as of June 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 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 Aridis 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.

***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.

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

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

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

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

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-

executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

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

***Intellectual property rights do not necessarily address all potential threats.***

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

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

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

## Risks Related to 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 level of statistical significance 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, our executive officers, directors and principal stockholders will maintain the ability to control all matters submitted to stockholders for approval.***

Assuming the sale by us of \_\_\_\_\_ shares of common stock in this offering (or \_\_\_\_\_ shares if the underwriters exercise their option to purchase additional shares to cover over-allotments in full) and based on the number of shares outstanding as of September 1, 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 \_\_\_\_\_ % of our capital stock (or \_\_\_\_\_ % 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, six 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 control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company that our public stockholders disagree with.

***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 \_\_\_\_\_ shares of common stock based on the number of shares outstanding as of September 1, 2017, assuming the automatic conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering (or \_\_\_\_\_ shares if the underwriters exercise their option to purchase additional shares in full). Of the \_\_\_\_\_ shares to be outstanding immediately after the closing of this offering, the \_\_\_\_\_ 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 26,261,121 shares currently are restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering as described in the “Shares Eligible for Future Sale” and “Underwriting” sections of this prospectus. Moreover, after this offering, holders of an aggregate of approximately 24,507,086 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.

***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 will be 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

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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 an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ \_\_\_\_\_ 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 assumed 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;
- 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 will be determined through negotiations with the underwriters. Although we have applied to have our common stock listed 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 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 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, in a manner that does not produce income or that loses value. See "Use of Proceeds."

***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;

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- 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 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.

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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;
- 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.

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***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.

## 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;
- 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;
- 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.

## USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering will be approximately \$ \_\_\_\_\_ million, assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. 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 \$ \_\_\_\_\_ million.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of June 30, 2017, we had cash of \$24.1 million, and we raised an additional \$5.0 million in gross proceeds from the sale of our Series D convertible preferred stock in September 2017. We currently estimate that we will use the net proceeds from this offering, together with our existing cash, as follows:

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

This expected use of net proceeds from this offering 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.

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 through \_\_\_\_\_, 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

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expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.

Pending our use of the net proceeds from this offering, 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.



## **DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. 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.

## CAPITALIZATION

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

- on an actual basis;
- on a pro forma basis to give effect to:
  - our issuance and sale in September 2017 of an aggregate of 1,540,500 shares of Series D convertible preferred stock for gross proceeds of \$5.0 million;
  - the automatic conversion of all outstanding shares of our preferred stock, including the shares of Series D convertible preferred stock that we issued and sold in September 2017, into an aggregate of 24,507,086 shares of common stock upon closing of this offering;
  - all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 35,549 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 our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. 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 June 30, 2017		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash	\$ 24,143	\$ 29,143	\$ _____
Loans payable, net of discount, including current portion	\$ 12,694	\$ 12,694	\$ _____
Warrant liability	36	—	
Redeemable convertible preferred stock (Series A-1, A-2, B, C and D), \$0.001 par value; 21,894,618 shares authorized, 20,328,596 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	85,805	—	
<b>Stockholders’ equity (deficit):</b>			
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, 1,754,035 shares issued and outstanding, actual; 200,000,000 shares authorized, 26,261,121 shares issued and outstanding, pro forma; 200,000,000 shares authorized, _____ shares issued and outstanding, pro forma as adjusted	2	26	
Additional paid-in capital	1,324	92,141	
Accumulated other comprehensive income	455	455	
Accumulated deficit	(69,478)	(69,478)	
<b>Total stockholders’ equity (deficit)</b>	<b>(67,697)</b>	<b>23,144</b>	
<b>Total capitalization</b>	<b>\$ 30,838</b>	<b>\$ 35,838</b>	<b>\$ _____</b>

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Our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$      million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, additional paid-in capital, total stockholders' equity and total capitalization by \$      million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

- 4,090,027 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2017, at a weighted average exercise price of \$1.64 per share;
- 582,093 shares of common stock available for future issuance under our 2011 Stock Incentive Plan, as amended, and 7,465 shares of common stock available for future issuance under our 2010 Special Stock Incentive Plan, as amended, in each case as of June 30, 2017;
- additional shares of our common stock that will become available under our 2017 Stock Incentive Plan in connection with this offering;
- additional shares of our common stock that will become available under our 2017 Employee Stock Purchase Plan in connection with this offering; and
- 35,549 shares of common stock issuable following the closing of this offering upon the exercise of warrants outstanding as of June 30, 2017, at a weighted average exercise price of \$4.36 per share.

## 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.

Our historical net tangible book value (deficit) as of June 30, 2017 was \$(67.7) million, or \$(38.60) 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 1,754,035 shares of our common stock outstanding as of June 30, 2017.

Our pro forma net tangible book value as of June 30, 2017 was \$23.1 million, or \$0.88 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) our issuance and sale in September 2017 of an aggregate of 1,540,500 shares of Series D convertible preferred stock for gross proceeds of \$5.0 million; (ii) the automatic conversion of all outstanding shares of our preferred stock, including the shares of Series D convertible preferred stock that we issued and sold in September 2017, into an aggregate of 24,507,086 shares of common stock upon closing of this offering; and (iii) all outstanding warrants to purchase shares of our preferred stock becoming warrants to purchase 35,549 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 June 30, 2017, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2017 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$ \_\_\_\_\_ to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$ \_\_\_\_\_ to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of June 30, 2017	\$(38.60)
Increase per share attributable to the pro forma adjustments described above	39.48
Pro forma net tangible book value per share as of June 30, 2017	0.88
Increase in pro forma net tangible book value per share attributable to new investors purchasing common stock in this offering	_____
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors purchasing common stock in this offering	\$ _____

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ and dilution per share to new investors purchasing common stock in this

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offering by \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share after this offering by \$ and decrease the dilution per share to new investors purchasing common stock in this offering by \$ , assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by \$ and increase the dilution per share to new investors purchasing common stock in this offering by \$ , assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 would be \$ , representing an immediate increase in pro forma as adjusted net tangible book value per share of \$ to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$ to new investors purchasing common stock in this offering, assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, as of June 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 at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
	(in thousands, except share and per share amounts)				
Existing stockholders	26,261,121	%	\$90,076,926	%	\$ 3.43
New investors					\$
Total		100.0%	\$	100.0%	

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed initial public offering price per share.

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

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our common stock held by existing stockholders would be reduced to % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to % of the total number of shares of our common stock outstanding after this offering.

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

- 4,090,027 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2017, at a weighted average exercise price of \$1.64 per share;
- 582,093 shares of common stock available for future issuance under our 2011 Stock Incentive Plan, as amended, and 7,465 shares of common stock available for issuance under our 2010 Special Stock Incentive Plan, as amended, in each case as of June 30, 2017;
- additional shares of our common stock that will become available under our 2017 Stock Incentive Plan in connection with this offering;
- additional shares of our common stock that will become available under our 2017 Employee Stock Purchase Plan in connection with this offering; and
- 35,549 shares of common stock issuable following the closing of this offering upon the exercise of warrants outstanding as of June 30, 2017, at a weighted average exercise price of \$4.36 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.

## SELECTED CONSOLIDATED FINANCIAL DATA

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 six months ended June 30, 2016 and 2017 and the consolidated balance sheet data as of June 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,		Six Months Ended June 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	\$ 6,165	\$ 8,297
General and administrative	2,119	6,515	3,092	3,174
Total operating expenses	<u>14,825</u>	<u>24,346</u>	<u>9,257</u>	<u>11,471</u>
Loss from operations	<u>(14,825)</u>	<u>(24,346)</u>	<u>(9,257)</u>	<u>(11,471)</u>
Other income (expense):				
Grant and incentive income	2,155	2,390	1,260	1,562
Interest expense	(472)	(2,515)	(1,065)	(1,463)
Change in fair value of warrant liability	1	39	6	11
Change in fair value of derivative liability	—	1,388	380	762
Loss on extinguishment of debt	—	(35)	(35)	(462)
Other income (expense), net	<u>(77)</u>	<u>104</u>	<u>51</u>	<u>(29)</u>
Total other income, net	<u>1,607</u>	<u>1,371</u>	<u>597</u>	<u>381</u>
Net loss	<u>(13,218)</u>	<u>(22,975)</u>	<u>(8,660)</u>	<u>(11,090)</u>
Accretion of redeemable convertible preferred stock to redemption value	<u>(19)</u>	<u>(25)</u>	<u>(12)</u>	<u>(20)</u>
Net loss attributable to common stockholders	<u>\$ (13,237)</u>	<u>\$ (23,000)</u>	<u>\$ (8,672)</u>	<u>\$ (11,110)</u>
Net loss per share attributable to common stockholders—basic and diluted <sup>(1)</sup>	<u>\$ (7.62)</u>	<u>\$ (13.12)</u>	<u>\$ (4.95)</u>	<u>\$ (6.33)</u>
Weighted average common shares outstanding—basic and diluted <sup>(1)</sup>	<u>1,736</u>	<u>1,753</u>	<u>1,751</u>	<u>1,754</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (2.30)</u>		<u>\$ (0.70)</u>
Pro forma weighted average common shares outstanding—basic and diluted (unaudited) <sup>(1)</sup>		<u>10,005</u>		<u>15,843</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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	<u>As of December 31,</u>		<u>As of</u>
	<u>2015</u>	<u>2016</u>	<u>June 30,</u>
	<u>(in thousands)</u>		
<b>Consolidated Balance Sheet Data:</b>			
Cash	\$ 6,759	\$ 3,035	\$ 24,143
Working capital (deficit) <sup>(1)</sup>	1,710	(6,344)	28,954
Total assets	9,510	7,604	39,518
Convertible promissory notes, net of discount	2,240	2,863	—
Loans payable, net of discount, including current portion	4,954	12,426	12,694
Warrant liability	26	47	36
Derivative liability	1,793	2,593	—
Redeemable convertible preferred stock	29,948	39,838	85,805
Total stockholders' deficit	(34,322)	(56,562)	(67,697)

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



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with 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 June 30, 2017 primarily with proceeds from the following sources:

- net cash proceeds of \$70.1 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 \$9.7 million of grant and loan proceeds, respectively, from our funding agreements with Österreichische Forschungsförderungsgesellschaft mbH, or FFG;
- proceeds of \$3.2 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.

In September 2017, we received gross cash proceeds of \$5.0 million from the sale of additional shares of our Series D convertible preferred stock.

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

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\$23.0 million for the years ended December 31, 2015 and 2016, respectively, and \$11.1 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of \$69.5 million. We expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from 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. 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 June 30, 2017, we had cash of \$24.1 million. In September 2017, we received gross cash proceeds of \$5.0 million from the sale of additional shares of our Series D convertible preferred stock. 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 through . 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, 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 September 20, 2017 issuance date of our interim financial statements for the six months ended June 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.

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,		Six Months Ended June 30,	
	2015	2016	2016	2017
	(in thousands)			
ASN100	\$ 5,846	\$ 9,722	\$2,298	\$4,314
ASN200	—	138	63	30
ASN300	333	59	20	2
ASN400	807	166	112	42
ASN500	—	3	3	281
ASN650	—	—	—	71
Unallocated research and development expenses	5,720	7,743	3,669	3,557
Total research and development expenses	<u>\$12,706</u>	<u>\$17,831</u>	<u>\$6,165</u>	<u>\$8,297</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 Six Months Ended June 30, 2016 and 2017**

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

	Six Months Ended June 30,		Change
	2016	2017	
	(in thousands)		
Operating expenses:			
Research and development	\$ 6,165	\$ 8,297	\$ 2,132
General and administrative	3,092	3,174	82
Total operating expenses	9,257	11,471	2,214
Loss from operations	(9,257)	(11,471)	(2,214)
Other income (expense):			
Grant and incentive income	1,260	1,562	302
Interest expense	(1,065)	(1,463)	(398)
Change in fair value of warrant liability	6	11	5
Change in fair value of derivative liability	380	762	382
Loss on extinguishment of debt	(35)	(462)	(427)
Other income (expense), net	51	(29)	(80)
Total other income, net	597	381	(216)
Net loss	<u>\$(8,660)</u>	<u>\$(11,090)</u>	<u>\$(2,430)</u>

**Research and Development Expenses.**

	Six Months Ended June 30,		Change
	2016	2017	
	(in thousands)		
Direct research and development expenses by program:			
ASN100	\$2,298	\$4,314	\$2,016
ASN200	63	30	(33)
ASN300	20	2	(18)
ASN400	112	42	(70)
ASN500	3	281	278
ASN650	—	71	71
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	2,571	2,614	43
Other	1,098	943	(155)
Total research and development expenses	<u>\$6,165</u>	<u>\$8,297</u>	<u>\$2,132</u>

Research and development expenses were \$6.2 million for the six months ended June 30, 2016, compared to \$8.3 million for the six months ended June 30, 2017. The increase of \$2.1 million was primarily due to an increase of \$2.0 million in direct costs for our ASN100 program and an increase of \$0.3 million in direct costs for our ASN500 program, which were partially offset by a decrease of \$0.1 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 six months ended June 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 \$3.1 million for the six months ended June 30, 2016, compared to \$3.2 million for the six months ended June 30, 2017. The increase of \$0.1 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), which was partially offset by a decrease of \$0.2 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 decrease in professional fees was due to our use in the six months ended June 30, 2016 of a temporary Chief Financial Officer and of outside consultants to aid with preparation for a government grant application.

**Other Income (Expense), Net.** Other income, net was \$0.6 million for the six months ended June 30, 2016, compared to \$0.4 million for the six months ended June 30, 2017. The decrease of \$0.2 million in other income, net was primarily due to an increase in interest expense of \$0.4 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 and January 2017; 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 an increase of \$0.1 million in other expense, net primarily related to foreign currency transaction losses. The increases in interest expense, loss on extinguishment of debt and other expense, net were partially offset by a \$0.8 million gain recognized for the six months ended June 30, 2017, compared to a \$0.4 million gain recognized for the six months ended June 30, 2016, as a result of a decrease in the fair value of the derivative liability associated with our convertible promissory notes, and an increase in grant and incentive income of \$0.3 million from our grant agreement with the Gates Foundation.

### **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	14,825	24,346	9,521
Loss from operations	(14,825)	(24,346)	(9,521)
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	(77)	104	181
Total other income, net	1,607	1,371	(236)
Net loss	<u>\$ (13,218)</u>	<u>\$ (22,975)</u>	<u>\$ (9,757)</u>



**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 establishing our website and 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 June 30, 2017, we had received net cash proceeds of \$70.1 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 \$9.7 million of grant and loan proceeds, respectively, from our funding agreement with FFG, \$3.2 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. In September 2017, we received gross cash proceeds of \$5.0 million from the sale of additional shares of our Series D convertible preferred stock.

### **Cash Flows**

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

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
	(in thousands)			
Net cash used in operating activities	\$(10,816)	\$(21,639)	\$(11,466)	\$(9,874)
Net cash used in investing activities	(247)	(138)	(58)	(8,326)
Net cash provided by financing activities	11,505	18,147	14,136	39,275
Effect of exchange rate changes on cash	(122)	(94)	(43)	33
Net increase (decrease) in cash	<u>\$ 320</u>	<u>\$ (3,724)</u>	<u>\$ 2,569</u>	<u>\$21,108</u>

**Operating Activities.** During the six months ended June 30, 2017, operating activities used \$9.9 million of cash, resulting from our net loss of \$11.1 million and net cash used by changes in our operating assets and liabilities of \$0.3 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 six months ended June 30, 2017 consisted primarily of a \$1.7 million increase in prepaid expenses and other current assets, a \$0.6 million decrease in accounts payable and a \$0.5 million increase in grant and incentive receivables, partially offset by a \$1.4 million increase in accrued expenses and a \$1.1 million increase in unearned income. 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 \$0.6 million was recognized as grant income as we incurred qualifying expenses under the agreement. The increase in accrued expenses was primarily due to increases in clinical trial costs associated with our Phase 2 clinical trial of ASN100. The increase in prepaid expenses and other current assets was primarily due to prepayments for clinical materials related to our Phase 2 clinical trial of ASN100. The increase in grant and incentive receivables was due to an increase in the amount of our qualifying expenditures as well as the timing of receipt of cash from FFG Grants. The decrease in accounts payable was a result of the timing of vendor invoices and payments.

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During the six months ended June 30, 2016, operating activities used \$11.5 million of cash, resulting from our net loss of \$8.7 million and net cash used by changes in our operating assets and liabilities of \$3.7 million, partially offset by net non-cash charges of \$0.9 million. Net cash used by changes in our operating assets and liabilities for the six months ended June 30, 2016 consisted primarily of a \$3.7 million increase in prepaid expenses and other current assets due to prepayments for clinical materials related to our Phase 2 clinical trial of ASN100, a \$0.6 million increase in grant and incentive receivables and a \$0.2 million decrease in unearned income related to FFG grant income, all partially offset by a \$0.4 million increase in accounts payable and a \$0.3 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 six months ended June 30, 2017, we used \$8.3 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 six months ended June 30, 2016, we used \$0.1 million of cash in investing activities, consisting of purchases of property and equipment.

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 six months ended June 30, 2017, net cash provided by financing activities was \$39.3 million, consisting primarily of net cash proceeds of \$34.9 million from our issuance of Series D convertible preferred stock in April 2017, proceeds of \$4.9 million from our issuance of convertible

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promissory notes in January 2017 and proceeds of \$0.7 million from loans under our funding agreements with FFG, partially offset by \$1.2 million of principal repayments under the 2012 Loan Agreement.

During the six months ended June 30, 2016, net cash provided by financing activities was \$14.1 million, consisting primarily of 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 net proceeds of \$3.5 million from borrowings under the 2012 Loan Agreement, 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 June 30, 2017, the outstanding principal amount under the 2012 Loan Agreement was \$7.0 million and \$5.8 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.

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 June 30, 2017, the outstanding principal amount under loans from FFG was \$8.0 million and \$9.7 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 June 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 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;

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- 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 through , 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;
- 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,

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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 June 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
Manufacturing commitments <sup>(1)</sup>	\$ 1,437	\$ 1,437	\$ —	\$ —	\$ —
Debt obligations <sup>(2)</sup>	16,525	2,609	9,065	3,990	861
Operating lease commitments <sup>(3)</sup>	2,572	1,003	1,162	407	—
Total	<u>\$20,534</u>	<u>\$ 5,049</u>	<u>\$ 10,227</u>	<u>\$4,397</u>	<u>\$ 861</u>

<sup>(1)</sup> Amounts in the table reflect commitments for costs associated with our external CMO, which we engaged to manufacture clinical trial materials.

Manufacturing commitments include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction.

<sup>(2)</sup> Amounts in the table reflect the contractually required principal and interest payable as of June 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 June 30, 2017.

<sup>(3)</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 and other third parties for clinical trials and preclinical research studies and testing. 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.

### **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



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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 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

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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.

***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

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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 \$2.44 per share as of December 31, 2015, \$2.75 per share as of April 22, 2016, \$1.57 per share as of December 31, 2016 and \$1.17 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.

**Options Granted.** The following table sets forth by grant date the number of shares subject to options granted from January 1, 2016 through September 1, 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	71,500	\$ 2.44	\$ 2.44	\$ 1.60
February 4, 2016	16,000	\$ 2.44	\$ 2.44	\$ 1.29
July 20, 2016	930,250	\$ 2.75	\$ 2.75	\$ 1.78
September 28, 2016	80,000	\$ 2.75	\$ 2.75	\$ 1.81
June 19, 2017	2,245,450	\$ 1.17	\$ 1.17	\$ 0.79

### ***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.

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

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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 June 30, 2017, we had \$7.0 million and \$5.8 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 June 30, 2017. Based on the principal amounts outstanding as of December 31, 2016 and June 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 June 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 \$9.7 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.

#### ***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 six months ended June 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 six months ended June 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.

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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.

## 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 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 a third party 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

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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.



## 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**

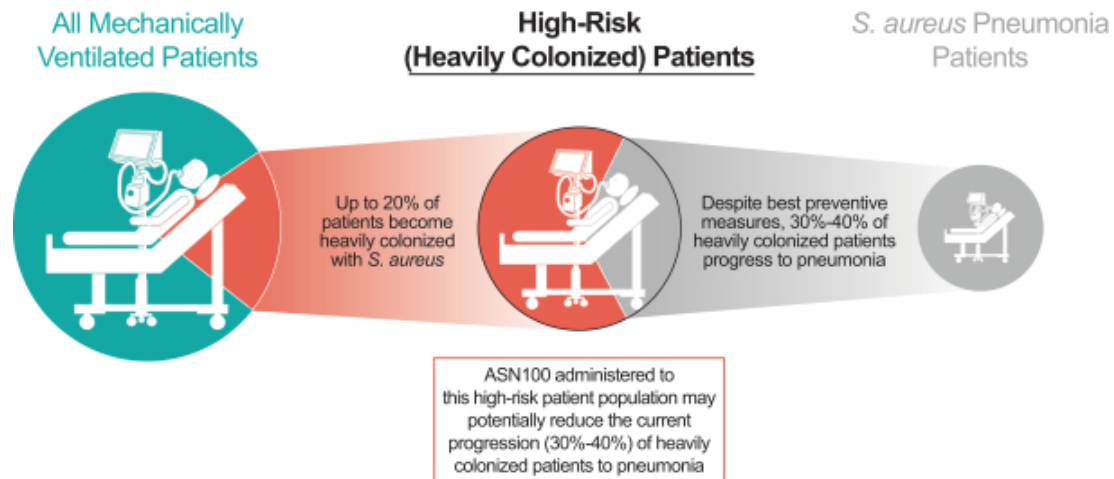
#### ***Our Lead Product Candidate: ASN100***

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

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 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 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%, with one study reporting an absolute increase in mortality of 6% for mechanically ventilated patients with pneumonia over those without pneumonia. In addition, 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,

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.

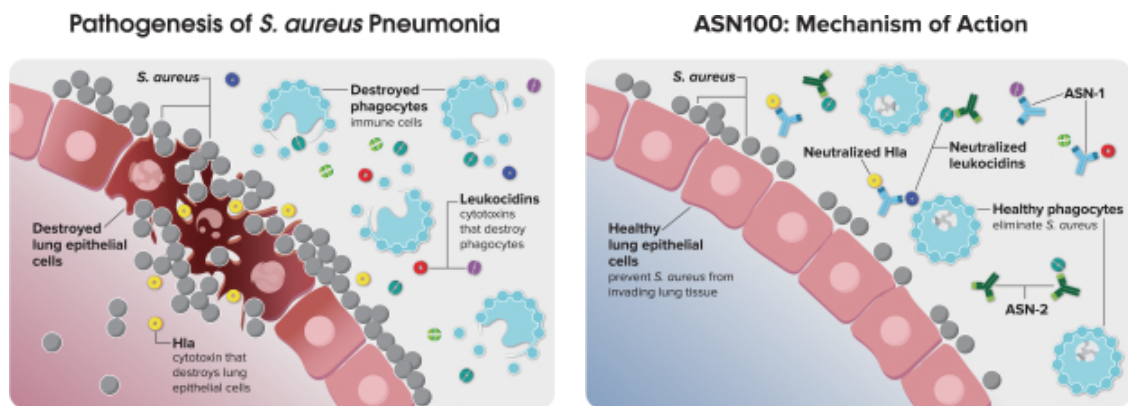
### ***S. aureus* Pneumonia – Mechanism of Disease**

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. ASN-2 is the only mAb in development that neutralizes LukGH, the fifth and most potent leukocidin. 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

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 and 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 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 statistically significant 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 pharmacokinetics 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 a third party 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**

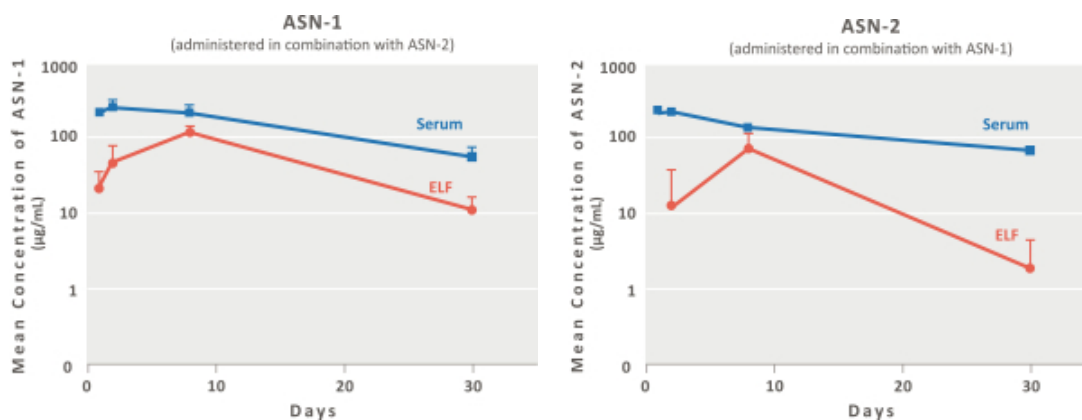
We successfully completed a Phase 1 single ascending dose clinical trial in 52 healthy volunteers to assess the safety, tolerability and pharmacokinetics of ASN100, both in the bloodstream and the lung. Forty-two volunteers received one dose of ASN-1 alone, ASN-2 alone or ASN-1 and ASN-2 in combination 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 dosing were measured out to 10 months following dosing and no generation of anti-drug antibodies was observed in any volunteer tested.

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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 *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.

### ASN100 Phase 1 Pharmacokinetics in Serum and Lung Epithelial Fluid



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. 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

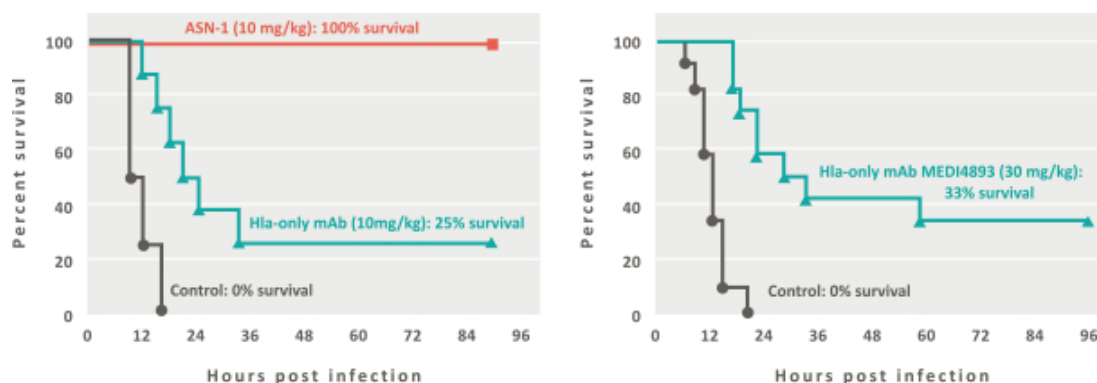
We tested ASN100 in preclinical efficacy studies against a variety of common and highly virulent *S. aureus* strains known to produce high levels of cytotoxins, including antibiotic-resistant strains. We also conducted investigational new drug application, or IND, enabling pharmacology and toxicology 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 Hla survived and no rabbits treated with a control mAb survived. In a separately published study of

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 in combination with antibiotics was also studied in an animal model of pneumonia treatment. In this model, ASN100 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 beyond VAP 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. Potential indications we are currently considering include: *S. aureus* pneumonia treatment, *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

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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, efficacy of these product candidates in *in vivo* models of infection prevention and, with respect to ASN200, potentiation of antibiotic efficacy 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.

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

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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.

## **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

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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 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 1, 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 11 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand and Russia. We expect that any patents that issue in this 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 11 pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand and Russia. We expect that any patents that issue in this fourth family will expire in December 2034. The fifth family consists of patent applications with method and kit claims covering diagnostics for predicting VAP using a specified biomarker of methicillin-susceptible *S. aureus* and includes one pending patent application in the United States, one pending patent application in Europe and three pending patent applications in other jurisdictions, including 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 nine pending patent applications in other jurisdictions, including Australia, Brazil, Canada, China, India, Israel, Korea, Mexico and Russia. We expect that any patents that issue in this second solely owned family will expire in November 2035. The third solely owned family consists of 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.

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- 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.

## **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

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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.

Under the Adimab Collaboration Agreement, as of June 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.

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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.

The Adimab Collaboration Agreement will expire on a country-by-country basis on the expiration of the last royalty term (as defined in the agreement) for a 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



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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 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.

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Under the Adimab Option Agreement, as of June 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 at the end of the option period. If we do exercise our option, the Adimab Option Agreement will expire on the last-to-expire royalty term (as defined in the agreement) for any and all products for which we are obligated to pay Adimab royalties under the Adimab Option Agreement. We have the right to terminate the Adimab Option Agreement for any reason by providing Adimab with a specified amount of prior written notice. Adimab has the right to terminate the Adimab Option Agreement if we materially breach the agreement and fail to cure such breach within a specified cure period, including, as discussed above, for our failure to use commercially reasonable efforts to develop and commercialize at least one product based on a licensed RSV antibody in major markets. If Adimab terminates the Adimab Option Agreement for our breach, or if we terminate the agreement for our convenience, then we must 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 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

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Foundation to fairly allocate expected benefits between developing countries and developed countries in a manner that would not be reasonably likely to have a material adverse effect on our business or operations. Such funding will create an obligation for us, alone or through a third party, to conduct such research, development and launch activities. At the request of the Gates Foundation, we will grant the Gates Foundation a non-exclusive, sublicensable license to any candidates or products developed under any of these programs, and all related technology necessary for the development, production and/or distribution or sale of the relevant product(s), for use in the prevention of neonatal sepsis caused by *S. aureus* and/or other bacterial pathogens. The Gates Foundation would only be permitted to exercise any license to our background intellectual property under specified circumstances, which we collectively call a charitability default, or in the event of any other specified triggering event. A charitability default would occur in the event of our material breach of any of our global access commitments under the letter agreement (other than for regulatory, technical or scientific failure not within our reasonable control or knowledge prior to the letter agreement), our failure to comply with the restrictions on our use of the proceeds from the Gates Foundation investment, or our failure to comply with any related U.S. legal obligations set forth in the letter agreement. Other triggering events that would allow the Gates Foundation to exercise the license to our background intellectual property include if we commit an uncured material breach of any grant agreement for any applicable funded project; if we are unwilling or unable or cease to promptly conduct or complete any of the programs described above in this paragraph; if the Gates Foundation reasonably determines (after good faith discussions with us) that we do not have the ability to conduct or complete our global access commitments under the letter agreement in any material respect; or if we become insolvent or cease to conduct business in the ordinary course. Any exercise by the Gates Foundation of the license described in this paragraph will be subject to payment of applicable royalties under the Adimab Collaboration Agreement and, in certain circumstances, may involve payment of a reasonable royalty to us on sales of applicable products outside of the developing countries.

Under the letter agreement, we 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.

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 charitability default or other triggering event (as described above).

We are required to obtain and maintain all necessary rights and licenses needed to perform our global access commitments under the letter agreement, and we are required to use reasonable efforts to obtain all necessary licenses in order to enable completion of all applicable products in accordance with such global access

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

### **Government Regulation 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.

***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

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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 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

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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 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



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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 \$2.0 million, and the sponsor of an approved BLA is also subject to annual product and establishment user fees, currently exceeding \$97,000 per product and \$512,000 per establishment. 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 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.

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 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.

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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 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

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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 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.

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.

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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.

### ***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 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.

**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 with the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics of these innovative products from referencing the innovator’s data to assess a generic (abbreviated) application for a period of eight years. During an additional two-year period of market exclusivity, a generic

marketing authorization application can be submitted and authorized, and the innovator's data may be referenced, but no generic medicinal product can be placed on the European Union market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

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

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

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

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

- Compliance with the European Union's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.

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- 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.
- 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 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

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implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable insurance coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

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

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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 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 1, 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

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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.

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

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<u>Name</u>	<u>Positions</u>
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
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.	Consulting Professor, Medical ICU, Hospital Pitié-Salpêtrière, Paris



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<u>Name</u>	<u>Positions</u>
Ralph Corey, M.D.	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 ABSSSI/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

**MANAGEMENT****Executive Officers and Directors**

The following table sets forth the name, age as of September 1, 2017 and position of each of our executive officers and directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive Officers</b>		
René Russo, Pharm.D., BCPS	42	President and Chief Executive Officer, Director
Eszter Nagy, M.D., Ph.D.	50	Co-Founder, Chief Scientific Officer, Managing Director of Arsanis Biosciences GmbH, Director
Michael Gray, M.B.A., C.P.A.	46	Chief Financial Officer and Chief Business 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.	53	Co-Founder, Chairman of the Board of Directors
Jan Adams, Ph.D.	48	Director
Daniel Burgess	55	Director
Carl Gordon, Ph.D., C.F.A.	52	Director
Terrance McGuire	61	Director
Claudio Nessi, Ph.D., M.B.A.	48	Director
Michael Ross, Ph.D.	68	Director
Amy Schulman, J.D.	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.

**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 has also served on our Board of Directors since January 2011. 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 Biotechnologies (Vienna) in 2012, and was on the Board of Directors of WittyCell, S.A.S (now part of

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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. Our board of directors believes that Dr. Nagy's deep knowledge of our company from her role as one of our co-founders and her service in our senior management, including her service as our President, her decades of experience in biotechnology research and her board service with other biotechnology companies provide her with the qualifications and skills to serve on our board of directors.

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

**Jan Adams, Ph.D.** Dr. Adams has served as a member of our board of directors since April 2016. Dr. Adams is Managing Director at EMBL Ventures and has served as its Investment Manager since 2002. He is currently representing EMBL Ventures on various portfolio boards, including Lipid Therapeutics GmbH, Topas Therapeutics GmbH, Vira Therapeutics GmbH and Opsona Therapeutics Ltd. Additionally, he has been a Member of the Advisory Boards of several biotechnology companies including ImevaX GmbH, Endoart Medical Technologies SA, JADO Technologies GmbH and Allegra Therapeutics GmbH. Dr. Adams was a Postdoctoral Fellow of the Ernst Schering Research Foundation at the University of Granada, Spain, where he worked in stem cell genetics. Prior to that, he was a Fellow of the Boehringer Ingelheim Research Foundation, conducting work on molecular transport mechanisms at the Wellcome CRC, Cambridge UK. Dr. Adams trained as a Biochemist at the University of Tübingen, where he received a M.S. in Biochemistry and Molecular Biology. Dr. Adams also completed a Ph.D. in Genetics at the University of Cambridge, United Kingdom. Our board of directors believes Dr. Adams' expertise and experience in the biotechnology industry through his role as Investment Manager at EMBL for over 10 years, in which he has been involved in the evaluation, investment and oversight of several biotechnology companies, his scientific educational background and subsequent direct research experience over several years, 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.

**Daniel Burgess.** Mr. Burgess has served as a member of our board of directors since October 2014. Mr. Burgess is currently a venture partner at SV Life Sciences, a position he has held since June 2014. From June 2011 until its acquisition by The Medicines Company in December 2013, he was the President and Chief Executive Officer of Rempex Pharmaceuticals, Inc., a privately held biopharmaceutical company. From December 2013 until June 2014, he ran the Rempex subsidiary of The Medicines Company. Previously, Mr. Burgess was President and Chief Executive Officer of Mpex Pharmaceuticals, Inc., a private biopharmaceutical company, from May 2007 until its acquisition by Aptalis Pharma Inc., now a subsidiary of Actavis, Inc., a publicly traded pharmaceutical company, in April 2011. From August 1999 to May 2007, Mr. Burgess was Chief Operating Officer and Chief Financial Officer of Harbor BioSciences, Inc., formerly Hollis-Eden Pharmaceuticals, Inc., a pharmaceutical company. Prior to joining Harbor BioSciences Mr. Burgess held positions at Nanogen, Inc., Gensia Sicor, Inc., Castle & Cooke, Inc. and Smith Barney, Harris Upham and Company. Mr. Burgess currently serves on the board of directors of Cidara Therapeutics, a publicly traded biotechnology company, where he has served since April 2014; as chairman of the supervisory board of Nabriva Therapeutics, a publicly traded biopharmaceutical company, a position he has held since August 2016; and on the board of directors of Arbutus Biopharma, a publicly traded therapeutic solutions company, where he has served since March 2017. From July 2004 until its acquisition by Salix Pharmaceuticals, Inc. in January 2014, Mr. Burgess served on the board of directors of Santarus, Inc., a publicly-traded biopharmaceutical company. Mr. Burgess holds a B.A. in economics from Stanford University and an M.B.A. from Harvard Business School. Our board of directors believes that Mr. Burgess' qualifications to serve on our board include his years of experience serving as a President and Chief Executive Officer, as well as in other executive leadership positions, of a number of biotech and pharmaceutical companies, as well as his experience as a director of several biotechnology companies, including public company board service.

**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

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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.

**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 Nesi, Ph.D., M.B.A.** Dr. Nesi has served as a member of our board of directors since August 2013. Dr. Nesi 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. Nesi has served as Managing Director of Omega Funds since November 2016. Dr. Nesi 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. Nesi is also currently serving on the Board of Directors of the private biotechnology companies Avitide, Inc., GenKyoTex SA and Anaconda Biomed. Dr. Nesi 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. Nesi'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

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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 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 Arsia Therapeutics, a Polaris-backed company, from July 2014 until its acquisition by Eagle Pharmaceuticals in November 2016. She served as director of Bind Therapeutics from September 2014 to June 2016. In July 2015, Ms. Schulman co-founded Lyndra, where she currently serves as CEO, and since January 2017 she has served as CEO of Olivo Laboratories, 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 \_\_\_\_\_ 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.

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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 \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in \_\_\_\_\_;
- the class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in \_\_\_\_\_ and \_\_\_\_\_;
- the class III directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their term will expire at the annual meeting of stockholders to be held in \_\_\_\_\_.

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 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. Gemgross, 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.

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Dr. Russo is not an independent director under these rules because she is our President and Chief Executive Officer. Dr. Nagy is not an independent director under these rules because she is our Chief Scientific Officer. 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. The composition of each committee will be effective as of the date of this prospectus.

#### ***Audit Committee***

The members of our audit committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. \_\_\_\_\_ 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 \_\_\_\_\_ 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.



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### **Compensation Committee**

The members of our compensation committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. \_\_\_\_\_ 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.

We believe that the composition of our compensation committee will meet the requirements for independence under current NASDAQ and SEC rules and regulations and that each director on the compensation committee is an "outside director" as that term is defined in Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended.

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

The members of our nominating and corporate governance committee are \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. \_\_\_\_\_ 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 believe that the composition of our nominating and corporate governance committee will meet the requirements for independence under current NASDAQ and SEC rules and regulations.

### **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 intend to adopt 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 intend to post 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.

**EXECUTIVE COMPENSATION**

The following discussion relates to the compensation of our President and Chief Executive Officer, René Russo, our Chief Financial Officer and Chief Business 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 (\$)</u>	<u>Bonus (\$)<sup>(1)</sup></u>	<u>Option Awards (\$)<sup>(2)</sup></u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</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 Financial Officer and Chief Business 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.

**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 163,000 shares of our common stock. In 2016, we granted to Mr. Gray an option to purchase 175,000 shares of our common stock and to Dr. Stevens an option to purchase 90,000 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.

Name	Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards; Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
René Russo, Pharm.D., BCPS	97,778	178,301 <sup>(1)</sup>	—	\$ 2.40	7/21/2025
	—	163,000 <sup>(2)</sup>	—	\$ 2.75	7/20/2026
Michael Gray, M.B.A., C.P.A.	—	175,000 <sup>(3)</sup>	—	\$ 2.75	7/20/2026
Chris Stevens, M.D.	—	90,000 <sup>(4)</sup>	—	\$ 2.75	7/20/2026

<sup>(1)</sup> Dr. Russo's option to purchase 276,079 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 163,000 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 175,000 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 90,000 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 twelve 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 twelve 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 twelve 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.

### ***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 112,500 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 175,000 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 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 twelve 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.

***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. Steven's letter agreement also provided that he was entitled to the grant of an option to purchase 90,000 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.

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 twelve 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 use is terminated, which options will remain exercisable for the time period set forth in the applicable grant agreement.

***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.

***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 Stock Incentive Plan, or the 2017

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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 2,000,000 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 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

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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 1, 2017, options to purchase 365,500 shares of common stock were outstanding under the 2010 Plan, at a weighted average exercise price of \$0.54 per share, and options to purchase 30,500 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 on or after the effectiveness of the registration statement for this offering; 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 1, 2017, a maximum of 4,433,620 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.

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;



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- 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.

As of September 1, 2017, options to purchase 3,720,527 shares of common stock were outstanding under the 2011 Plan, at a weighted average exercise price of \$1.75 per share, and options to purchase zero shares of our common stock had been exercised under the 2011 Plan.

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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 on or after the effectiveness of the registration statement for this offering; however, awards outstanding under the 2011 Plan will continue to be governed by their existing terms.

### **2017 Stock Incentive Plan**

We expect our board of directors to adopt and our stockholders to approve the 2017 Plan, which will become effective immediately prior to the effectiveness of the registration statement for this offering. 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. Upon effectiveness of the 2017 Plan, the number of shares of our common stock that will be reserved for issuance under the 2017 Plan will be the sum of: (1) \_\_\_\_\_; plus (2) the number of shares (up to \_\_\_\_\_ shares) equal to the sum of the number of shares of our common stock then available for issuance under the 2010 Plan and the 2011 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, 2028, equal to the lowest of \_\_\_\_\_ shares of our common stock, \_\_\_\_\_ % 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 will be 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 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.

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**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 company and will, unless our board of directors may otherwise determine, apply to the cash, securities or other

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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**

We expect our board of directors to adopt and our stockholders to approve the 2017 ESPP, which will become effective upon the closing of this offering. 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 \_\_\_\_\_ 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, beginning with the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2028, equal to the lowest of \_\_\_\_\_ shares of our common stock, \_\_\_\_\_ % 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

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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 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

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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.

### **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 indemnification agreements with all of our 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

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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 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.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)<sup>(1)</sup></u>	<u>Total (\$)</u>
Tillman U. Gerngross, Ph.D.	67,500	231,974	299,474
Jan Adams, Ph.D.	—	—	—
Daniel Burgess	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 132,000 shares of common stock at an exercise price of \$2.75 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 91,500 shares of common stock at an exercise price of \$0.54 per share that was fully vested, Mr. Burgess held an option to purchase 22,124 shares of common stock at an exercise price of \$2.36 per share that was vested with respect to 12,445 shares and Ms. Schulman held an option to purchase 22,124 shares of common stock at an exercise price of \$2.36 per share that was vested with respect to 10,601 shares. As of December 31, 2016, there were no other stock awards or option awards outstanding and held by our non-employee directors.

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. Drs. Russo and Nagy, two of our directors who also serve as our President and Chief Executive Officer and Chief Scientific Officer, respectively, do not receive any additional compensation for their service as directors. 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 is one of our executive officers who is not a named executive officer.

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In \_\_\_\_\_, our board of directors approved a director compensation program that will become effective on \_\_\_\_\_. 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 and 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 fees paid to non-employee directors for service on the board of directors 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>
Board of Directors	\$	\$
Audit Committee	\$	\$
Compensation Committee	\$	\$
Nominating and Corporate Governance Committee	\$	\$

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 he or she serves.

In addition, under our director compensation program effective on \_\_\_\_\_, each non-employee director will receive under the 2017 Plan, upon his or her initial election to our board of directors, an option to purchase \_\_\_\_\_ shares of our common stock. Each of these options will vest as to \_\_\_\_\_ of the shares of our common stock underlying such option on \_\_\_\_\_ until \_\_\_\_\_, subject to the non-employee director's continued service as a director. Further, on \_\_\_\_\_, each non-employee director that has served on our board of directors for at least \_\_\_\_\_ will receive, under the 2017 Plan, an option to purchase \_\_\_\_\_ shares of our common stock. Each of these options will vest \_\_\_\_\_ unless otherwise provided at the time of grant, subject to the non-employee director's continued service as a director. 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.



**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>Cash Purchase Price</u>	<u>Principal Cancelled under 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>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.

### 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 and one of our directors, 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 €47,000 (or \$52,000) 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.

### 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.

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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 indemnification agreements with all of our executive officers prior to the completion of this offering.

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

Our board of directors intends to adopt 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.

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.

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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 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.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of September 1, 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” is based on a total of 26,261,121 shares of our common stock outstanding as of September 1, 2017, assuming the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 24,507,086 shares of our common stock upon the closing of this offering. The column entitled “Percentage of Shares Beneficially Owned—After Offering” is based on 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, 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 1, 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.

<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</u>	<u>After Offering</u>
<b>5% Stockholders:</b>			
Entities affiliated with Polaris Ventures <sup>(1)</sup>	4,672,287	17.79%	
Entities affiliated with SV Life Sciences <sup>(2)</sup>	4,672,289	17.79%	
OrbiMed Private Investments IV LP <sup>(3)</sup>	4,672,291	17.79%	
NeoMed Innovation V L.P. <sup>(4)</sup>	1,937,358	7.38%	
Bill & Melinda Gates Foundation <sup>(5)</sup>	2,464,799	9.39%	
Section 32 Fund I, LP <sup>(6)</sup>	1,540,500	5.87%	
GV 2016, L.P. <sup>(7)</sup>	1,540,499	5.87%	
<b>Directors and Named Executive Officers:</b>			
René Russo, Pharm.D., BCPS <sup>(8)</sup>	216,419	*	
Eszter Nagy, M.D., Ph.D. <sup>(9)</sup>	1,248,367	4.70%	
Michael Gray, M.B.A., C.P.A. <sup>(10)</sup>	69,271	*	
Chris Stevens, M.D. <sup>(11)</sup>	30,000	*	
Tillman U. Gerngross, Ph.D. <sup>(12)</sup>	823,849	3.12%	
Jan Adams, Ph.D. <sup>(13)</sup>	1,196,102	4.55%	
Daniel Burgess <sup>(14)</sup>	17,054	*	
Carl Gordon, Ph.D., C.F.A. <sup>(15)</sup>	4,672,291	17.79%	

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Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Terrance McGuire <sup>(16)</sup>	4,672,287	17.79%	
Claudio Nesi, Ph.D., M.B.A. <sup>(17)</sup>	1,937,358	7.38%	
Michael Ross, Ph.D. <sup>(18)</sup>	4,672,289	17.79%	
Amy Schulman, J.D. <sup>(19)</sup>	15,210	*	
All current executive officers and directors as a group (13 persons) <sup>(20)</sup>	19,608,830	72.28%	

\* Less than one percent

(1) Consists of (a) 4,508,454 shares of common stock issuable upon conversion of preferred stock held by Polaris Venture Partners V, L.P., (b) 87,870 shares of common stock issuable upon conversion of preferred stock held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., (c) 30,881 shares of common stock issuable upon conversion of preferred stock held by Polaris Venture Partners Founders' Fund V, L.P. and (d) 45,082 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 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) 3,082,327 shares of common stock issuable upon conversion of preferred stock held by SV Life Sciences Fund V, L.P. ("SVLS V LP"), (b) 65,137 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) 1,474,348 shares of common stock issuable upon conversion of preferred stock held by SV Life Sciences Fund VI, L.P. ("SVLS VI LP") and (d) 50,477 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 4,672,291 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

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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 1,937,358 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 2,464,799 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 1,540,500 shares of common stock issuable upon conversion of Series D convertible preferred stock held by Section 32 Fund 1, LP. Section 32 GP 1, LLC, the general partner of Section 32 Fund 1, LP, 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.
- (7) Consists of 1,540,499 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.
- (8) Consists of shares of common stock underlying options held by Dr. Russo that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (9) Consists of (a) 933,333 shares of common stock owned by Dr. Nagy and (b) 315,034 shares of common stock underlying options held by Dr. Nagy that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (10) Consists of shares of common stock underlying options held by Mr. Gray that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (11) Consists of shares of common stock underlying options held by Dr. Stevens that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (12) Consists of (a) 350,000 shares of common stock owned by Mr. Gerngross, (b) 308,099 shares of common stock issuable upon conversion of preferred stock held by Mr. Gerngross and (c) 165,750 shares of common stock underlying options held by Mr. Gerngross that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (13) Consists of 1,196,102 shares of common stock issuable upon conversion of preferred stock held by EMBL Technology Fund II GmbH & Co. KG ("EMBL Tech Fund II"). Dr. Adams is a partner with EMBL Ventures GmbH ("EMBL"), which is the managing limited partner of EMBL Tech Fund II. By virtue of such relationship, Dr. Adams may be deemed to have voting and investment power with respect to the shares held by EMBL Tech Fund II. Each of EMBL and Dr. Adams disclaims beneficial ownership of the shares held by EMBL Tech Fund II, except to the extent of its or his pecuniary interest therein, if any. The address for the EMBL is Boxbergring 107, 69126 Heidelberg, Germany.
- (14) Consists of shares of common stock underlying options held by Mr. Burgess that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (15) Consists of the shares described in note 3 above.



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- (16) Consists of the shares described in note 1 above.
- (17) Consists of the shares described in note 4 above.
- (18) Consists of the shares described in note 2 above.
- (19) Consists of shares of common stock underlying options held by Ms. Schulman that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.
- (20) Includes 867,071 shares of common stock underlying options that are exercisable as of September 1, 2017 or will become exercisable within 60 days after such date.

## DESCRIPTION OF CAPITAL STOCK

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 1, 2017, we had issued and outstanding:

- 1,754,035 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 200,001 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 2,582,588 shares of our common stock;
- 2,762,431 shares of our Series B convertible preferred stock held by 8 stockholders of record, convertible into 4,209,638 shares of our common stock;
- 1,031,342 shares of our Series C convertible preferred stock held by 10 stockholders of record, convertible into 1,754,075 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 15,760,784 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 24,507,086 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 1, 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 13,450 shares of our common stock, at an exercise price of \$3.72 per share and
- the Series B warrant will become exercisable for an aggregate of 22,099 shares of our common stock, at an exercise price of \$4.75 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 1, 2017, options to purchase an aggregate of 4,086,027 shares of our common stock, at a weighted average exercise price of \$1.64 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 24,507,086 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.

#### ***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 will be American Stock Transfer & Trust Company, LLC.

### **NASDAQ Global Market**

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol “ASNS.”

## 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 1,754,035 shares of our common stock that were outstanding on September 1, 2017, upon the closing of this offering, we will have outstanding \_\_\_\_\_ shares of our common stock, after giving effect to the issuance of \_\_\_\_\_ shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase \_\_\_\_\_ additional shares of our common stock to cover over-allotments, and the conversion of all outstanding shares of our preferred stock into an aggregate of 24,507,086 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 26,261,121 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 \_\_\_\_\_ shares immediately after this offering; 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 \_\_\_\_\_ 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 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 \_\_\_\_\_ shares of our common stock, based on shares outstanding as of \_\_\_\_\_, 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 24,507,086 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 1, 2017, we had outstanding options to purchase an aggregate of 4,086,027 shares of our common stock, of which options to purchase 1,072,215 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.



**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.

**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.**

## 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.	
Cowen and Company, LLC	
Piper Jaffray & Co.	
Total	

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 \$ \_\_\_\_\_ 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.

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 \_\_\_\_\_ 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. 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 will be 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

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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.

We have applied to have our shares of common stock listed 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:

	<u>Per share</u>	<u>Total</u>	
		<u>No exercise</u>	<u>Full exercise</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$

We estimate that expenses payable by us in connection with this offering, exclusive of underwriting discounts and commissions, will be approximately \$ . We have also agreed to reimburse the underwriters for expenses in an amount up to \$ 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.
  - 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.

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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.

### **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 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.

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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.

### **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.

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

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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.

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;

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- 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.

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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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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

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

	<u>December 31,</u>		<u>June 30,</u>	<u>Pro Forma</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>June 30,</u>
			<u>(unaudited)</u>	<u>2017</u>
				<u>(unaudited)</u>
<b>Assets</b>				
Current assets:				
Cash	\$ 6,759	\$ 3,035	\$ 24,143	\$ 24,143
Grant and incentive receivables	1,541	1,345	2,018	2,018
Restricted cash	—	—	8,361	8,361
Prepaid expenses and other current assets	87	1,336	3,207	3,207
Total current assets	<u>8,387</u>	<u>5,716</u>	<u>37,729</u>	<u>37,729</u>
Property and equipment, net	760	519	496	496
Restricted cash	338	394	340	340
Deferred offering costs	—	9	—	—
Other assets	25	966	953	953
Total assets	<u>\$ 9,510</u>	<u>\$ 7,604</u>	<u>\$ 39,518</u>	<u>\$ 39,518</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>				
Current liabilities:				
Accounts payable	\$ 423	\$ 1,645	\$ 1,109	\$ 1,109
Accrued expenses	1,541	2,156	3,704	3,704
Unearned income	430	504	1,656	1,656
Loans payable, net of discount	250	2,299	2,306	2,306
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>8,775</u>	<u>8,775</u>
Loans payable, net of discount and current portion	4,704	10,127	10,388	10,388
Unearned income	2,433	2,054	2,186	2,186
Other long-term liabilities	70	87	61	25
Total liabilities	<u>13,884</u>	<u>24,328</u>	<u>21,410</u>	<u>21,374</u>
Commitments and contingencies (Note 16)				
Redeemable convertible preferred stock (Series A-1, A-2, B, C and D), \$0.001 par value; 5,087,982, 6,711,755 and 21,894,618 shares authorized as of December 31, 2015 and 2016 and June 30, 2017 (unaudited), respectively; 5,076,970, 6,108,312 and 20,328,596 shares issued and outstanding as of December 31, 2015 and 2016 and June 30, 2017 (unaudited), respectively; aggregate liquidation preference of \$39,952 and \$86,107 as of December 31, 2016 and June 30, 2017 (unaudited), respectively; no shares issued or outstanding, pro forma as of June 30, 2017 (unaudited)				
	<u>29,948</u>	<u>39,838</u>	<u>85,805</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 June 30, 2017 (unaudited), respectively; 1,754,035 shares issued and outstanding as of December 31, 2015 and 2016 and June 30, 2017 (unaudited); 24,720,621 shares issued and outstanding, pro forma as of June 30, 2017 (unaudited)				
	2	2	2	25
Additional paid-in capital	371	990	1,324	87,142
Accumulated other comprehensive income	718	834	455	455
Accumulated deficit	<u>(35,413)</u>	<u>(58,388)</u>	<u>(69,478)</u>	<u>(69,478)</u>
Total stockholders' equity (deficit)	<u>(34,322)</u>	<u>(56,562)</u>	<u>(67,697)</u>	<u>18,144</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 9,510</u>	<u>\$ 7,604</u>	<u>\$ 39,518</u>	<u>\$ 39,518</u>

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

## ARSANIS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
			(unaudited)	
Operating expenses:				
Research and development	\$ 12,706	\$ 17,831	\$ 6,165	\$ 8,297
General and administrative	2,119	6,515	3,092	3,174
Total operating expenses	14,825	24,346	9,257	11,471
Loss from operations	(14,825)	(24,346)	(9,257)	(11,471)
Other income (expense):				
Grant and incentive income	2,155	2,390	1,260	1,562
Interest expense	(472)	(2,515)	(1,065)	(1,463)
Change in fair value of warrant liability	1	39	6	11
Change in fair value of derivative liability	—	1,388	380	762
Loss on extinguishment of debt	—	(35)	(35)	(462)
Other income (expense), net	(77)	104	51	(29)
Total other income, net	1,607	1,371	597	381
Net loss	(13,218)	(22,975)	(8,660)	(11,090)
Accretion of redeemable convertible preferred stock to redemption value	(19)	(25)	(12)	(20)
Net loss attributable to common stockholders	\$ (13,237)	\$ (23,000)	\$ (8,672)	\$ (11,110)
Net loss per share attributable to common stockholders—basic and diluted	\$ (7.62)	\$ (13.12)	\$ (4.95)	\$ (6.33)
Weighted average common shares outstanding—basic and diluted	1,736,110	1,752,756	1,750,875	1,754,035
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited)		\$ (2.30)		\$ (0.70)
Pro forma weighted average common shares outstanding—basic and diluted (unaudited)		10,005,425		15,842,764

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

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

	<u>Year Ended</u> <u>December 31,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
Net loss	\$(13,218)	\$(22,975)	\$(8,660)	\$(11,090)
Other comprehensive income (loss):			(unaudited)	
Foreign currency translation gain (loss)	316	116	(181)	(379)
Comprehensive loss	<u>\$ (12,902)</u>	<u>\$ (22,859)</u>	<u>\$ (8,841)</u>	<u>\$ (11,469)</u>

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



**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	1,724,093	\$ 2	\$ 249	\$ 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	—	—	30,500	—	15	—	—	15
Forfeiture of unvested restricted common stock	—	—	(558)	—	—	—	—	—
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	1,754,035	2	371	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	1,754,035	2	990	834	(58,388)	(56,562)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of \$208	10,799,880	34,845	—	—	—	—	—	—
Issuance of Series D redeemable convertible preferred stock in connection with the extinguishment of convertible promissory notes	3,420,404	11,102	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	(379)	—	(379)
Stock-based compensation expense	—	—	—	—	354	—	—	354
Accretion of redeemable convertible preferred stock to redemption value	—	20	—	—	(20)	—	—	(20)
Net loss	—	—	—	—	—	—	(11,090)	(11,090)
<b>Balances as of June 30, 2017 (unaudited)</b>	<u>20,328,596</u>	<u>\$ 85,805</u>	<u>1,754,035</u>	<u>\$ 2</u>	<u>\$ 1,324</u>	<u>\$ 455</u>	<u>\$ (69,478)</u>	<u>\$ (67,697)</u>

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

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

	<b>Year Ended</b>		<b>Six Months Ended</b>	
	<b>December 31,</b>		<b>June 30,</b>	
	<b>2015</b>	<b>2016</b>	<b>2016</b>	<b>2017</b>
	<b>(unaudited)</b>			
<b>Cash flows from operating activities:</b>				
Net loss	\$ (13,218)	\$ (22,975)	\$ (8,660)	\$ (11,090)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	126	644	105	354
Depreciation and amortization expense	389	285	177	96
Non-cash interest expense	394	2,307	991	1,377
Non-cash rent expense	47	9	17	(11)
Loss on extinguishment of debt	—	35	35	462
Change in fair value of warrant liability	(1)	(39)	(6)	(11)
Change in fair value of derivative liability	—	(1,388)	(380)	(762)
Changes in operating assets and liabilities:				
Grant and incentive receivables	(56)	152	(553)	(547)
Prepaid expenses and other current assets	(31)	(1,278)	(3,677)	(1,721)
Other assets	—	(941)	—	13
Accounts payable	77	1,264	375	(563)
Accrued expenses	758	521	324	1,434
Unearned income	699	(235)	(214)	1,095
Net cash used in operating activities	<u>(10,816)</u>	<u>(21,639)</u>	<u>(11,466)</u>	<u>(9,874)</u>
<b>Cash flows from investing activities:</b>				
Purchases of property and equipment	(170)	(73)	(58)	(41)
Changes in restricted cash	(77)	(65)	—	(8,285)
Net cash used in investing activities	<u>(247)</u>	<u>(138)</u>	<u>(58)</u>	<u>(8,326)</u>
<b>Cash flows from financing activities:</b>				
Proceeds from issuance of redeemable convertible preferred stock	7,000	5,500	5,500	35,053
Proceeds from issuance of loans payable	—	7,000	3,500	—
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	—	666
Exercise of stock options	16	—	—	—
Repayments of loans payable	(1,000)	(250)	(250)	(1,165)
Payments of issuance costs of convertible promissory notes	(26)	—	—	(17)
Payments of issuance costs of redeemable convertible preferred stock	(12)	(87)	(87)	(197)
Payments of issuance costs of loans payable	—	(30)	(27)	—
Net cash provided by financing activities	<u>11,505</u>	<u>18,147</u>	<u>14,136</u>	<u>39,275</u>
<b>Effect of exchange rate changes on cash</b>	<u>(122)</u>	<u>(94)</u>	<u>(43)</u>	<u>33</u>
<b>Net increase (decrease) in cash</b>	<u>320</u>	<u>(3,724)</u>	<u>2,569</u>	<u>21,108</u>
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>\$ 9,328</u>	<u>\$ 24,143</u>
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid for interest	\$ 81	\$ 291	\$ 66	\$ 155
Cash paid for taxes	\$ 29	\$ 4	\$ —	\$ 2
<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	\$ 1	\$ —
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	\$ 35	\$ —
Accretion of redeemable convertible preferred stock to redemption value	\$ 19	\$ 25	\$ 12	\$ 20

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

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 June 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 \$11.1 million for the six months ended June 30, 2017 (unaudited). In addition, as of December 31, 2016 and June 30, 2017 (unaudited), the Company had an accumulated deficit of \$58.4 million and \$69.5 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

**ARSANIS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 September 20, 2017, the issuance date of the interim financial statements for the six months ended June 30, 2017, the Company expects that its cash of \$24.1 million as of June 30, 2017 (unaudited), together with the \$5.0 million of gross cash proceeds received from the Company's sale of additional shares of Series D redeemable convertible preferred stock in September 2017 (see Note 21), 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.

ARSANIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

***Unaudited Interim Financial Information***

The accompanying consolidated balance sheet as of June 30, 2017, the consolidated statements of operations, of comprehensive loss and of cash flows for the six months ended June 30, 2016 and 2017, and the consolidated statement of redeemable convertible preferred stock and stockholders' deficit for the six months ended June 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 June 30, 2017 and the results of its operations and its cash flows for the six months ended June 30, 2016 and 2017. The financial data and other information disclosed in these notes related to the six months ended June 30, 2016 and 2017 are also unaudited. The results for the six months ended June 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 June 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 22,966,586 shares of common stock and all outstanding warrants to purchase shares of redeemable convertible preferred stock as of June 30, 2017 becoming warrants to purchase shares of common stock as if the Company's proposed IPO had occurred on June 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 six months ended June 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 June 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 June 30, 2017 (unaudited), \$1.0 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.

**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 June 30, 2017 (unaudited), \$7.3 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 June 30, 2017 (unaudited), restricted cash (non-current) consisted of \$0.1 million, \$0.1 million and \$0.1 million, respectively, held in connection with the Company's corporate credit cards and \$0.3 million, \$0.3 million and \$0.3 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 \$0 as of December 31, 2015 and 2016 and June 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 June 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:

	<b>Estimated Useful Life</b>
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

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 June 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).

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



**ARSANIS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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.

**ARSANIS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 six months ended June 30, 2016 and 2017 (unaudited), comprehensive loss included \$0.2 million and \$0.4 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.

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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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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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. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its 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

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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. 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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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 June 30, 2017 Using: (unaudited)			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	\$ —	\$ —	\$ 36	\$ 36
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 36</u>	<u>\$ 36</u>

During the years ended December 31, 2015 and 2016 and the six months ended June 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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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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):

	<u>Warrant Liability</u>	<u>Derivative Liability</u>
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	(11)	(762)
Extinguishment of derivative liability in connection with extinguishment of 2016 and 2017 Notes	—	(2,234)
Balance as of June 30, 2017 (unaudited)	<u>\$ 36</u>	<u>\$ —</u>



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**4. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,		June 30,
	2015	2016	2017 (unaudited)
Prepaid clinical trial costs	\$—	\$1,246	\$ 3,062
Other	87	90	145
	<u>\$ 87</u>	<u>\$1,336</u>	<u>\$ 3,207</u>

**5. Property and Equipment, Net**

Property and equipment, net consisted of the following (in thousands):

	December 31,		June 30,
	2015	2016	2017 (unaudited)
Laboratory and office equipment	\$ 1,522	\$ 1,489	\$ 1,647
Furniture and fixtures	376	374	403
Leasehold improvements	240	265	284
Computer equipment and software	169	166	180
	<u>2,307</u>	<u>2,294</u>	<u>2,514</u>
Less: Accumulated depreciation and amortization	<u>(1,547)</u>	<u>(1,775)</u>	<u>(2,018)</u>
	<u>\$ 760</u>	<u>\$ 519</u>	<u>\$ 496</u>

Depreciation and amortization expense for the years ended December 31, 2015 and 2016 and for the six months ended June 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):

	December 31,		June 30,
	2015	2016	2017 (unaudited)
Accrued clinical trial costs	\$ 2	\$ 481	\$ 1,778
Accrued compensation and benefits	949	1,295	1,280
Other	590	380	646
	<u>\$1,541</u>	<u>\$2,156</u>	<u>\$ 3,704</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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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 on the expiration of the last royalty term for a product for which the Company is obligated to pay Adimab royalties in such country under the Adimab Collaboration Agreement. The Company has the right to terminate the Adimab Collaboration Agreement for any reason by providing Adimab with a specified amount of prior written notice. Adimab has the right to terminate the Adimab Collaboration Agreement if the Company materially breaches the agreement and fails to cure such breach within a specified cure period, including for its failure to use commercially reasonable efforts to develop and commercialize at least one product directed at a target for which the Company has exercised an

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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 six months ended June 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 at the end of the option period. If the Company does exercise its option, the Adimab Option Agreement will expire on the last-to-expire royalty term 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

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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, or if the Company terminates the agreement for convenience, then the Company must 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 six months ended June 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 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.

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During the six months ended June 30, 2017 (unaudited), the Company recognized grant income of \$0.6 million under the grant agreement with the Gates Foundation upon incurring qualifying expenses. As of June 30, 2017 (unaudited), unearned income under the grant agreement with the Gates Foundation was \$1.0 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 six months ended June 30, 2017 (unaudited), the Company incurred qualifying expenses of \$0.7 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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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 \$0.3 million and \$0.3 million during the six months ended June 30, 2016 and 2017 (unaudited), respectively. As of December 31, 2015 and 2016 and June 30, 2017 (unaudited), the Company recorded grant receivables from FFG of \$0.4 million, \$36,000 and \$0.1 million, respectively, for qualifying expenses incurred that were reimbursable under the funding agreements. As of December 31, 2015 and 2016 and June 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 \$0.2 million and \$0.3 million during the six months ended June 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 \$0.6 million as of December 31, 2015 and 2016 and June 30, 2017 (unaudited), respectively, and unearned income (non-current) related to such benefit was \$2.4 million, \$2.1 million and \$2.2 million as of December 31, 2015 and 2016 and June 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 \$0.7 million and \$0.5 million during the six months ended June 30, 2016 and 2017 (unaudited), respectively, in connection with the Austrian research and development incentive program. As of December 31, 2015 and 2016 and June 30, 2017 (unaudited), the Company recorded receivables for amounts due under the program of \$1.1 million, \$1.3 million and \$1.9 million, respectively, which amounts were included in grant and incentive receivables in the consolidated balance sheet.

## 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 June 30, 2017 (unaudited) consisted of the following (in thousands):

	<u>December 31,</u>		<u>June 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
Term loans under 2012 Loan Agreement	\$ 250	\$ 7,000	\$ 5,835
FFG loans	7,567	8,047	9,705
	<u>\$7,817</u>	<u>\$15,047</u>	<u>\$ 15,540</u>

Current and non-current debt obligations reflected in the consolidated balance sheets as of December 31, 2015 and 2016 and June 30, 2017 (unaudited) consisted of the following (in thousands):

	<u>December 31,</u>		<u>June 30,</u>
	<u>2015</u>	<u>2016</u>	<u>2017</u>
			<u>(unaudited)</u>
<b>Current liabilities:</b>			
Term loans under 2012 Loan Agreement	\$ 250	\$ 2,333	\$ 2,334
FFG loans	—	—	—
Unamortized debt discount	—	(34)	(28)
Loans payable, net of discount	<u>250</u>	<u>2,299</u>	<u>2,306</u>
<b>Non-current liabilities:</b>			
Term loans under 2012 Loan Agreement	—	4,667	3,501
FFG loans	7,567	8,047	9,705
Unamortized debt discount	(2,863)	(2,587)	(2,818)
Loans payable, net of discount and current portion	<u>4,704</u>	<u>10,127</u>	<u>10,388</u>
<b>Total loans payable, net of discount</b>	<u>\$ 4,954</u>	<u>\$12,426</u>	<u>\$ 12,694</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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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 June 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 \$0.1 million and \$0.2 million during the six months ended June 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 \$35,000 and \$0.1 million during the six months ended June 30, 2016 and 2017 (unaudited), respectively. As of December 31, 2015 and 2016 and June 30, 2017 (unaudited), the unamortized debt discount was \$0, \$0.1 million and \$44,000, respectively.

During the years ended December 31, 2015 and 2016 and the six months ended June 30, 2017 (unaudited), the Company made aggregate principal payments in connection with the 2012 Loan Agreement of \$1.0 million, \$0.3 million and \$1.2 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 \$9.7 million as of December 31, 2015 and 2016 and June 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 June 30, 2017 (unaudited), the unamortized debt discount related to FFG loans was \$2.9 million, \$2.6 million and \$2.8 million, respectively.

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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 \$0.3 million during each of the six months ended June 30, 2016 and 2017 (unaudited) 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 \$0.2 million and \$0.3 million during the six months ended June 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 six months ended June 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	3,624
	<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 June 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 six months ended June 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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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 and \$0.9 million, including amortization of debt discount of \$1.3 million and \$0.9 million during the year ended December 31, 2016 and the six months ended June 30, 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

**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 six months ended June 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>				
<b>Date Exercisable</b>	<b>Number of Shares Issuable</b>	<b>Exercise Price</b>	<b>Exercisable for</b>	<b>Classification</b>	<b>Expiration</b>
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>				

June 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 was issued at an exercise 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 June 30, 2017 (unaudited) and determined that the fair value of the warrant liability was \$26,000, \$12,000 and \$9,000, respectively. The Company recognized a gain (loss) of \$1,000, \$14,000, \$(3,000) and \$3,000 within other income (expense), net in the consolidated statements of operations for the years ended December 31, 2015 and 2016 and the six months ended June 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 was issued at an exercise 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 June 30, 2017 (unaudited) and determined that the fair value of the warrant liability was \$35,000 and \$27,000, respectively. The Company recognized a gain of \$25,000, \$9,000 and \$8,000 within other income (expense), net in the consolidated statements of operations for the year ended December 31, 2016 and the six months ended June 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 June 30, 2017 (unaudited), the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 6,711,755 shares and 21,894,618 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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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 (see Note 21).

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	200,001
Series A-2 preferred stock	2,125,550	2,114,538	9,599	9,600	2,114,538
Series B preferred stock	2,762,431	2,762,431	19,955	20,000	2,762,431
	<u>5,087,982</u>	<u>5,076,970</u>	<u>\$29,948</u>	<u>\$ 30,000</u>	<u>5,076,970</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	200,001
Series A-2 preferred stock	2,125,550	2,114,538	9,599	9,600	2,114,538
Series B preferred stock	2,776,934	2,762,431	19,966	20,000	2,762,431
Series C preferred stock	1,609,270	1,031,342	9,878	9,952	1,031,342
	<u>6,711,755</u>	<u>6,108,312</u>	<u>\$39,838</u>	<u>\$ 39,952</u>	<u>6,108,312</u>
	June 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	\$ 395	\$ 400	200,001
Series A-2 preferred stock	2,125,550	2,114,538	9,599	9,600	2,582,588
Series B preferred stock	2,776,933	2,762,431	19,970	20,000	4,209,638
Series C preferred stock	1,031,342	1,031,342	9,886	9,952	1,754,075
Series D preferred stock	15,760,792	14,220,284	45,955	46,155	14,220,284
	<u>21,894,618</u>	<u>20,328,596</u>	<u>\$85,805</u>	<u>\$ 86,107</u>	<u>22,966,586</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 June 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 \$50.0 million and at a price per share of not less than \$9.83, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization, 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 \$2.00 per share for Series A-1, \$4.54 per share for Series A-2, \$7.24 per share for Series B and \$9.65 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 June 30, 2017 (unaudited), the Conversion Price was \$2.00 per share for Series A-1, \$3.7172 per share for Series A-2, \$4.7510 per share for Series B, \$5.6739 per share for Series C and \$3.2457 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 June 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, respectively,

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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 June 30, 2017 (unaudited), no cash dividends have been declared or paid.

As of December 31, 2016 and June 30, 2017 (unaudited), the Company had reserved 8,129,792 shares and 27,681,720 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 1,750,000 shares as of December 31, 2016, of which 114,923 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 1,750,000 shares to 4,433,620 shares, of which 582,093 shares remained available for future grant as of June 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 2,000,000 shares as of December 31, 2016 and June 30, 2017 (unaudited), of which 7,465 shares remained available for future grant as of December 31, 2016 and June 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 348,827 shares and 1,081,750 shares, respectively, of common stock to employees and directors. During the six months ended June 30, 2016 and 2017 (unaudited), the Company granted options to purchase 71,500 shares and 2,245,450 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 \$0.1 million and \$0.3 million during six months ended June 30, 2016 and 2017 (unaudited), respectively.

During the years ended December 31, 2015 and 2016, the Company granted options to purchase 8,000 shares and 16,000 shares, respectively, of common stock to non-employees. During the six months ended June 30, 2016 and 2017 (unaudited), the Company granted options to purchase 16,000 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 \$7,000 and \$5,000 during six months ended June 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>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2016</u>	<u>2016</u>	<u>2017</u>
			(unaudited)	
Risk-free interest rate	1.81%	1.26%	1.40%	1.91%
Expected term (in years)	5.98	5.80	5.90	6.08
Expected volatility	75.3%	75.3%	75.3%	76.2%
Expected dividend yield	0%	0%	0%	0%

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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:

	<b>Year Ended December 31,</b>		<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2016</b>	<b>2016</b>	<b>2017</b>
			(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 six months ended June 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):

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding as of December 31, 2015	790,431	\$ 1.49	8.34	\$ 720
Granted	1,097,750	2.73		
Exercised	—	—		
Forfeited	(14,604)	1.13		
Outstanding as of December 31, 2016	1,873,577	\$ 2.22	8.62	\$ 1,000
Granted	2,245,450	1.17		
Exercised	—	—		
Forfeited	(29,000)	2.70		
Outstanding as of June 30, 2017 (unaudited)	4,090,027	\$ 1.64	9.13	\$ 236
Options exercisable as of December 31, 2016	740,022	\$ 1.53	7.53	\$ 903
Options exercisable as of June 30, 2017 (unaudited)	980,486	\$ 1.81	7.46	\$ 236
Options unvested as of December 31, 2016	1,133,555	\$ 2.66	9.34	\$ 97
Options unvested as of June 30, 2017 (unaudited)	3,109,541	\$ 1.59	9.66	\$ —

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 \$1.58 and \$1.76, respectively. The weighted average grant-date fair value per share of stock options granted during the six months ended June 30, 2016 and 2017 (unaudited) was \$1.54 and \$0.79, respectively.

The total fair value of options vested during the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017 (unaudited) was \$43,000, \$0.5 million, \$39,000 and \$0.4 million, respectively.

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**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:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2015	5,062	\$ —
Issued	—	—
Vested	(5,062)	—
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 six months ended June 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):

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016	2017
Research and development expenses	\$ 43	\$294	\$ 33	\$ 124
General and administrative expenses	83	350	72	230
	<u>\$126</u>	<u>\$644</u>	<u>\$ 105</u>	<u>\$ 354</u>

As of December 31, 2016 and June 30, 2017 (unaudited), total unrecognized compensation cost related to the unvested stock-based awards was \$1.8 million and \$3.2 million, respectively, which is expected to be recognized over weighted average periods of 2.84 and 3.14 years, respectively.

**14. Income Taxes**

During the years ended December 31, 2015 and 2016 and the six months ended June 30, 2016 and 2017, 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	10,367	18,004
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.

## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

During the six months ended June 30, 2017 (unaudited), gross deferred tax assets increased by approximately \$4.1 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 June 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>



ARSANIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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):

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016 (unaudited)	2017
<b>Numerator:</b>				
Net loss	\$ (13,218)	\$ (22,975)	\$ (8,660)	\$ (11,090)
Accretion of redeemable convertible preferred stock to redemption value	(19)	(25)	(12)	(20)
Net loss attributable to common stockholders	<u>\$ (13,237)</u>	<u>\$ (23,000)</u>	<u>\$ (8,672)</u>	<u>\$ (11,110)</u>
<b>Denominator:</b>				
Weighted average common shares outstanding—basic and diluted	<u>1,736,110</u>	<u>1,752,756</u>	<u>1,750,875</u>	<u>1,754,035</u>
Net loss per share attributable to common stockholders— basic and diluted	<u>\$ (7.62)</u>	<u>\$ (13.12)</u>	<u>\$ (4.95)</u>	<u>\$ (6.33)</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:

	Year Ended December 31,		Six Months Ended June 30,	
	2015	2016	2016 (unaudited)	2017
Options to purchase common stock	790,431	1,873,577	871,744	4,090,027
Restricted common stock	5,062	—	750	—
Redeemable convertible preferred stock (as converted to common stock)	5,076,970	6,108,312	6,108,312	22,966,586
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	11,013	25,515	18,264	35,549
	<u>5,883,476</u>	<u>8,007,404</u>	<u>6,999,070</u>	<u>27,092,162</u>

## 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 six months ended June 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 June 30, 2017 into common stock and all warrants to purchase shares of Preferred Stock outstanding as of June 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 six months ended June 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):

	Year Ended December 31, 2016	Six Months Ended June 30, 2017
	(unaudited)	
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (23,000)	\$ (11,110)
Accretion of redeemable convertible preferred stock to redemption value	25	20
Change in fair value of warrant liability	(39)	(11)
Pro forma net loss attributable to common stockholders	<u>\$ (23,014)</u>	<u>\$ (11,101)</u>
<b>Denominator:</b>		
Weighted average common shares outstanding—basic and diluted	1,752,756	1,754,035
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	8,252,669	14,088,729
Pro forma weighted average common shares outstanding—basic and diluted	<u>10,005,425</u>	<u>15,842,764</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted	<u>\$ (2.30)</u>	<u>\$ (0.70)</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

**ARSANIS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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, \$0.6 million and \$0.6 million during the years ended December 31, 2015 and 2016 and the six months ended June 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	151
	<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 June 30, 2017 (unaudited), the Company had committed to minimum payments under this agreement totaling \$3.2 million and \$1.4 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,

ARSANIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 June 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 six months ended June 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 six months ended June 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 June 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 six months ended June 30, 2017 (unaudited), the Company made payments to Adimab of \$13,000 and recognized \$0.1 million of research and development expense under the Adimab Option Agreement. As of June 30, 2017 (unaudited), the Company owed \$0.1 million 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 six months ended June 30, 2017 (unaudited), the Company recognized grant income of \$0.6 million under the grant agreement upon incurring qualifying expenses. As of June 30, 2017 (unaudited), unearned income under the grant agreement was \$1.0 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

## ARSANIS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

the consolidated balance sheet due to restrictions on the use of funds imposed by the agreements (see Note 2). During the six months ended June 30, 2017 (unaudited), the Company incurred qualifying expenses of \$0.7 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 six months ended June 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 six months ended June 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 and June 30, 2017 (unaudited), no amounts were due from EveliQure. As of December 31, 2016, amounts due from EveliQure totaled \$13,000.

**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 six months ended June 30, 2017 (unaudited).

**19. Geographic Information**

The Company's property and equipment, net by location was as follows (in thousands):

	December 31,		June 30,
	2015	2016	2017
United States	\$ 57	\$ 68	\$ 51
Austria	703	451	445
Total property and equipment, net	<u>\$760</u>	<u>\$519</u>	<u>\$ 496</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.

**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.

ARSANIS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 is \$3.2457 per share, and each share of Series D preferred stock is convertible into common stock on a one-for-one basis.

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 52,894,409 shares, consisting of 21,894,618 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 \$3.7172 per share for Series A-2, \$4.7510 per share for Series B and \$5.6739 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.

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 1,750,000 shares to 4,433,620 shares.

In June 2017, the Company granted options to purchase 2,245,450 shares of common stock, at an exercise price of \$1.17 per share, to employees as compensation for future services to the Company.

**21. Subsequent Events (Unaudited)**

For its interim consolidated financial statements as of June 30, 2017 and for the six months then ended, the Company evaluated subsequent events through September 20, 2017, the date on which those financial statements were issued.

***Sale of Series D Redeemable Convertible Preferred Stock***

In September 2017, the Company issued and sold 1,540,500 shares of Series D preferred stock, at a price of \$3.2457 per share, for gross proceeds of \$5.0 million.

Shares



**Common Stock**

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PRELIMINARY PROSPECTUS

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**Citigroup**

**Cowen**

**Piper Jaffray**

, 2017

Until \_\_\_\_\_, 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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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

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

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by the Registrant. All amounts are estimates except the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., filing fee and The NASDAQ Global Market initial listing fee.

	<u>Amount</u>
Securities and Exchange Commission registration fee	\$ *
Financial Industry Regulatory Authority, Inc. filing fee	*
NASDAQ Global Market initial listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	<u>\$ *</u>

\* To be filed by amendment.

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

Section 102 of the Delaware General Corporation Law, or the DGCL, permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation that will be effective upon the closing of this offering provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation that will be effective upon the closing of the offering provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action

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by or in the right of us), by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our certificate of incorporation that will be effective upon the closing of the offering also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

In addition, we have entered into indemnification agreements with our directors, and we intend to enter into indemnification agreements with all of our executive officers prior to the completion of this offering. In general, these agreements provide that we will indemnify the executive officer or director to the fullest extent permitted by law for claims arising in his or her capacity as an executive officer or director of our company or in connection with his or her service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that an executive officer or director makes a claim for indemnification and establish certain presumptions that are favorable to the executive officer or director.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

Insofar as the foregoing provisions permit indemnification of directors, executive officers or persons controlling us for liability arising under the Securities Act of 1933, as amended, or the Securities Act, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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

Set forth below is information regarding shares of our common stock, shares of our preferred stock, warrants to purchase shares of our preferred stock and stock options granted by us within the past three years that

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were not registered under the Securities Act. Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

### ***(a) Issuances of Convertible Preferred Stock and Convertible Promissory Notes***

On May 22, 2015, we issued and sold 966,851 shares of our Series B convertible preferred stock to 8 investors at a price per share of \$7.24 for an aggregate purchase price of \$7.0 million.

On December 16, 2015, we issued and sold an aggregate principal amount of \$4.0 million of convertible promissory notes to 8 investors for an aggregate purchase price of \$4.0 million. The convertible promissory notes accrued interest at a rate of 0.56% per annum and had a maturity date of December 16, 2016. On April 12, 2016, all outstanding principal and interest accrued under the convertible promissory notes was converted into shares of our Series C convertible preferred stock at approximately \$8.69 per share.

On April 12, 2016, we issued and sold 1,031,342 shares of our Series C convertible preferred stock to 10 investors, consisting of (i) 569,946 shares sold for cash at a price per share of \$9.65 for an aggregate cash purchase price of \$5.5 million and (ii) 461,396 shares issued upon conversion of \$4.0 million in outstanding principal and interest under our convertible promissory notes issued on December 16, 2015, at a price per share of approximately \$8.69. In addition, on April 12, 2016, we issued and sold an aggregate principal amount of \$5.5 million of convertible promissory notes to 10 investors for an aggregate purchase price of \$5.5 million. The convertible promissory notes accrued interest at a rate of 0.7% per annum and had a maturity date of October 12, 2017. On April 24, 2017, all principal and interest accrued under the convertible promissory notes was converted into shares of our Series D convertible preferred stock at approximately \$2.92 per share.

On January 23, 2017, we issued and sold an aggregate principal amount of \$4.9 million in convertible promissory notes to 11 investors for an aggregate purchase price of \$4.9 million. The convertible promissory notes accrued interest at a rate of 0.96% per annum and had a maturity date of October 12, 2017. On April 24, 2017, all principal and interest accrued under the convertible promissory notes was converted into shares of our Series D convertible preferred stock at approximately \$3.2457 per share.

On April 24, 2017, we issued and sold 14,220,284 shares of our Series D convertible preferred stock to 18 investors, consisting of (i) 12,323,987 shares sold for an aggregate of \$35.1 million in cash and conversion of \$4.9 million in outstanding principal and interest under our convertible promissory notes issued on January 23, 2017 at a price per share of approximately \$3.2457 and (ii) 1,896,297 shares issued upon conversion of \$5.5 million in outstanding principal and interest under our convertible promissory notes issued on April 12, 2016 at a price per share of approximately \$2.92.

On September 1, 2017, we issued and sold 1,540,500 shares of our Series D convertible preferred stock to one investor, at a price of \$3.2457 per share, for an aggregate purchase price of \$5.0 million.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and, in certain cases, Regulation D thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

### ***(b) Stock Option Grants and Exercises***

Between August 10, 2014 and September 20, 2017, we granted options to purchase an aggregate of 3,700,027 shares of common stock, with exercise prices ranging from \$1.17 to \$2.75 per share, to our employees, directors, advisors and consultants pursuant to our 2011 Stock Incentive Plan. Between August 10, 2014 and September 20, 2017, we issued 30,500 shares of our common stock upon the exercise of stock options outstanding under our 2010 Special Stock Incentive Plan for aggregate consideration of \$16,470.

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The stock options and the shares of common stock issued upon the exercise of stock options described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information.

### **(c) Issuance of Warrant**

On February 19, 2016, we issued a warrant to purchase an aggregate of 14,502 shares of our Series B convertible preferred stock at a price of \$7.24 per share to Silicon Valley Bank in connection with an amendment to our loan and security agreement with Silicon Valley Bank.

The issuance of this warrant was made in reliance on the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The investor represented that it was an accredited investor and was acquiring the warrants for its own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that it could bear the risks of the investment and could hold the warrant for an indefinite period of time and appropriate legends were affixed to the instruments representing such warrants issued in such transactions. Such recipient either received adequate information about us or had, through their relationships with us, access to such information.

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

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

### **Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
1.1**	Form of Underwriting Agreement
3.1*	Third Amended and Restated Certificate of Incorporation of the Registrant
3.2*	Restated By-laws of the Registrant, as amended
3.3**	Form of Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.4**	Form of Amended and Restated By-laws of the Registrant (to be effective upon the closing of this offering)
4.1**	Specimen Stock Certificate evidencing the shares of common stock
5.1**	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
10.1	Second Amended and Restated Investors' Rights Agreement, as amended
10.2*	2010 Special Stock Incentive Plan, as amended
10.3*	Form of Non-Statutory Stock Option Agreement under the 2010 Special Stock Incentive Plan
10.4*	2011 Stock Incentive Plan, as amended
10.5*	Form of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan
10.6*	Form of Non-Statutory Stock Option Agreement under the 2011 Stock Incentive Plan
10.7**	2017 Stock Incentive Plan
10.8**	Form of Incentive Stock Option Agreement under the 2017 Stock Incentive Plan
10.9**	Form of Nonstatutory Stock Option Agreement under the 2017 Stock Incentive Plan
10.10**	2017 Employee Stock Purchase Plan
10.11*	Offer letter, dated July 12, 2015, by and between the Registrant and René Russo
10.12*	Offer letter, dated January 15, 2016, by and between the Registrant and Michael Gray
10.13*	Offer letter, dated April 28, 2016, by and between the Registrant and Chris Stevens
10.14*	Form of Indemnification Agreement between Registrant and each of Carl Gordon, Claudio Nessi, Jan Adams, Michael Ross, Terrance McGuire, Amy Schulman and Daniel Burgess
10.15*	Form of Indemnification Agreement between Registrant and each of Eszter Nagy, Tillman U. Gerngross and Rene Russo
10.16*	Lease, dated October 30, 2015, by and between the Registrant and Waltham Winter Street 890 LP and the Registrant
10.17*	Lease Agreement, dated November 26, 2010, by and between Arsanis Biosciences GmbH and Wüstenrot Marxbox GmbH & Co. OG (as successor-in-interest to Marxbox Bauprojekt GmbH & Co. OG), as amended (English translation)
10.18*†	Collaboration Agreement, dated as of May 1, 2011, by and between the Registrant and Adimab, LLC, as amended
10.19†	Option and License Agreement, dated as of February 27, 2017, by and between the Registrant and Adimab, LLC

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<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.20*†	Grant Agreement, dated February 20, 2017, by and between the Registrant and Bill & Melinda Gates Foundation, as amended
10.21*†	Letter agreement, dated as of April 24, 2017, by and between the Registrant and Bill & Melinda Gates Foundation
10.22*	Loan and Security Agreement, dated as of December 7, 2012, by and between the Registrant and Silicon Valley Bank, as amended
10.23*	Warrant to purchase shares of Series A-2 Convertible Preferred Stock issued by the Registrant to Silicon Valley Bank
10.24*	Warrant to purchase shares of Series B Convertible Preferred Stock issued by the Registrant to Silicon Valley Bank
10.25*	Funding contract, dated September 20, 2011, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.26*	Funding contract, dated July 2, 2012, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.27*	Funding contract, dated December 5, 2012, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.28*	Funding contract, dated March 29, 2013, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.29*	Funding contract, dated August 6, 2013, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.30*	Funding contract, dated April 3, 2014, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.31*	Funding contract, dated June 9, 2014, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.32*	Funding contract, dated July 20, 2015, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.33*	Funding contract, dated July 20, 2015, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.34*	Funding contract, dated July 14, 2016, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
10.35*	Funding contract, dated March 23, 2017, by and between Arsanis Biosciences GmbH and Österreichische Forschungsförderungsgesellschaft mbH (English translation)
21.1*	List of Subsidiaries
23.1**	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm
23.2**	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page)

\* Previously filed

\*\* To be filed by amendment.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on this      day of      , 2017.

**ARSANIS, INC.**

By: \_\_\_\_\_  
René Russo  
*President and Chief Executive Officer*

## SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Arsanis, Inc., hereby severally constitute and appoint René Russo and Michael Gray, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for her or him and in her or his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any other registration statement for the same offering pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ René Russo	President and Chief Executive Officer, Director (Principal Executive Officer)	, 2017
_____ Michael Gray	Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	, 2017
_____ Tillman U. Gerngross	Chairman of the Board	, 2017
_____ Jan Adams	Director	, 2017
_____ Daniel Burgess	Director	, 2017
_____ Carl Gordon	Director	, 2017

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Terrance McGuire	Director	, 2017
_____ Eszter Nagy	Chief Scientific Officer, Director	, 2017
_____ Claudio Nesi	Director	, 2017
_____ Michael Ross	Director	, 2017
_____ Amy Schulman	Director	, 2017



**ARSANIS, INC.**

**SECOND AMENDED AND RESTATED  
INVESTORS' RIGHTS AGREEMENT**

**Dated as of April 12, 2016**

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ARSANIS, INC.

**SECOND AMENDED AND RESTATED  
INVESTORS' RIGHTS AGREEMENT**

This Second Amended and Restated Investors' Rights Agreement (this "Agreement") is entered into this 12<sup>th</sup> day of April, 2016, by and among Arsanis, Inc., a Delaware corporation (the "Company") and the individuals and entities listed on Exhibit A attached hereto (the "Investors").

Recitals

WHEREAS, the Company and the Investors are parties to that certain Series C Securities Purchase Agreement of even date herewith (the "Purchase Agreement");

WHEREAS, certain of the Investors (the "Existing Investors") hold certain shares of the Company's Series A-1 Convertible Preferred Stock, \$0.001 par value per share (the "Series A-1 Preferred Stock"), certain shares of the Company's Series A-2 Convertible Preferred Stock, \$0.001 par value per share (the "Series A-2 Preferred Stock" and, together with the Series A-1 Preferred Stock, the "Series A Preferred Stock") and certain shares of the Company's Series B Preferred Stock, \$0.001 par value per shares (the "Series B Preferred Stock"), and possess registration rights, rights to certain information, rights of first refusal with respect to the sale of certain securities of the Company and other rights pursuant to that certain Amended and Restated Investors' Rights Agreement dated as of July 30, 2013 by and among the Company and such Existing Investors (the "Prior Agreement");

WHEREAS, the undersigned Existing Investors hold a majority of the Registrable Shares (as defined in the Prior Agreement), and desire to amend and restate the Prior Agreement in its entirety and to accept the rights created pursuant to this Agreement in lieu of the rights granted to them under the Prior Agreement; and

WHEREAS, in order to induce the Company to enter into the Purchase Agreement and to induce the Investors to purchase shares of the Company's Series C Preferred Stock, \$0.001 par value per shares (the "Series C Preferred Stock" and, together with the Series A Preferred Stock and the Series B Preferred Stock, the "Preferred Stock") pursuant to the Purchase Agreement, the parties hereto agree that this Agreement shall provide for rights of the Investors in connection with (i) certain arrangements with respect to the registration of shares of capital stock of the Company under the Securities Act of 1933, as amended, (ii) a right of first refusal with respect to the sale of any securities of the Company, and (iii) certain affirmative covenants of the Company, and shall govern certain other matters as set forth in this Agreement.

NOW, THEREFORE, the parties agree that the provisions of the Prior Agreement are hereby amended and restated in their entirety, and hereby further agree, as follows:

## ARTICLE I. DEFINITIONS

As used in this Agreement, the following terms shall have the following respective meanings:

“Commission” means the United States Securities and Exchange Commission, or any other federal agency at the time administering the Securities Act.

“Common Stock” means the common stock, \$0.001 par value per share, of the Company.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, or any similar federal statute, and the rules and regulations of the Commission issued under such Act, as they each may, from time to time, be in effect.

“Founders” means Eszter Nagy, Tillman U. Gerngross and Errik B. Anderson.

“Initial Public Offering” means the sale of shares of Common Stock in the Company’s first firm commitment underwritten public offering pursuant to a Registration Statement at a price to the public of at least \$28.95 per share (adjusted for stock splits, stock dividends and similar events) and an aggregate offering price of at least \$50,000,000 (based on the market price or fair value at the time of such offering).

“Registration Statement” means a registration statement filed by the Company with the Commission for a public offering and sale of Common Stock by the Company (other than a registration statement on Form S-8 or Form S-4, or their successors, or any other form for a similar limited purpose, or any registration statement covering only securities proposed to be issued in exchange for securities or assets of another corporation).

“Registration Expenses” means the expenses described in Section 2.4.

“Registrable Shares” means (i) the shares of Common Stock issued or issuable upon conversion of the Shares, (ii) any shares of Common Stock, and any shares of Common Stock issued or issuable upon the conversion or exercise of any other securities, acquired by the Investors pursuant to Article III of this Agreement or pursuant to the Second Amended and Restated Stockholders’ Agreement of even date herewith among the Company, the Investors and certain other parties thereto, and (iii) any other shares of Common Stock issued in respect of such shares (because of stock splits, stock dividends, reclassifications, recapitalizations, or similar events); provided, however, that shares of Common Stock which are Registrable Shares shall cease to be Registrable Shares (a) upon any sale of such shares pursuant to a Registration Statement or Rule 144 under the Securities Act, (b) upon any sale of such shares in any manner to a person or entity which, by virtue of Section 5.2 is not entitled to the rights provided by this Agreement, or (c) at such time as they become eligible for resale without restriction pursuant to Rule 144(b)(1) under the Securities Act. Wherever reference is made in this Agreement to a request or consent of holders of a certain percentage of Registrable Shares, the determination of such percentage shall include shares of Common Stock issuable upon conversion of the Shares even if such conversion has not been effected at the time of such determination.

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“Securities Act” means the Securities Act of 1933, as amended, or any similar federal statute, and the rules and regulations of the Commission issued under such Act, as they each may, from time to time, be in effect.

“Shares” means the shares of Preferred Stock held by the Investors.

“Stockholders” means the Investors and any persons or entities to whom the rights granted to the Investors under this Agreement are transferred by the Investors or their successors or permitted assigns pursuant to Section 5.2.

## **ARTICLE II. REGISTRATION RIGHTS**

### **2.1. Required Registrations.**

(a) At any time after the date which is six (6) months after the closing of the Company’s first firm commitment underwritten public offering of shares of Common Stock pursuant to a Registration Statement, a Stockholder or Stockholders holding at least 25% of the Registrable Shares may request, in writing, that the Company effect the registration on Form S-1 (or any successor form) of Registrable Shares owned by such Stockholders having an aggregate offering price of at least \$10,000,000 (based on the market price or fair value at the time of such request). If the Stockholders initiating the registration intend to distribute the Registrable Shares by means of an underwriting, they shall so advise the Company in their request. Upon receipt of any such request, the Company shall promptly give written notice of such proposed registration to all Stockholders. Such Stockholders shall have the right, by giving written notice to the Company within ten (10) business days after the Company provides its notice, to elect to have included in such registration such of their Registrable Shares as such Stockholders may request in such notice of election; provided, however, if the underwriter (if any) managing the offering determines that, because of marketing factors, not all of the Registrable Shares requested to be registered by all of the Stockholders may be included in the offering, then all Stockholders who have requested registration shall participate in the registration pro rata based upon the number of Registrable Shares which they have requested to be so registered. Thereupon, the Company shall, as expeditiously as possible, use its reasonable best efforts to effect the registration on Form S-1 (or any successor form) of all Registrable Shares which the Company has been requested to so register.

(b) At any time after the Company becomes eligible to file a Registration Statement on Form S-3 (or any successor form relating to secondary offerings) and subject to paragraph (c) below, a Stockholder or Stockholders may request the Company, in writing, to effect the registration on Form S-3 (or such successor form), of Registrable Shares having an aggregate offering price of at least \$1,000,000 (based on the public market price at the time of such request). If the Stockholders initiating the registration intend to distribute the Registrable Shares by means of an underwriting, they shall so advise the Company in their request. Upon receipt of any such request, the Company shall promptly give written notice of such proposed registration to all Stockholders. Such Stockholders shall have the right, by giving written notice to the Company within ten (10) business days after the Company provides its notice, to elect to have included in such registration such of their Registrable Shares as such Stockholders may request in such notice of election; provided, however, if the underwriter (if any) managing the offering

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determines that, because of marketing factors, not all of the Registrable Shares requested to be registered by all of the Stockholders may be included in the offering, then all Stockholders who have requested registration shall participate in the registration pro rata based upon the number of Registrable Shares which they have requested to be so registered. Thereupon, subject to this Section 2.1(b), the Company shall, as expeditiously as possible, use its reasonable best efforts to effect the registration on Form S-3 (or such successor form) of all Registrable Shares which the Company has been requested to so register. The Company shall have the right to reasonably approve the managing underwriter of any underwritten offering effected pursuant to Section 2.1(a) or this Section 2.1(b).

(c) The Company shall not be required to effect more than two registrations pursuant to Section 2.1(a) and shall not be required to effect more than two registrations pursuant to Section 2.1(b) in any 12-month period; provided, however, that such obligations shall be deemed satisfied only when a registration statement covering the applicable Registrable Shares shall have (i) become effective or (ii) been withdrawn at the request of the Stockholders requesting such registration (other than as a result of information concerning the business or financial condition of the Company which is made known to the Stockholders after the date on which such registration was requested).

(d) Notwithstanding the foregoing obligations, if at the time of any request to register Registrable Shares pursuant to this Section 2.1, the Company is engaged or has plans to engage within 30 days of the time of the request in a registered public offering of securities for its own account or is engaged in any other activity which, in the good faith determination of the Company's Board of Directors, would be adversely affected by the requested registration to the material detriment of the Company, then the Company may at its option direct that such request be delayed for a period not in excess of three months from the effective date of such offering or the date of commencement of such other material activity, as the case may be, such right to delay a request to be exercised by the Company not more than once in any 12-month period.

### 2.2. Incidental Registration.

(a) Whenever the Company proposes to file a Registration Statement at any time and from time to time, it will, prior to such filing, give written notice to all Stockholders of its intention to do so and, upon the written request of a Stockholder or Stockholders, given within ten (10) business days after the date that the Company provides such notice (which request shall state the intended method of disposition of such Registrable Shares), the Company shall use its reasonable best efforts to cause all Registrable Shares which the Company has been requested by such Stockholder or Stockholders to register, to be registered under the Securities Act to the extent necessary to permit their sale or other disposition in accordance with the intended methods of distribution specified in the request of such Stockholder or Stockholders; provided, however, that the Company shall have the right to postpone or withdraw any registration effected pursuant to this Section 2.2 without obligation to any Stockholder.

(b) In connection with any registration under this Section 2.2 involving an underwriting, the Company shall not be required to include any Registrable Shares in such registration unless the holders thereof accept the terms of the underwriting as agreed upon between the Company and the underwriters selected by it. If in the opinion of the managing

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underwriter it is desirable because of marketing factors to limit the number of Registrable Shares to be included in the offering, then the Company shall be required to include in the registration only that number of Registrable Shares, if any, which the managing underwriter believes should be included therein; provided, however, that no persons or entities other than the Company, the Stockholders and other persons or entities holding registration rights shall be permitted to include securities in the offering. If the number of Registrable Shares to be included in the offering in accordance with the foregoing is less than the total number of shares which the holders of Registrable Shares have requested to be included, then the holders of Registrable Shares who have requested registration and other holders of securities entitled to include them in such registration shall participate in the registration pro rata based upon their total ownership of shares of Common Stock (giving effect to the conversion into Common Stock of all securities convertible thereinto). If any holder would thus be entitled to include more securities than such holder requested to be registered, the excess shall be allocated among other requesting holders pro rata in the manner described in the preceding sentence.

2.3. Registration Procedures. If and whenever the Company is required by the provisions of this Agreement to use its reasonable best efforts to effect the registration of any of the Registrable Shares under the Securities Act, the Company shall:

(a) as expeditiously as possible prepare and file with the Commission a Registration Statement with respect to such Registrable Shares and use its reasonable best efforts, including preparing and filing any amendments and supplements to the Registration Statement and the prospectus included therein, to cause that Registration Statement to become and remain effective for 180 days from the effective date or such lesser period until all such Registrable Shares are sold;

(b) as expeditiously as possible furnish to each selling Stockholder such reasonable numbers of copies of the prospectus, including a preliminary prospectus, in conformity with the requirements of the Securities Act, and such other documents as the selling Stockholder may reasonably request in order to facilitate the public sale or other disposition of the Registrable Shares owned by the selling Stockholder;

(c) as expeditiously as possible use its best reasonable efforts to register or qualify the Registrable Shares covered by the Registration Statement under the securities or Blue Sky laws of such states as the selling Stockholders shall reasonably request, and do any and all other acts and things that may be necessary or desirable to enable the selling Stockholders to consummate the public sale or other disposition in such states of the Registrable Shares owned by the selling Stockholders; provided, however, that the Company shall not be required in connection with this paragraph 2.3(c) to qualify as a foreign corporation or execute a general consent to service of process in any jurisdiction;

(d) in the case of an underwritten offering, enter into an underwriting agreement containing such terms as are customarily included in an underwriting agreement for comparable offerings, including requirements that the Company's counsel furnish a customary legal opinion and that the Company's accountants furnish a customary comfort letter.

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(e) use its commercially reasonable efforts to cause all such Registrable Shares covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(f) provide a transfer agent and registrar for all Registrable Shares registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Shares, in each case not later than the effective date of such registration;

(g) promptly make available for inspection by the selling Stockholders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Stockholders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(h) notify each selling Stockholder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(i) after such registration statement becomes effective, notify each selling Stockholder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

If the Company has delivered preliminary or final prospectuses to the selling Stockholders and after having done so the prospectus is amended to comply with the requirements of the Securities Act, the Company shall promptly notify the selling Stockholders and, if requested, the selling Stockholder shall immediately cease making offers of Registrable Shares and return all prospectuses to the Company. The Company shall promptly provide each selling Stockholder with revised prospectuses and, following receipt of the revised prospectuses, the selling Stockholder shall be free to resume making offers of the Registrable Shares.

Notwithstanding the foregoing, each selling Stockholder shall cease making offers or sales pursuant to a "shelf" Registration Statement during any Postponement Period (not to exceed 90 days in the aggregate in any 12-month period). A "Postponement Period" shall be any period in which there exists at the time material non-public information relating to the Company disclosure of which, the Company, in its good faith judgment by the Board of Directors reasonably believes:

(i) that the filing thereof at the time requested, or the offering of Registrable Shares pursuant thereto, would materially and adversely affect (A) a pending or scheduled public offering or private placement of the Company's securities, (B) an acquisition, merger, consolidation or similar transaction by or of the Company, or (C) pre-existing and continuing negotiations, discussions or pending proposals with respect to any of the foregoing transactions; and



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(ii) that the failure to disclose any material information with respect to the foregoing would cause a violation of the Securities Act or the Exchange Act.

If, after a Registration Statement becomes effective, the Company becomes engaged in any activity which, in the good faith determination of the Company's Board of Directors, involves information that would have to be disclosed in the Registration Statement but which the Company desires to keep confidential for valid business reasons including any event giving rise to a Postponement Period, then the Company may at its option, by notice to such Stockholders, require that the Stockholders who have included Registrable Shares in such Registration Statement cease sales of such Registrable Shares under such Registration Statement for a period not in excess of 90 days in the aggregate in any 12-month period. If, in connection therewith, the Company considers it appropriate for such Registration Statement to be amended, the Company shall so amend such Registration Statement as promptly as practicable and such Stockholders shall suspend any further sales of their Registrable Shares until the Company advises them that such Registration Statement has been amended. The time periods referred to in this Section 2.3 during which such Registration Statement must be kept effective shall be extended for an additional number of days equal to the number of days during which the right to sell Registrable Shares was suspended pursuant to this paragraph.

2.4. Allocation of Expenses. The Company will pay all Registration Expenses of all registrations under this Agreement. For purposes of this Section 2.4, the term "Registration Expenses" shall mean all expenses incurred by the Company in complying with this Article II, including, without limitation, all registration and filing fees, exchange listing fees, printing expenses, fees and expenses of counsel for the Company to represent the selling Stockholder(s), state Blue Sky fees and expenses, the expense of any special audits incidental to or required by any such registration, and the reasonable fees and expenses of one counsel for the selling Stockholders selected by the Stockholders holding a majority of the Registrable Shares to be registered, but excluding underwriting discounts and selling commissions.

### 2.5. Indemnification and Contribution.

(a) In the event of any registration of any of the Registrable Shares under the Securities Act pursuant to this Agreement, the Company will indemnify and hold harmless the seller of such Registrable Shares and the partners, members, officers, directors and stockholders of each such stockholder, each underwriter of such Registrable Shares, and each other person, if any, who controls such seller or underwriter within the meaning of the Securities Act or the Exchange Act against any losses, claims, damages or liabilities, joint or several, to which such seller, underwriter or controlling person may become subject under the Securities Act, the Exchange Act, state securities or Blue Sky laws or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in any Registration Statement under which such Registrable Shares were registered under the Securities Act, any preliminary prospectus or final prospectus contained in the Registration Statement, or any amendment or supplement to such Registration Statement, or arise out of or are based upon the

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omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and the Company will reimburse such seller, underwriter and each such controlling person for any legal or any other expenses reasonably incurred by such seller, underwriter or controlling person in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any untrue statement or omission made in such Registration Statement, preliminary prospectus or final prospectus, or any such amendment or supplement, in reliance upon and in conformity with information furnished to the Company, in writing, by or on behalf of such seller, underwriter or controlling person specifically for use in the preparation thereof.

(b) In the event of any registration of any of the Registrable Shares under the Securities Act pursuant to this Agreement, each seller of Registrable Shares, severally and not jointly, will indemnify and hold harmless the Company, each of its directors and officers and each underwriter (if any) and each person, if any, who controls the Company or any such underwriter within the meaning of the Securities Act or the Exchange Act, against any losses, claims, damages or liabilities, joint or several, to which the Company, such directors and officers, underwriter or controlling person may become subject under the Securities Act, Exchange Act, state securities or Blue Sky laws or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any Registration Statement under which such Registrable Shares were registered under the Securities Act, any preliminary prospectus or final prospectus contained in the Registration Statement, or any amendment or supplement to the Registration Statement, or arise out of or are based upon any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, if the statement or omission was made in reliance upon and in conformity with information relating to such seller furnished in writing to the Company by or on behalf of such seller specifically for use in connection with the preparation of such Registration Statement, prospectus, amendment or supplement; provided, however, that the obligations of each such Stockholder hereunder shall be limited to an amount equal to the proceeds to such Stockholder of Registrable Shares sold in connection with such registration.

(c) Each party entitled to indemnification under this Section 2.5 (the "Indemnified Party") shall give notice to the party required to provide indemnification (the "Indemnifying Party") promptly after such Indemnified Party has actual knowledge of any claim as to which indemnity may be sought, and shall permit the Indemnifying Party to assume the defense of any such claim or any litigation resulting therefrom; provided, that counsel for the Indemnifying Party, who shall conduct the defense of such claim or litigation, shall be approved by the Indemnified Party (whose approval shall not be unreasonably withheld); and, provided, further, that the failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Section 2.5, unless and except to the extent that the Indemnifying Party is prejudiced by the failure of the Indemnified Party to provide timely notice. The Indemnified Party may participate in such defense at such party's expense; provided, however, that the Indemnifying Party shall pay such expense if representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party

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represented by such counsel in such proceeding. No Indemnifying Party, in the defense of any such claim or litigation shall, except with the consent of each Indemnified Party, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect of such claim or litigation, and no Indemnified Party shall consent to entry of any judgment or settle such claim or litigation without the prior written consent of the Indemnifying Party.

(d) In order to provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any holder of Registrable Shares exercising rights under this Agreement, or any controlling person of any such holder, makes a claim for indemnification pursuant to this Section 2.5 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.5 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any such selling Stockholder or any such controlling person in circumstances for which indemnification is provided under this Section 2.5; then, in each such case, the Company and such Stockholder will contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in such proportions so that such holder is responsible for the portion represented by the percentage that the public offering price of its Registrable Shares offered by the Registration Statement bears to the public offering price of all securities offered by such Registration Statement, and the Company is responsible for the remaining portion; provided, however, that, in any such case, (A) no such holder will be required to contribute any amount in excess of the proceeds to it of all Registrable Shares sold by it pursuant to such Registration Statement, and (B) no person or entity guilty of fraudulent misrepresentation, within the meaning of Section 11(f) of the Securities Act, shall be entitled to contribution from any person or entity who is not guilty of such fraudulent misrepresentation.

2.6. Indemnification with Respect to Underwritten Offering. In the event that Registrable Shares are sold pursuant to a Registration Statement in an underwritten offering pursuant to Section 2.1 hereof, the Company agrees to enter into an underwriting agreement containing customary representations and warranties with respect to the business and operations of an issuer of the securities being registered and customary covenants and agreements to be performed by such issuer, including, without limitation, customary provisions with respect to indemnification by the Company of the underwriters of such offering.

2.7. Information by Holder. Each Stockholder including Registrable Shares in any registration shall furnish to the Company such information regarding such Stockholder and the distribution proposed by such Stockholder as the Company may reasonably request in writing and as shall be required in connection with any registration, qualification or compliance referred to in this Agreement.

2.8. “Stand-Off” Agreement. Each Stockholder, if requested by the Company and the managing underwriter of an offering by the Company of Common Stock or other securities of the Company pursuant to a Registration Statement, shall agree not to sell publicly or otherwise transfer or dispose of any Registrable Shares or other securities of the Company held by such

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Stockholder for a specified period of time (not to exceed 180 days, which period may be extended upon the request of the managing underwriter for a period of up to fifteen (15) days if the Company issues or proposes to issue an earnings or other public release within fifteen (15) days of the expiration of the 180-day lockup period) following the effective date of such Registration Statement; provided, that:

(a) all officers and directors of the Company, all holders of 1% or more of the Company's equity securities and all selling stockholders in such offering enter into similar agreements, and any discretionary modification, waiver or termination of the restrictions of such agreements (including this agreement) by the Company or the managing underwriter shall apply to all persons subject to such agreements on a pro rata basis, based upon the number of shares held by each subject to such agreements;

(b) such agreement shall only apply to the first Registration Statement covering Common Stock to be sold by or on behalf of the Company to the public in an underwritten offering; and

(c) such agreement shall not apply to securities acquired in an open market transaction after such Registration Statement is declared effective.

2.9. Limitations on Subsequent Registration Rights. The Company shall not, without the prior written consent of Stockholders holding at least a majority of the Registrable Shares held by the Stockholders, enter into any agreement (other than this Agreement) with any holder or prospective holder of any securities of the Company which would allow such holder or prospective holder to include securities of the Company in any Registration Statement upon terms which are more favorable to such holder or prospective holder than the terms on which holders of Registrable Shares may include shares in such registration.

2.10. Rule 144 Requirements. After the earliest of (a) the closing of the sale of securities of the Company pursuant to a Registration Statement, (b) the registration by the Company of a class of securities under Section 12 of the Exchange Act, or (c) the issuance by the Company of an offering circular pursuant to Regulation A under the Securities Act, the Company agrees to:

(i) comply with the requirements of Rule 144(c) under the Securities Act with respect to current public information about the Company;

(ii) use its best efforts to file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements); and

(iii) furnish to any holder of Registrable Shares upon request (A) a written statement by the Company as to its compliance with the requirements of said Rule 144(c), and the reporting requirements of the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements), (B) a copy of the most recent annual or quarterly report of the Company, and (C) such other reports and documents of the Company as such holder may reasonably request to avail itself of any similar rule or regulation of the Commission allowing it to sell any such securities without registration.

### ARTICLE III. RIGHT OF FIRST REFUSAL

#### 3.1. Right of First Refusal.

(a) So long as at least twenty percent (20%) of the Shares that have been issued remain outstanding, the Company shall not issue, sell or exchange, agree to issue, sell or exchange, or reserve or set aside for issuance, sale or exchange, (i) any shares of its Common Stock, (ii) any other equity securities of the Company, including, without limitation, shares of preferred stock, (iii) any option, warrant or other right to subscribe for, purchase or otherwise acquire any equity securities of the Company, or (iv) any debt securities convertible into capital stock of the Company (collectively, the “Offered Securities”), unless in each such case the Company shall have first complied with Article III of this Agreement.

(b) The Company shall deliver to each Investor a written notice of any proposed or intended issuance, sale or exchange of Offered Securities (the “Offer”), which Offer shall (i) identify and describe the Offered Securities, (ii) describe the price and other terms upon which they are to be issued, sold or exchanged, and the number or amount of the Offered Securities to be issued, sold or exchanged, (iii) identify the persons or entities, if known, to which or with which the Offered Securities are to be offered, issued, sold or exchanged, and (iv) offer to issue and sell to or exchange with such Investor (A) that number of the Offered Securities which represents the same percentage of the total Offered Securities as the number of shares of Common Stock into which all of the Company’s capital stock held by such Investor are convertible represents of the total number of outstanding shares of Common Stock (including all shares of the Company’s capital stock convertible into Common Stock, counting such shares as if converted (the “Basic Amount”)) and (B) such additional portion of the Offered Securities as such Investor shall indicate it will purchase or acquire should any other Investor subscribe for less than its Basic Amount (the “Undersubscription Amount”). Each Investor shall have the right, for a period of 10 business days following delivery of the Offer, to accept the Offer in the manner provided in paragraph 3.1(c) below. The Offer by its terms shall remain open and irrevocable until the earlier of the expiration of such 10-business-day period or the receipt by the Company of notice from all of the Investors.

(c) To accept an Offer, in whole or in part, an Investor must deliver a written notice to the Company prior to the end of the 10-business-day period of the Offer, setting forth the portion of the Investor’s Basic Amount that such Investor elects to purchase and, if such Investor shall elect to purchase all of its Basic Amount, the Undersubscription Amount (if any) that such Investor elects to purchase (the “Notice of Acceptance”). If the Basic Amounts subscribed for by all Investors are less than the total Basic Amounts, then each Investor who has set forth an Undersubscription Amount in its Notice of Acceptance shall be entitled to purchase, in addition to the Basic Amounts subscribed for, the Undersubscription Amount it has subscribed for; provided, however, that should the Undersubscription Amounts subscribed for exceed the difference between the total Basic Amounts and the Basic Amounts subscribed for (the “Available Undersubscription Amount”), each Investor who has subscribed for any Undersubscription Amount shall be entitled to purchase only that portion of the Available Undersubscription Amount as the Undersubscription Amount subscribed for by such Investor bears to the total Undersubscription Amounts subscribed for by all Investors, subject to rounding by the Board of Directors to the extent it reasonably deems necessary.

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(d) In the event that Notices of Acceptance are not given by such Investors in respect of all the Offered Securities, the Company shall have 90 days from the expiration of the 10-day period set forth in Section 3.1(b) hereof, to issue, sell or exchange all or any part of such Offered Securities as to which a Notice of Acceptance has not been given by the Investors (the “Refused Securities”), but only to the offerees or purchasers described in the Offer and only upon terms and conditions (including, without limitation, unit prices and interest rates) which are not more favorable, in the aggregate, to the acquiring person or persons or less favorable to the Company than those set forth in the Offer.

(e) In the event the Company shall propose to sell less than all of the Refused Securities, then each Investor may, at its sole option and in its sole discretion, reduce the number or amount of the Offered Securities specified in its Notice of Acceptance to an amount that shall be not less than the number or amount of the Offered Securities that the Investor elected to purchase pursuant to Section 3.1(c) hereof, multiplied by a fraction (i) the numerator of which shall be the number or amount of Offered Securities the Company actually proposes to issue, sell or exchange (including Offered Securities to be issued or sold to Investors pursuant to Section 3.1(c) hereof prior to such reduction) and (ii) the denominator of which shall be the amount of all Offered Securities. In the event that an Investor so elects to reduce the number or amount of Offered Securities specified in its Notice of Acceptance, the Company may not issue, sell or exchange more than the reduced number or amount of the Offered Securities unless and until such securities have again been offered to the Investors in accordance with Section 3.1(b) hereof.

(f) Upon (i) the closing of the issuance, sale or exchange of all or less than all the Refused Securities or (ii) such other date agreed to by the Company and Investors who have subscribed for over 66.67% of the Offered Securities subscribed for by the Investors, the Investors shall acquire from the Company, and the Company shall issue to the Investors, the number or amount of Offered Securities specified in the Notices of Acceptance, as reduced pursuant to Section 3.1(e) hereof if the Investors have so elected, upon the terms and conditions specified in the Offer. The purchase by the Investors of any Offered Securities is subject in all cases to the preparation, execution and delivery by the Company and the participating Investors of a purchase agreement relating to such Offered Securities reasonably satisfactory in form and substance to the participating Investors and the Company.

(g) Any Offered Securities not acquired by the Investors or other persons in accordance with Section 3.1(d) hereof may not be issued, sold or exchanged until they are again offered to the Investors under the procedures specified in this Section 3.1.

3.2. Excluded Issuances. The rights of the Investors under this Article III shall not apply to:

(a) shares of Common Stock issued or issuable upon conversion of shares of Preferred Stock pursuant to the Company’s Certificate of Incorporation;

(b) shares of Common Stock issued or issuable as a dividend or distribution on Preferred Stock;

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(c) shares of Common Stock issued or issuable by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Article Fourth, Section B.5.5 or B.5.6 of the Company's Certificate of Incorporation, as the same may be amended from time to time;

(d) up to 2,650,000 shares of Common Stock (inclusive of shares of Common Stock or options granted prior to the date of this Agreement under a plan), or options exercisable therefor (subject to appropriate adjustment for stock splits, stock dividends, reclassifications, recapitalizations and other similar events affecting such shares), plus such additional number of shares as may be approved by the Board of Directors of the Company, issued or issuable to officers, directors, consultants and employees of the Company or any subsidiary pursuant to any plan, agreement or arrangement approved by the Board of Directors of the Company;

(e) securities issued solely in connection with the acquisition (whether by merger or otherwise) by the Company or any of its subsidiaries of all or substantially all of the stock or assets of any other entity; provided, that such offering is approved by the Board of Directors of the Company; or

(f) securities issued to financial institutions or lessors in connection with commercial credit arrangements, equipment financings or similar transactions, provided, in each case, such is approved by holders of at least a majority of the then outstanding Shares voting together as a single class on an as-converted to Common Stock basis.

### **ARTICLE IV. AFFIRMATIVE COVENANTS**

4.1. Inspection. The Company shall permit each Investor, or any authorized representative thereof, so long as (i) such Investor shall own an aggregate of at least ten percent (10%) of the Shares (including shares of the Common Stock into which such Shares shall have been converted) originally purchased by such Investor, and (ii) at least an aggregate of twenty percent (20%) of the Shares (including shares of the Common Stock into which such Shares shall have been converted) are outstanding at such time, to visit and inspect the properties of the Company, including its corporate and financial records, and to discuss its business and finances with officers of the Company, during normal business hours following reasonable notice and as often as may be reasonably requested.

4.2. Financial Statements and Other Information. The Company shall deliver to each Investor, or any authorized representative thereof, so long as (i) such Investor shall own an aggregate of at least ten percent (10%) of the Shares (including shares of the Common Stock into which such Shares shall have been converted) originally purchased by such Investor, and (ii) at least an aggregate of twenty percent (20%) of the Shares (including shares of the Common Stock into which such Shares shall have been converted) are outstanding at such time:

(a) within 150 days after the end of each fiscal year of the Company, an audited balance sheet of the Company as at the end of such year and audited statements of income and of cash flows of the Company for such year, certified by certified public accountants selected by the Company who are acceptable to the Investors holding at least a majority of the Shares then outstanding, and prepared in accordance with generally accepted accounting principles ("GAAP");

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(b) within 45 days after the end of each calendar quarter, an unaudited balance sheet of the Company as at the end of such quarter, and unaudited statements of income and of cash flows of the Company for such quarter and for the current fiscal year;

(c) within 30 days after the end of each calendar month, an unaudited balance sheet of the Company as at the end of such month, and unaudited statements of income and of cash flows of the Company for such month and for the current fiscal year and the fiscal quarter to the end of such month;

(d) as soon as available, but in any event 30 days prior to the commencement of each new fiscal year, an operating plan and budget for such fiscal year;

(e) such other notices, information and data with respect to the Company and its subsidiaries as the Company delivers to the holders of its capital stock at the same time it delivers such items to such holders; and

(f) with reasonable promptness, such other information and data as such Investor may from time to time reasonably request.

4.3. Material Changes and Litigation. The Company shall promptly notify the Investors of any material adverse change in the business, prospects, assets or condition, financial or otherwise, of the Company and of any litigation or governmental proceeding or investigation brought or, to the Company's knowledge, threatened against the Company, or against the Founders, or an officer, director, key employee or principal stockholder of the Company which, if adversely determined, would have a material adverse effect on the Company.

4.4. Confidentiality of Records. Each Investor agrees, severally and not jointly, to use confidential information provided by the Company only for monitoring its investment in Company and not to disclose any such confidential information to any third party, except with the consent of the Company. The foregoing requirements of confidentiality shall not apply to information: (i) that is now or in the future becomes freely available to the public through no fault of or action by the using or disclosing party; (ii) that is in the possession of the using or disclosing party prior to the time such information was obtained from the Company or that is independently acquired by the using or disclosing party without the aid, application or use of such other information; (iii) that is obtained by the using or disclosing party in good faith without knowledge of any breach of a secrecy arrangement from a third party; (iv) that is required to be disclosed by applicable law or order of government agency or self-regulatory body; (v) that is disclosed to any partner, parent or subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such person that such information is confidential and directs such person to maintain the confidentiality of such information; or (vi) that is disclosed in connection with any bona-fide offer to purchase any shares in the Company, provided, that the proposed transferor obtains an undertaking from the proposed transferee to keep such information confidential in accordance with the provision of this Section 4.4 prior to such disclosure.



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4.5. Other Investments. The Company acknowledges that the Investor may be in the business of venture capital investing and therefore, may review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement shall preclude or in any way restrict the Investor from investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.

4.6. Agreements with Employees. The Company shall require each present or future employee or consultant who is an executive officer of the Company or has duties in the areas of technology, sales or marketing to enter into non-disclosure, non-competition and assignment of intellectual property agreement in such form as has been or may be approved by the Board of Directors of the Company, including a majority of the Preferred Directors (as defined in the Company's Certificate of Incorporation).

4.7. Reservation of Shares. The Company shall reserve and maintain a sufficient number of shares of Common Stock for issuance upon conversion of the Shares.

4.8. Employee Stock Options and Restricted Stock. Unless otherwise unanimously approved by the Company's Board of Directors, any restricted stock or stock options issued by the Company after the date hereof to any employee or consultant shall vest 25% on the first anniversary of the first day of such employee or consultant's employment or consultancy relationship with the Company with ratable monthly vesting over the next three years and, in the event of a Change of Control (as defined in the Company's 2010 Special Stock Incentive Plan or the Company's 2011 Stock Incentive Plan, as the case may be), (1) if, following such Change of Control, either (i) such employee or consultant is terminated without Cause (as defined in the Company's 2010 Special Stock Incentive Plan or the Company's 2011 Stock Incentive Plan, as the case may be) by the surviving entity in such Change of Control or (ii) such employee or consultant voluntarily terminates his or her employment or consulting relationship with the Company for Good Reason (as defined in the Company's 2010 Special Stock Incentive Plan or the Company's 2011 Stock Incentive Plan, as the case may be), any option held by such employee or consultant shall become fully-vested and exercisable in full and any shares of restricted stock held by such employee or consultant shall become fully-vested and no longer subject to forfeiture or repurchase by the Company and (2) if, within thirty (30) days prior to such Change of Control, such employee or consultant's employment or consultancy relationship with the Company is terminated by the Company without Cause (as defined in the Company's 2010 Special Stock Incentive Plan or the Company's 2011 Stock Incentive Plan, as the case may be) or by such employee or consultant for Good Reason (as defined in the Company's 2010 Special Stock Incentive Plan or the Company's 2011 Stock Incentive Plan, as the case may be), then, on the effective date of such Change of Control, any option held by such employee or consultant shall become fully-vested and exercisable in full and any shares of restricted stock held by such employee or consultant shall become fully-vested and no longer subject to forfeiture or repurchase by the Company.

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4.9. Insurance. The Company shall use its commercially reasonable efforts to maintain Directors and Officers liability insurance and term “key person” insurance on any employee requested by the Board of Directors (including a majority of the directors designated by the holders of Preferred Stock), each in an amount and on terms and conditions satisfactory to the Board of Directors (including a majority of the directors designated by the holders of Preferred Stock) until such time as the Board of Directors (including a majority of the directors designated by the holders of Preferred Stock) determines that such insurance should be discontinued. The key person policy shall name the Company as loss payee, and neither policy shall be cancelable by the Company without prior approval by the Board of Directors (including a majority of the directors designated by the holders of Preferred Stock).

### 4.10. Board Matters.

(a) The Company shall reimburse the directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company’s travel policy) in connection with attending meetings of the Board of Directors. At the request of a majority of the Preferred Directors (as defined in the Company’s Certificate of Incorporation), the Company shall cause to be established, as soon as practicable after such request, and will maintain an audit and/or compensation committee, as applicable, each of which shall consist solely of non-management directors. Each non-employee director shall be entitled in such person’s discretion to be a member of any Board committee, except with respect to any committee of the Board of Directors formed for the purpose of acting as the administrator of the Company’s 2010 Special Stock Incentive Plan, and each committee of the Board of Directors, if any, shall include at least one of the Preferred Directors.

(b) Except as may otherwise be set forth in any applicable management rights letter or other written agreement with an Investor, a board observer may participate in person at the Company’s Board of Directors meetings only at the explicit invitation of the Chairman of the Board of Directors, where such invitation may be granted solely at the Chairman’s discretion (each a “Chairman Invited Observer”). The Company shall reimburse up to 50% of a Chairman Invited Observer’s reasonable out of pocket travel expenses incurred (consistent with the Company’s travel policy) in connection with attending any meeting of the Board of Directors to which he or she is invited.

4.11. Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other person or entity and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company’s Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.

4.12. Termination of Covenants. The covenants of the Company contained in Sections 4.1 through 4.8 shall terminate, and be of no further force or effect, upon (i) the effective date of a registration statement filed by the Company under the Securities Act, covering the Initial Public Offering, or (ii) upon a sale of the Company by merger in which the shareholders of the Company in their capacity as such no longer own a majority of the outstanding equity securities of the Company (or its successor), or (iii) for the covenants in

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Sections 4.1, 4.2, and 4.3 only, at such time when less than 20% of the Shares that have been issued (including shares of Common Stock into which such Shares shall have been converted) remain outstanding.

4.13. Subsidiaries. Unless approved by Stockholders holding at least a majority of the Registrable Shares, each subsidiary of the Company shall comply with the covenants set forth in Sections 4.1, 4.2, 4.3, 4.6, 4.9, 4.10, and 4.11 above to the same extent as the Company.

### ARTICLE V. GENERAL

5.1. Termination. Article III of this Agreement shall terminate in its entirety upon the earlier of: (a) an Acquisition (as defined below); (b) immediately prior to the closing of an Initial Public Offering; (c) the date upon which less than 20% of the Shares remain outstanding, or (d) the redemption of all Shares. An “Acquisition” shall mean any (i) merger or consolidation which results in the voting securities of the Company outstanding immediately prior thereto representing immediately thereafter (either by remaining outstanding or by being converted into voting securities of the surviving or acquiring entity) less than a majority of the combined voting power of the voting securities of the Company or such surviving or acquiring entity outstanding immediately after such merger or consolidation, (ii) sale of all or substantially all the assets of the Company and the distribution of the net proceeds therefrom in accordance with the Company’s Certificate of Incorporation or (iii) sale of shares of capital stock of the Company, in a single transaction or series of related transactions, representing more than 50% of the voting power of the voting securities of the Company.

5.2. Transfers of Rights. This Agreement, and the rights and obligations of each Investor hereunder, may be assigned by such Investor (i) to any person or entity to which such Investor transfers a number of shares of Preferred Stock equal to not less than five percent (5%) of the total number of shares of Preferred Stock held by such Investor (subject to adjustment for any stock dividend, stock split, stock split-up, combination or shares or the like) immediately following the Closing (as defined in the Purchase Agreement), (ii) if such Investor is an individual, to any family member or trust or partnership established for such family member, or (iii) if such Investor is a corporation, partnership, limited liability company or other entity, to any current or former partner (including general partner and limited partner), shareholder, member or other affiliate of such Investor, provided that, in any case, the transferee is not a competitor of the Company as determined in good faith by the Board of Directors of the Company, and provided further that a private equity fund shall not be considered a competitor of the Company for purposes of this Section 5.2. Such transferee shall be deemed an “Investor” for purposes of this Agreement, provided that the transferee provides written notice of such assignment to the Company and agrees in writing to be bound by the terms and conditions set forth herein as if he, she or it were an original Investor.

5.3. Severability. The provisions of this Agreement are severable, so that the invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement, which shall remain in full force and effect.

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5.4. Specific Performance. In addition to any and all other remedies that may be available at law in the event of any breach of this Agreement, each Investor shall be entitled to specific performance of the agreements and obligations of the other parties hereunder and to such other injunctive or other equitable relief as may be granted by a court of competent jurisdiction.

### 5.5. Governing Law.

(a) This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (without reference to the conflicts of law provisions thereof). Subject to Subsection 5.6(b), the parties (i) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of Massachusetts and to the jurisdiction of the United States District Court for the District of Massachusetts for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (ii) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of Massachusetts or the United States District Court for the District of Massachusetts, and (iii) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

(b) Notwithstanding the foregoing Subsection 5.6(a), in the event there is a suit, action or other proceeding of the type described in Article Eleventh of the Company's Amended and Restated Certificate of Incorporation (i) pending in the Court of Chancery in the State of Delaware or (ii) to be filed simultaneously with the Court of Chancery in the State of Delaware, in either case with respect to facts related to any suit, action or proceeding under this Agreement, then any suit, action or other proceeding under this Agreement must be brought exclusively in the Court of Chancery in the State of Delaware and the parties (x) hereby irrevocably and unconditionally submit to the jurisdiction of the Court of Chancery in the State of Delaware and (y) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

5.6. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (i) personal delivery to the party to be notified, (ii) when sent, if sent by electronic mail or facsimile during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next business day, (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one (1) business day after deposit with a nationally recognized overnight courier, freight prepaid, specifying next business day delivery, with written verification of receipt:

(a) If to the Company, at 890 Winter Street, Suite 230, Waltham, Massachusetts 02451, Attn: Michael Gray, or at such other address or addresses as may have been furnished in writing by the Company to the Investors, with a copy to Foley Hoag LLP, 155 Seaport Boulevard, Boston, Massachusetts 02210, Attention: Robert L. Birnbaum, Esq.

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(b) If to an Investor, at its address set forth on Exhibit A attached hereto, or at such other address or addresses as may have been furnished in writing by such Investor to the Company.

Notices provided in accordance with this Section 5.6 shall be deemed delivered upon personal delivery, one business day after being sent via a reputable nationwide overnight courier service, or two business days after deposit in the mail.

### 5.7. Complete Agreement; Amendments; Waivers.

(a) This Agreement constitutes the full and complete agreement of the parties hereto with respect to the subject matter hereof.

(b) This Agreement may be amended at any time by a written instrument signed by the Company and Stockholders holding at least a majority of the Registrable Shares. The applicability of any provisions of this Agreement in a particular instance may be waived by the party entitled to the benefit of such provision(s) as follows: in the case of the Company, by written instrument signed on behalf of the Company by a duly authorized officer; and in the case of the Stockholders, by a written instrument signed by the Stockholders holding at least a majority of the Registrable Shares. No waivers of or exceptions to any term, condition or provision of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision. Any such amendment or waiver effected in accordance with this Section 5.7(b) shall be binding on all parties hereto, even if they did not consent to such amendment or waiver.

5.8. Construction. A reference to a Section or Exhibit shall mean a Section in or Exhibit to, this Agreement unless otherwise expressly stated. The titles and headings herein are for reference purposes only and shall not in any manner limit the construction of this Agreement which shall be considered as a whole. The words “include,” “includes” and “including” when used herein shall be deemed in each case to be followed by the words “without limitation.” Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa.

5.9. Counterparts; Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one Agreement binding on all the parties hereto. This Agreement may be executed by facsimile signatures.

5.10. Aggregation of Shares. All shares of capital stock of the Company held or acquired by affiliated entities or persons shall be aggregated together for the purpose of determining the availability of any rights under this Agreement.

**[Remainder of this page intentionally left blank.]**

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IN WITNESS WHEREOF, this Second Amended and Restated Investors' Rights Agreement has been executed under seal as of the date first written above.

**COMPANY:**

ARSANIS, INC.

By: /s/ Tillman Gerngross

Name: Tillman Gerngross

Title: President

**INVESTORS:**

ORBIMED PRIVATE INVESTMENTS IV LP

By: OrbiMed Capital GP IV LLC  
Its General Partner

By: OrbiMed Advisors LLC,  
Its Managing Member

By: /s/ Carl L. Gordon  
Name: Carl L. Gordon  
Title: Member

**INVESTORS:**

POLARIS VENTURE PARTNERS V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ William E. Bilodeau  
Name: William E. Bilodeau  
Title: Attorney-in-fact

POLARIS VENTURE PARTNERS ENTREPRENEURS'  
FUND V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ William E. Bilodeau  
Name: William E. Bilodeau  
Title: Attorney-in-fact

POLARIS VENTURE PARTNERS FOUNDERS'  
FUND, V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ William E. Bilodeau  
Name: William E. Bilodeau  
Title: Attorney-in-fact

POLARIS VENTURE PARTNERS SPECIAL  
FOUNDERS' FUND V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ William E. Bilodeau  
Name: William E. Bilodeau  
Title: Attorney-in-fact



**INVESTORS:**

SV LIFE SCIENCES FUND V, L.P.

By: SV Life Sciences Fund V (GP), L.P.,  
Its sole General Partner

By: SVLSF V, LLC,  
Its sole General Partner

By: /s/ Denise W. Marks  
Name: Denise W. Marks  
Title: SVLSF V, LLC, Member

SV LIFE SCIENCES FUND V STRATEGIC PARTNERS,  
L.P.

By: SV Life Sciences Fund V (GP), L.P.,  
Its sole General Partner

By: SVLSF V, LLC,  
Its sole General Partner

By: /s/ Denise W. Marks  
Name: Denise W. Marks  
Title: SVLSF V, LLC, Member

**INVESTORS:**

NEOMED INNOVATION V L.P.

By: /s/ Peter Canham  
Name: Peter Canham  
Title: Alternative Director

By: /s/ Tamara Williams  
Name: Tamara Williams  
Title: Director

**INVESTORS:**

EMBL TECHNOLOGY FUND II GMBH & CO. KG

By: EMBL VENTURES VERWALTUNGS GMBH, its  
General Partner

By: /s/ Jan Adams

Name: Jan Adams

Title: Executive Director

By: /s/ Stefan Herr

Name: Stefan Herr

Title: Executive Director

**INVESTORS:**

Anna-Maria and Stephen Kellen Foundation, Inc.

By: /s/ Michael M. Kellen

Name: Michael M. Kellen

Title: President

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
RIGHTS AGREEMENT**

The undersigned is executing and delivering this Joinder Agreement pursuant to the Second Amended and Restated Investors' Rights Agreement dated as of April 12, 2016, as amended by that certain First Amendment to the Second Amended and Restated Investors' Rights Agreement dated as of April 24, 2017 (as so amended and as the same may be amended or amended and restated hereafter, the "**Agreement**"), by and among Arsanis, Inc., a Delaware corporation (the "**Company**") and the other parties named therein.

By executing and delivering to the Company this Joinder Agreement, the undersigned hereby (a) agrees that it is a party to the Agreement as an "Investor" and "Stockholder" (each as defined in the Agreement) for all purposes thereunder; and (b) adopts the Agreement as of the date written below, with the same force and effect as if the undersigned were originally a party thereto. Any notice required or permitted by the Agreement shall be given to Investor at the address or facsimile number listed below Investor signature hereto.

Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

**ALEXANDRIA VENTURE INVESTMENTS, LLC,**  
a Delaware limited liability company

By: ALEXANDRIA REAL ESTATE EQUITIES, INC.,  
a Maryland corporation, managing member

By: /s/ Aaron Jacobson  
Name: Aaron Jacobson  
Title: VP – Corporate Counsel

Address: 385 E. Colorado Blvd., Suite 299  
Pasadena, CA 91101 Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo  
Name: Rene Russo  
Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

**GV 2016, L.P.**

By: GV 2016 GP, L.P., its General Partner

By: GV 2016 GP, L.L.C., its General Partner

By: /s/ Jennifer L. Kercher

Name: Jennifer L. Kercher

Title: Authorized Signatory

Address:

Attn: Jennifer L. Kercher

c/o GV

1600 Amphitheatre Parkway

Mountain View, CA 94043

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo

Name: Rene Russo

Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

**N5 Investment AS**

By: /s/ Pål R. Jenson  
Pål Jenson, an authorized person, for and on its behalf

Address:

Parkveien 55  
0256 Oslo  
Norway

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo  
Name: Rene Russo  
Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

**Bill & Melinda Gates Foundation**

By: /s/ Jim Bromley  
Name: Jim Bromley  
Title: Chief Financial Officer

Address: 1432 Elliot Ave W.  
Seattle, WA 98119  
Attention: General Counsel

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo  
Name: Rene Russo  
Its: President and Chief Executive Officer



**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

**SV LIFE SCIENCES FUND VI, L.P.**

By: SV Life Sciences Fund VI (GP), L.P.,  
Its sole General Partner

By: SVLSF VI, LLC,  
Its sole General Partner

By: /s/ Denise W. Marks  
Name: **Denise W. Marks**  
Title: **SVLSF VI, LLC, Member**

Address: OneBoston Place  
201 Washington Street, Suite, 3900  
Boston, MA 02108  
Attn: Denise Marks

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo  
Name: Rene Russo  
Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

**SV LIFE SCIENCES FUND VI STRATEGIC PARTNERS,  
L.P.**

By: SV Life Sciences Fund VI (GP), L.P.,  
Its sole General Partner

By: SVLSF VI, LLC,  
Its sole General Partner

By: /s/ Denise W. Marks  
Name: **Denise W. Marks**  
Title: **SVLSF VI, LLC, Member**

Address: One Boston Place  
201 Washington Street, Suite, 3900  
Boston, MA 02108  
Attn: Denise Marks

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo  
Name: Rene Russo  
Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
RIGHTS AGREEMENT**

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By executing and delivering to the Company this Joinder Agreement, the undersigned hereby (a) agrees that it is a party to the Agreement as an "Investor" and "Stockholder" (each as defined in the Agreement) for all purposes thereunder; and (b) adopts the Agreement as of the date written below, with the same force and effect as if the undersigned were originally a party thereto. Any notice required or permitted by the Agreement shall be given to Investor at the address or facsimile number listed below Investor signature hereto.

Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

/s/ Tillman U. Gerngross

Tillman U. Gerngross

Address: \_\_\_\_\_

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo

Name: Rene Russo

Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of the 24 day of April, 2017.

/s/ Michael W. Bonney

\_\_\_\_\_  
Michael W. Bonney

Address: 536 Commercial Street  
Boston, MA 02109

Accepted and agreed:

ARSANIS, INC.

By: /s/ Rene Russo

\_\_\_\_\_  
Name: Rene Russo

Its: President and Chief Executive Officer

**JOINDER AGREEMENT TO SECOND AMENDED AND RESTATED INVESTORS'  
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The undersigned is executing and delivering this Joinder Agreement pursuant to the Second Amended and Restated Investors' Rights Agreement dated as of April 12, 2016, as amended by that certain First Amendment to the Second Amended and Restated Investors' Rights Agreement dated as of April 24, 2017 (as so amended and as the same may be amended or amended and restated hereafter, the "**Agreement**"), by and among Arsanis, Inc., a Delaware corporation (the "**Company**") and the other parties named therein.

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Accordingly, the undersigned has executed and delivered this Joinder Agreement as of September 1, 2017.

**SECTION 32 FUND 1, LP**

By: Section 32 GP 1, LLC  
its General Partner

By: /s/ Jennifer L. Kercher  
Jennifer L. Kercher  
Chief Operating Officer

ACCEPTED AND AGREED:

**ARSANIS, INC.**

By: /s/ Rene Russo

Name: René Russo

Its: President and Chief Executive Officer

EXHIBIT A

**SCHEDULE OF INVESTORS**

OrbiMed Private Investments IV, LP  
601 Lexington Avenue (at 53rd Street)  
54th Floor  
New York, NY 10022-4629

Polaris Venture Partners V, L.P.  
One Marina Park Drive, 10th Floor  
Boston, MA 02210

Polaris Venture Partners Entrepreneurs' Fund V, L.P.  
[Same address as above]

Polaris Venture Partners Founders' Fund V, L.P.  
[Same address as above]

Polaris Venture Partners Special Founders' Fund V, L.P.  
[Same address as above]

SV Life Sciences Fund V, L.P.  
One Boston Place  
201 Washington Street, Suite 3900  
Boston, MA 02108  
Attn: Denise Marks

SV Life Sciences Fund V Strategic Partners, L.P.  
[Same address as above]

SV Life Sciences Fund VI, L.P.  
[Same address as above]

SV Life Sciences Fund VI Strategic Partners, L.P.  
[Same address as above]

NeoMed Innovation V L.P.  
13, Castle Street  
Jersey, JE4 5UT  
cc to: claudio@neomed.net

EMBL Technology Fund II GmbH & Co. KG Boxbergring 107  
D-69126 Heidelberg  
Germany  
Attn: Jan Adams

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Anna-Maria and Stephen Kellen Foundation, Inc.  
1345 Avenue of the Americas, 48<sup>th</sup> Floor  
New York, NY 10105-0048  
Attn. Michael M. Kellen

Bill & Melinda Gates Foundation  
Address:

For UPS, FedEx, DHL:  
Bill & Melinda Gates Foundation  
1432 Elliott Ave West  
Seattle, WA 98119

For United States Postal Service  
Bill & Melinda Gates Foundation  
PO Box 23350  
Seattle, WA 98102

For Messengers & Courier Service  
Bill & Melinda Gates Foundation  
ATTN: Loading Dock  
500 Fifth Ave N  
Seattle, WA 98109-4636  
Fax No. 206.497.7100  
Attn: Jim Bromley, Chief Financial Officer

With a copy (which shall not constitute notice):  
Andrew Farnum, Director Program-Related Investments

With a copy (which shall not constitute notice):  
Claire White  
K&L Gates LLP  
925 4th Ave, Suite 2900  
Seattle WA, 98104

GV 2016, L.P.  
Email: [notice@gv.com](mailto:notice@gv.com)  
Attn: Jennifer L. Kercher  
c/o GV  
1600 Amphitheatre Parkway  
Mountain View, CA 94043

Alexandria Venture Investments, LLC  
385 E. Colorado Blvd., Suite 299  
Pasadena, CA 91101

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Michael W. Bonney  
536 Commercial Street  
Boston, MA 02109

N5 Investments AS  
Parkveien 55  
0256 Oslo  
Norway

Tillman U. Gerngross

Section 32 Fund 1, LP  
2033 San Elijo Avenue #565  
Cardiff by the Sea, CA 92007



**ARSANIS, INC.**  
**FIRST AMENDMENT**  
**TO THE**  
**SECOND AMENDED AND RESTATED**  
**INVESTORS' RIGHTS AGREEMENT**

This FIRST AMENDMENT TO THE SECOND AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT (this "**Amendment**") is entered into as of April 24, 2017, by and among Arsanis, Inc. (the "**Company**") and the existing investors listed on the signature pages hereto under the heading "Investors" (the "**Existing Investors**"). Capitalized terms used herein but not defined herein shall have the meanings ascribed to them in the Rights Agreement (as defined below).

**RECITALS**

WHEREAS, the Existing Investors are holders of the Company's Series A Preferred Stock, Series B Preferred Stock and/or Series C Preferred Stock;

WHEREAS, the Company and the Existing Investors are parties to that certain Second Amended and Restated Investors' Rights Agreement dated as of April 12, 2016 (the "**Rights Agreement**");

WHEREAS, the Company proposes to issue and sell shares of its Series D Convertible Preferred Stock, \$0.001 par value per share (the "**Series D Preferred Stock**"), pursuant to the Series D Preferred Stock Purchase Agreement (the "**Purchase Agreement**") of even date herewith, to be entered into by the Company, the Existing Investors and certain new investors;

WHEREAS, the Company and the Existing Investors wish to amend the Rights Agreement to, among other things, clarify that the Series D Preferred Stock is deemed to be "Preferred Stock" as defined in the Recitals to the Rights Agreement;

WHEREAS, pursuant to Section 5.7(b) of the Rights Agreement, the Rights Agreement may be amended with the written consent of (i) the Company and (ii) the holders of a majority of the Registrable Shares (the "**Required Holders**");

WHEREAS, the undersigned Existing Investors constitute the Required Holders; and

WHEREAS, the parties intend that these recitals be a part of the Rights Agreement, as amended by this Amendment.

NOW, THEREFORE, in consideration of the mutual agreements, covenants and considerations contained herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Amendments to the Rights Agreement.

1.1 Preamble. The Preamble to the Rights Agreement is hereby replaced in its entirety to read as follows:

“This Second Amended and Restated Investors’ Rights Agreement, as amended from time to time (this “Agreement”), is entered into this 12th day of April, 2016, by and among Arsanis, Inc., a Delaware corporation (the “Company”) and the individuals and entities listed on Exhibit A attached hereto (together with any subsequent investors, or transferees, who become parties hereto as “Investors” pursuant to Sections 5.2 and 5.7 below, the “Investors”).”

1.2 Definitions.

(a) The Rights Agreement is hereby amended such that the dollar amount “\$28.95” as it appears in the definition of “Initial Public Offering” therein is hereby deleted and replaced with the dollar amount “\$9.83.”

(b) The Rights Agreement is hereby amended so that the defined term “Preferred Stock” set forth therein (or herein) shall include the Series D Preferred Stock for all purposes thereunder (or hereunder), all terms defined in this Amendment shall apply as if set forth in full in the Rights Agreement, and in the event of any conflict between a term defined in the Rights Agreement and this Amendment, the meaning set forth in this Amendment shall control.

1.3 Excluded Issuances. Section 3.2(d) of the Rights Agreement is hereby replaced in its entirety to read as follows:

“up to 6,433,620 shares of Common Stock (inclusive of shares of Common Stock or options granted prior to April 24, 2017 under a plan), or options exercisable therefor (subject to appropriate adjustment for stock splits, stock dividends, reclassifications, recapitalizations and other similar events affecting such shares), plus such additional number of shares as may be approved by the Board of Directors of the Company, issued or issuable to officers, directors, consultants and employees of the Company or any subsidiary pursuant to any plan, agreement or arrangement approved by the Board of Directors of the Company;”

1.4 Financial Statements. The Rights Agreement is hereby amended such that number “150” as it appears in Section 4.2(a) thereof is hereby deleted and replaced with the number “180,” and such that the number “45” as it appears in Section 4.2(b) thereof is hereby deleted and replaced with the number “60.”

1.5 Confidentiality Obligations. The Rights Agreement is hereby amended such that a new sentence is added to Section 4.4 at the end thereof as follows:

“Notwithstanding the foregoing, nothing in this Agreement will prevent or limit the Company from fulfilling its obligations under, or the rights of the Bill & Melinda Gates Foundation pursuant to, that certain letter agreement, dated on or about April 24, 2017, between the Company and the Bill & Melinda Gates Foundation (the “Letter Agreement”).”

1.6 Other Investments. Section 4.5 of the Rights Agreement is hereby replaced in its entirety to read as follows:

“The Company acknowledges that the Investor may be in the business of venture capital investing (or in the case of the Bill & Melinda Gates Foundation, is a charitable trust) and therefore, may review the business plans and related proprietary information of, or other confidential information relating to, many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement will preclude or in any way restrict the Investor from investing or participating in, or granting any funds or support to, any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.”

1.7 Transfer of Rights. The Rights Agreement is hereby amended so that the first sentence of Section 5.2 is replaced in its entirety to read as follows:

“This Agreement, and the rights and obligations of each Investor hereunder, may be assigned by such Investor (a) to any person or entity to which such Investor transfers a number of shares of Preferred Stock equal to not less than five percent (5%) of the total number of shares of Preferred Stock held by such Investor (subject to adjustment for any stock dividend, stock split, stock split-up, combination or shares or the like) immediately following the Initial Closing (as defined in the Purchase Agreement), (b) if the Investor is an individual, to any family member or trust or partnership established for such family member, (c) if the Investor is a corporation, partnership, limited liability company or other entity, to any current or former partner (including general partner and limited partner), shareholder, member, or other affiliate of the Investor, or (d) in the case of the Bill & Melinda Gates Foundation, to a charitable trust or other entity a majority of the trustees of which are also trustees of the Bill & Melinda Gates Foundation; provided that, in any case, the transferee is not a competitor of the Company as determined in good faith by the Board of Directors of the Company, and provided further that a private equity fund, venture capital fund or charitable organization shall not be considered a competitor of the Company for the purposes of this Section 5.2; provided further that such transferee shall provide written notice of such assignment to the Company and agree in writing to be bound by the terms and conditions set forth herein as if he, she or it were an original Investor and thereafter such transferee shall be deemed an “Investor” for purposes of this Agreement.”

1.8 Governing Law. The Rights Agreement is hereby amended such that the reference to “Subsection 5.6(b)” as it appears in Section 5.5(a) thereof is hereby deleted and replaced with the reference to “Subsection 5.5(b),” and such that the reference to “Subsection 5.6(a)” in Section 5.5(b) thereof is hereby deleted and replaced with the reference to “Subsection 5.5(a).”

1.9 Amendments; Waivers. Section 5.7 of the Rights Agreement is hereby amended as follows:

(i) Section 5.7(a) is replaced in its entirety to read as follows:

“This Agreement constitutes the full and complete agreement of the parties hereto with respect to the subject matter hereof; provided, that, in the case of the Gates Foundation, this Agreement and the Letter Agreement, taken together, constitute the full and complete agreement of the Gates Foundation and the Company with respect to the subject matter hereof.”

(ii) Section 5.7(b) is amended by adding a new sentence at the end thereof as follows:

“Notwithstanding the foregoing, the provisions of Section 4.4 and 5.7(a) that are specific to the Bill & Melinda Gates Foundation, and Section 5.2(d), may not be amended or waived without the written consent of the Bill & Melinda Gates Foundation.”

(iii) Section 5.7 is amended by adding a new Section 5.7(c) at the end thereof as follows:

“(c) Notwithstanding anything else to the contrary in this Section 5.7, no consent shall be necessary to add additional Investors as signatories to this Agreement and to update Exhibit A accordingly; provided that such Investors have purchased Series D Preferred Stock pursuant to and in accordance with applicable terms and conditions of the Purchase Agreement. In such event, each such person thereafter shall be deemed an Investor and Stockholder for all purposes under this Agreement.”

1.10 Exhibit A. Each individual or entity listed on Exhibit A attached hereto is hereby added to Exhibit A of the Rights Agreement, and the term “Investors” thereunder and hereunder shall include each such individuals and entities, subject to the execution by each such individual and entity of a counterpart signature page to the Rights Agreement, as amended by this Amendment.

2. No Further Amendment. The Rights Agreement, as amended by this Amendment, is hereby ratified and confirmed in all respects, shall continue in full force and effect and shall, together with this Amendment, be read and construed as a single agreement.

3. Successors and Assigns. This Amendment shall be binding upon and inure to the benefit of all of the parties to the Rights Agreement, their successors and assigns, heirs, devisees, legates and personal representatives.

4. Counterparts. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original for all purposes and all of which shall be deemed collectively to be one agreement.

5. Governing Law. This Amendment shall be governed by and construed under the laws of the State of Delaware as applied to agreements among Delaware residents entered into and to be performed entirely within Delaware.

*[Remainder of page intentionally left blank.]*

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**IN WITNESS WHEREOF**, the parties hereto have executed this First Amendment to the Second Amended and Restated Investors' Rights Agreement as of the date set forth in the first paragraph hereof.

**COMPANY:**

ARSANIS, INC.

By: /s/ Rene Russo

Name: Rene Russo

Title: President and Chief Executive Officer

*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*

**INVESTORS:**

ORBIMED PRIVATE INVESTMENTS IV LP

By: OrbiMed Capital GP IV LLC  
Its General Partner

By: OrbiMed Advisors LLC,  
Its Managing Member

By: /s/ Carl Gordon  
Name: Carl Gordon  
Title: Member

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*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*

**INVESTORS:**

POLARIS VENTURE PARTNERS V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ Max Eisenberg

Name: Max Eisenberg

Title: Attorney-in-fact

POLARIS VENTURE PARTNERS  
ENTREPRENEURS' FUND V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ Max Eisenberg

Name: Max Eisenberg

Title: Attorney-in-fact

POLARIS VENTURE PARTNERS FOUNDERS'  
FUND, V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ Max Eisenberg

Name: Max Eisenberg

Title: Attorney-in-fact

POLARIS VENTURE PARTNERS SPECIAL  
FOUNDERS' FUND, V, L.P.

By: Polaris Venture Management Co. V, L.L.C.,  
Its General Partner

By: /s/ Max Eisenberg

Name: Max Eisenberg

Title: Attorney-in-fact

*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*



**INVESTORS:**

SV LIFE SCIENCES FUND V, L.P.

By: SV Life Sciences Fund V (GP), L.P.,  
Its sole General Partner

By: SVLSF V, LLC,  
Its sole General Partner

By: /s/ Denise W. Marks  
Name: Denise W. Marks  
Title: SVLSF V, LLC, Member

SV LIFE SCIENCES FUND V STRATEGIC PARTNERS,  
L.P.

By: SV Life Sciences Fund V (GP), L.P.,  
Its sole General Partner

By: SVLSF V, LLC,  
Its sole General Partner

By: /s/ Denise W. Marks  
Name: Denise W. Marks  
Title: SVLSF V, LLC, Member

*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*

**INVESTORS:**

NEOMED INNOVATION V L.P.

By: /s/ Tamara Williams  
Name: Tamara Williams  
Title: Director

By: /s/ James Keating  
Name: James Keating  
Title: Director

ACTING BY ITS GENERAL PARTNER  
NEOMED INNOVATION V LIMITED

*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*

**INVESTORS:**

EMBL TECHNOLOGY FUND II GMBH & CO. KG

By: EMBL VENTURES VERWALTUNGS GMBH, its  
General Partner

By: /s/ Dr. Jan Adams  
Name: Jan Adams  
Title: Managing Director

By: /s/ Dr. Stefan Herr  
Name: Stefan Herr  
Title: Managing Director

*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*

**INVESTORS:**

Anna-Maria and Stephen Kellen Foundation, Inc.

By: /s/ Michael M. Kellen

Name: Michael M. Kellen

Title: President

*Signature page to First Amendment to Second Amended and Restated Investors' Rights Agreement*

EXHIBIT A

Bill & Melinda Gates Foundation  
Address:

For UPS, FedEx, DHL:  
Bill & Melinda Gates Foundation  
1432 Elliott Ave West  
Seattle, WA 98119

For United States Postal Service  
Bill & Melinda Gates Foundation  
PO Box 23350  
Seattle, WA 98102

For Messengers & Courier Service  
Bill & Melinda Gates Foundation  
ATTN: Loading Dock  
500 Fifth Ave N  
Seattle, WA 98109-4636  
Fax No. 206.497.7100  
Attn: Jim Bromley, Chief Financial Officer

With a copy (which shall not constitute notice):  
Andrew Farnum, Director Program-Related Investments

With a copy (which shall not constitute notice):  
Claire White  
K&L Gates LLP  
925 4th Ave, Suite 2900  
Seattle WA, 98104

GV 2016, L.P.  
Email: [notice@gv.com](mailto:notice@gv.com)  
Attn: Jennifer L. Kercher  
c/o GV  
1600 Amphitheatre Parkway  
Mountain View, CA 94043

Alexandria Venture Investments, LLC  
385 E. Colorado Blvd., Suite 299  
Pasadena, CA 91101

Michael W. Bonney  
536 Commercial Street  
Boston, MA 02109

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N5 Investments AS  
Parkveien 55  
0256 Oslo  
Norway

SV Life Sciences Fund VI, L.P.  
One Boston Place  
201 Washington Street, Suite 3900  
Boston, MA 02108  
Attn: Denise Marks

SV Life Sciences Fund VI Strategic Partners, L.P.  
One Boston Place  
201 Washington Street, Suite 3900  
Boston, MA 02108  
Attn: Denise Marks

Tillman U. Gerngross

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

Execution Copy  
CONFIDENTIAL

### OPTION AND LICENSE AGREEMENT

**THIS OPTION AND LICENSE AGREEMENT** (the “**Agreement**”) is made effective as of February 27, 2017 (the “**Effective Date**”), by and between **ADIMAB, LLC**, a Delaware limited liability company having an address at 7 Lucent Drive, Lebanon, NH 03766 (“**Adimab**”), and **ARSANIS INC.**, a Delaware corporation having an address at 890 Winter Street, Suite 230, Waltham, MA 02451-1472 (“**Arsanis**”).

### BACKGROUND

**WHEREAS**, Adimab has proprietary antibodies against RSV;

**WHEREAS**, Arsanis desires to develop, manufacture and commercialize one or more RSV Antibodies against RSV in accordance with the terms hereof; and

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Adimab and Arsanis hereby agree as follows:

### ARTICLE 1

#### DEFINITIONS.

The following initially capitalized terms have the following meanings (and derivative forms of them shall be interpreted accordingly):

**1.1 “Adimab”** has the meaning set forth in the recitals.

**1.2 “Adimab Derived Antibody”** has the meaning set forth in Section 1.7(b) (*Adimab RSV Antibody*).

**1.3 “Adimab Indemnitees”** has the meaning set forth in Section 8.2 (*Indemnification by Arsanis*).

**1.4 “Adimab Materials”** means any tangible biological or chemical materials (including all [\*\*] and other [\*\*] in the form of tangible biological or chemical materials) used or created by Adimab under a previously performed RSV research program, [\*\*].

**1.5 “Adimab Platform Patents”** means all Patents [\*\*] the [\*\*] that [\*\*]. For clarity, Adimab Platform Patents specifically exclude: (a) RSV Antibody Patents; and (b) any Patents Controlled by Adimab to the extent that they Cover any invention or subject matter other than the manner in which Adimab discovered the Adimab RSV Antibodies.

**1.6 “Adimab Platform Technology”** means (a) methods of discovery and optimization of antibodies, which methods include the use of synthetic DNA antibody libraries and engineered strains of yeast and interrogating repertoires generated through B-cell cloning, (b) all methods, materials and other Know-How used in the foregoing and (c) platforms embodying any of the foregoing in (a) or (b), or components, component steps or other portions thereof; in each case, solely to the extent the foregoing either (i) are Covered by Patents Controlled by Adimab or (ii) constitute Confidential Information of Adimab. For clarity, Adimab Platform Technology includes technology Controlled by, or confidential or proprietary to, Adimab that is used by Adimab in the discovery and optimization of any Adimab RSV Antibody, in each case based on the manner in which Adimab discovered or optimized such Adimab RSV Antibody, but not based on the specific composition of or any Sequence information regarding such Adimab RSV Antibody (or any product containing an Adimab RSV Antibody), but Adimab Platform Technology excludes: (A) Adimab RSV Antibodies; and (B) technology Controlled by, or confidential or proprietary to, Adimab that is related to: (1) product formulation; (2) manufacturing, purification, or production; (3) modification or optimization of antibodies; (4) RSV (including any antigen representation thereof), or any mechanism of action via interaction with RSV, or methods of using antibodies based on their interaction with RSV; or (5) if other than an IgG, the construct of any Product.

**1.7 “Adimab RSV Antibody”** means:

(a) any RSV-specific antibody discovered or identified by or on behalf of Adimab, on or before the Effective Date, in any biological material obtained from a Donor, as listed on **Exhibit A** hereto (each, an **“Initial RSV Antibody”**); or

(b) any modified or derivative form of any Initial RSV Antibody (including an scFv or Fab) created by or on behalf of Adimab (whether before, on, or after the Effective Date), including any fragment or pegylated version (whether or not including amino acid changes) of an Initial RSV Antibody and including chemically modified versions (including associated amino acid substitutions) of an Initial RSV Antibody, and including an antibody designed or derived using the Sequence of any Initial RSV Antibody, polynucleotide encoding it, and any cell line or cellular or bacterial expression system or vector expressing any Initial RSV Antibody or incorporating the polynucleotide encoding an Initial RSV Antibody (in each case, an **“Adimab Derived Antibody”**). For clarity, any modified or derivative form of any Adimab Derived Antibody created by or on behalf of Adimab shall itself be an Adimab Derived Antibody.

**1.8 “Administrator”** has the meaning set forth in Section 10.4(b)(i) (*Arbitration*).

**1.9 “Affiliate”** means an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with a Party. For this purpose, “control” means the possession, directly or indirectly, of fifty percent (50%) or more of the voting securities entitled to elect the directors or management of the entity, or of the actual power to elect or direct the management of the entity.



**1.10 “Agreement”** has the meaning set forth in the recitals.

**1.11 “Antibody”** means any full-length antibody, fragment thereof, and chemically modified version thereof (including any pegylated versions and regardless of whether containing amino acid substitutions), all of the foregoing whether naturally occurring, artificially produced, raised in an artificial system, or created through modification of an antibody produced in any of the foregoing ways or otherwise, and whether represented by physical material, nucleic acid sequences, or amino acid sequences.

**1.12 “Arsanis”** has the meaning set forth in the recitals.

**1.13 “Arsanis Approvals”** has the meaning set forth in Section 3.6 (*Regulatory*).

**1.14 “Arsanis Derived Antibody”** means any modified or derivative form of an Adimab RSV Antibody (including an scFv or Fab) created by or on behalf of Arsanis or its Licensees or the Foundation, including any fragment or pegylated version (whether or not including amino acid changes) of an Adimab RSV Antibody and including chemically modified versions (including associated amino acid substitutions) of an Adimab RSV Antibody, and including an antibody designed or derived using the Sequence of any Adimab RSV Antibody, polynucleotide encoding it, and any cell line or cellular or bacterial expression system or vector expressing any Adimab RSV Antibody or incorporating the polynucleotide encoding an Adimab RSV Antibody. For clarity, any modified or derivative form of any Arsanis Derived Antibody shall itself be an Arsanis Derived Antibody.

**1.15 “Arsanis Indemnitees”** has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

**1.16 “Arsanis Invention”** means any invention, whether or not patentable, that is made solely by one or more employees, consultants or contractors of Arsanis in the course and as a result of: (a) the practice of the Research License during the Evaluation Term; or (b) the practice of the License or the discovery, optimization, research, development, manufacture or commercialization of Arsanis Derived Antibodies or Products during the Post-Exercise Term.

**1.17 “Arsanis Know-How”** shall mean all Know-How Controlled by Arsanis as of the effective date of termination of this Agreement that is necessary or useful for the development, manufacture or commercialization of RSV Antibodies in the Field, including, without limitation, all data and results of any research, preclinical, clinical, stability, toxicology or other study of any RSV Antibody conducted by or on behalf of Arsanis.

**1.18 “Arsanis Materials”** means (a) any tangible biological or chemical materials (including antigen samples and other Know-How in the form of tangible biological or chemical materials) created by Arsanis in the practice of the Research License or the License or in the development or manufacture of Licensed Antibodies and Products, and (b) from and after the time of the Option exercise, the quantities of Selected Antibody provided to Arsanis by Adimab under this Agreement.

**1.19 “Arsanis Patents”** means Patents Covering Arsanis Inventions.

1.20 “**Arsanis Regulatory Filings**” has the meaning set forth in Section 3.6 (*Regulatory*).

1.21 “**Assignment**” has the meaning set forth in Section 3.1(a) (*Assignment*).

1.22 “**Background Technology**” has the meaning provided in the Grant Documents. For clarity, Adimab RSV Antibodies are Background Technology, and will remain Background Technology even if (i) such Adimab RSV Antibodies are assayed or otherwise used in the performance of the Funded Project to generate data (understanding that such data may be Funded Developments rather than Background Technology) or (ii) Arsanis Derived Antibodies are created from them (understanding that such Arsanis Derived Antibodies may be Funded Developments rather than Background Technology).

1.23 “**Bankruptcy Laws**” has the meaning set forth in Section 10.2 (*Bankruptcy Code*).

1.24 “**Biosimilar**” means, with respect to a Product in a country, any pharmaceutical biologic product that (a) is similar to such Product; (b) has the same route of administration, dosage form and strength as such Product; (c) obtained regulatory approval under a biosimilar application submitted in accordance with the then-current rules and regulations in such country that referred to or relied on data submitted by Arsanis, or any of its Affiliates or Licensees, in an NDA for the Product in such country; and (d) is sold in the same country as such Product by a Third Party that is not a Licensee of Arsanis or its Affiliates and did not purchase such product in a chain of distribution that included any of Arsanis or its Affiliates or Licensees.

1.25 “**Blocking Arsanis Patents**” shall mean:

(a) in the case of (i) expiration of this Agreement pursuant to clause (a) of Section 9.1 (*Term*), or (ii) termination of this Agreement prior to Option exercise either (A) by Adimab pursuant to Section 9.2 (*Termination for Material Breach*) or (B) by Arsanis pursuant to Section 9.3 (*Termination for Convenience*): Arsanis Patents that, in the absence of a license thereunder, would be infringed by the manufacture, use, sale, offer for sale or import of any RSV Antibody; *provided, however*, that “Blocking Arsanis Patents” shall exclude any and all Patents licensed to Arsanis by any Third Party; and

(b) in the case of termination of this Agreement during the Post-Exercise Term either (i) by Adimab pursuant to Section 9.2 (*Termination for Material Breach*) or (ii) by Arsanis pursuant to Section 9.3 (*Termination for Convenience*): Arsanis Patents that, in the absence of a license thereunder, would be infringed by the manufacture, use, sale, offer for sale or import of any Adimab RSV Antibody; *provided, however*, that “Blocking Arsanis Patents” shall exclude any and all Patents licensed to Arsanis by any Third Party.

1.26 “**CDR**” means the complementarity determining regions of an antibody.

1.27 “**Combination Product**” means a product containing a Licensed Antibody in combination with one or more Other Active(s).

**1.28 “Commercially Reasonable Efforts”** means with respect to Arsanis’ obligation under this Agreement to conduct a particular activity, a level of efforts and resources similar to those efforts and resources normally used by Arsanis for a similar product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential, based on conditions then prevailing and taking into account safety, efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the product, the regulatory structure involved, the market potential and profitability of the product, and other relevant scientific, technical and commercial factors.

**1.29 “Companion Diagnostic”** means an *in vitro* diagnostic device consisting of or containing Licensed Antibody(ies) that provides information for the safe and effective use of a particular therapeutic Product, where the use of such *in vitro* diagnostic device is stipulated in the instructions for use in the labeling of both such *in vitro* diagnostic device and the corresponding therapeutic Product approved by the applicable Regulatory Authority.

**1.30 “Compulsory License”** means, in the case of a Product in a country, a compulsory license obtained by a Third Party through the order, decree or grant of a Regulatory Authority or other governmental authority of such country, authorizing such Third Party to manufacture, use, sell, offer for sale or import such Product in such country.

**1.31 “Confidential Information”** has the meaning set forth in Section 6.1(a) (*Confidential Information*).

**1.32 “Control”** means, with respect to any Know-How or Patent[\*\*]other than pursuant to this Agreement[\*\*] of the [\*\*] as provided for in this Agreement without violating the terms of any written agreement with any Third Party.

**1.33 “Cover”** or “**Covering**” or the like, means, with respect to a particular Licensed Antibody or Product and a particular Patent, that the [\*\*] of such [\*\*] or [\*\*].

**1.34 “Disclosing Party”** has the meaning set forth in Section 6.2 (*Exclusions from Nondisclosure Obligation*).

**1.35 “Dispute”** has the meaning set forth in Section 10.4(a) (*Initial Dispute Resolution*).

**1.36 “Donor”** means either of the human donors identified by Adimab as “patient #[\*\*]” and “patient #[\*\*].”

**1.37 “Effective Date”** has the meaning set forth in the recitals.

**1.38 “EMA”** means the European Medicines Agency or any successor agency thereto in the European Union having substantially the same function.

**1.39 “Evaluation Term”** means the time period beginning upon the Effective Date and ending on the earlier of (a) [\*\*] months from the date upon which Adimab has delivered to Arsanis both (i) the Sequences of all Adimab RSV Antibodies and (ii) [\*\*] IgG material of each of the Highest-Affinity Initial RSV Antibodies, and (b) the date that is [\*\*] days after Arsanis receives funding from the Foundation for the conduct of the Funded Project activities described under “Milestone 3 – Phase 1 ready” in the Grant Documents which funding is payable upon achievement of “Milestone 2 – Process Lock” as described in the Grant Documents.

1.40 “**Evaluation Term Data**” has the meaning set forth in Section 2.9 (*Effect of Expiration of Option Without Exercise*).

1.41 “**Evaluation Term Patents**” means any application for an Arsanis Patent filed by or on behalf of Arsanis during the Evaluation Term that Covers any Arsanis Derived Antibody and all Arsanis Patents corresponding to such patent application.

1.42 “**Excluded Technology**” means Third Party technology (and the Patents that Cover and the Know-How that embodies such Third Party technology) related to:

[\*\*].

1.43 “**FDA**” means the United States Food and Drug Administration or any successor agency thereto in the U.S. having substantially the same function.

1.44 “**Field**” means all indications and uses; *provided, however*, that if Arsanis proposes to commercialize any Product as a diagnostic (other than as a Companion Diagnostic) or as a research reagent, the Parties will first negotiate commercially reasonable financial terms for such field of use. For clarity: (a) no further negotiation will be required for the development, manufacture, or commercialization of any Companion Diagnostic; (b) Arsanis shall pay royalties with respect to Net Sales of Companion Diagnostics in accordance with Section 4.3 of this Agreement; (c) no Milestone Payments shall be payable with respect to any Companion Diagnostic; and (d) no other or additional financial terms will apply to the development, manufacture, or commercialization of any Companion Diagnostic.

1.45 “**First Commercial Sale**” means, with respect to a Product in any country, the first sale, transfer or disposition for value or for end use or consumption of such Product in such country after Marketing Approval (and, if legally required, pricing approval) for such Product has been received in such country.

1.46 “**First Product**” has the meaning set forth in Section 4.2(a) (*Milestone Events*).

1.47 “**Force Majeure**” means conditions beyond a Party’s reasonable control or ability to plan for, including acts of God, war, terrorism, civil commotion, labor strike or lock-out; epidemic; failure or default of public utilities or common carriers; and destruction of facilities or materials by fire, earthquake, storm or like catastrophe.

1.48 “**Foundation**” means the Bill & Melinda Gates Foundation or its designee(s).

1.49 “**Foundation Rights**” means the licenses and other rights granted by Arsanis to the Foundation under the Grant Documents with respect to Funded Developments and any Background Technology incorporated into a Funded Development or required to use a Funded Development.

**1.50 “FTE”** means the equivalent of a full-time employee’s working days over a twelve (12) month period (taking account of normal vacations, sick days and holidays not being considered working days), which equates to a total of [\*\*] hours per twelve (12) month period of work performed by a fully qualified Adimab employee or consultant. To provide an FTE over a given period that is less than a year means to provide the proportionate share (corresponding to the proportion that such period bears to a full year) during such period of a full year’s FTE.

**1.51 “FTE Rate”** means [\*\*] dollars (\$[\*\*]) per FTE.

**1.52 “Fully Paid Product”** has the meaning set forth in Section 9.5(b)(i)(2)(A) (*Termination But For Fully-Paid Products*).

**1.53 “Funded Developments”** has the meaning provided in the Grant Documents.

**1.54 “Funded Project”** means the project described in the Project Plan incorporated by reference in the Grant Documents.

**1.55 “Global Access Commitment”** means Arsanis’ obligations described under the heading “Global Access” in the “Terms and Conditions” included in the Grant Documents.

**1.56 “Grant Documents”** means the Grant Agreement between Arsanis and the Foundation dated as of February 20, 2017, including all Attachments thereto.

**1.57 “Highest-Affinity Initial RSV Antibodies”** has the meaning set forth in Section 2.3 (*Delivery of Adimab RSV Antibodies*).

**1.58 “IND”** means: (a) in the United States, an Investigational New Drug application (as more fully described in 21 CFR Part 312, or its successor regulation), filed with the FDA, or any successor application to the foregoing; or (b) in any other country or group of countries, the equivalent application or filing filed with the governing Regulatory Authority in such country or group of countries necessary to commence human clinical trials in such jurisdiction.

**1.59 “Indemnified Party”** has the meaning set forth in Section 8.3 (*Indemnification Procedures*).

**1.60 “Indemnify”** has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

**1.61 “Indemnifying Party”** has the meaning set forth in Section 8.3 (*Indemnification Procedures*).

**1.62 “Indemnitees”** has the meaning set forth in Section 8.3 (*Indemnification Procedures*).

**1.63 “Initial RSV Antibody”** has the meaning set forth in Section 1.7(a) (*Adimab RSV Antibody*).

**1.64 “Know-How”** means all technical information and know-how in any tangible or intangible form, including (a) inventions, discoveries, trade secrets, data, specifications, instructions, processes, formulae, materials (including cell lines, vectors, plasmids, nucleic acids and the like), methods, protocols, expertise and any other technology, including the applicability of any of the foregoing to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and (b) all data, instructions, processes, formulae, strategies, and expertise, whether biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical, analytical, or otherwise and whether related to safety, quality control, manufacturing or other disciplines; that, in each case, are not in the public domain. Notwithstanding the foregoing, Know-How excludes Patent claims.

**1.65 “License”** has the meaning set forth in Section 3.1(b) (*License*).

**1.66 “Licensed Antibody”** means: (a) any Selected Antibody; or (b) any Arsanis Derived Antibody created from any Selected Antibody, whether before or after exercise of the Option.

**1.67 “Licensee”** means a Third Party to whom Arsanis or its Affiliate has granted, directly or indirectly through one or more tiers of sublicense, a license, sublicense or other right to develop, manufacture, and/or commercialize any Licensed Antibody or Product; but specifically excluding (a) the Foundation and (b) any Third Party contract service provider. For clarity, licensees of RSV Antibody Patents and sublicensees of the License (excluding, in each case, the Foundation) shall be Licensees.

**1.68 “Licensee Agreement”** has the meaning set forth in Section 3.2 (*Licensees and Sublicensees*).

**1.69 “Losses”** has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

**1.70 “Major European Market”** means any of [\*\*].

**1.71 “Major Market”** means any of the [\*\*].

**1.72 “Marketing Approval”** means, within any given country, approval to market and sell a Product legally as a drug or biologic, including approval of an NDA. Pricing approval need not be obtained in order for Marketing Approval to be achieved.

**1.73 “Milestone Event”** has the meaning set forth in Section 4.2(a) (*Milestone Events*).

**1.74 “Milestone Payment”** has the meaning set forth in Section 4.2(a) (*Milestone Events*).

**1.75 “NDA”** means: (a) in the United States, as applicable, a New Drug Application (as more fully described in 21 CFR Part 314.50, et seq., or its successor regulation) or a Biologics License Application (as more fully described in 21 CFR Part 601, et seq., or its successor regulation), filed with the FDA, or any successor application to either of the foregoing; or (b) in any other country or group of countries, the equivalent application or submission for approval to market a pharmaceutical product filed with the governing Regulatory Authority in such country or group of countries.

**1.76 “Net Sales”** means the gross amounts invoiced for sales or other dispositions of Products (including Companion Diagnostics) by or on behalf of Arsanis, its Affiliates and Licensees, and to the extent such sales or other dispositions are not NGO Sales, the Foundation (each, a “**Selling Party**”) to Third Parties (other than a Selling Party), less the following deductions actually incurred, allowed, paid, accrued or otherwise specifically allocated to Products by the Selling Party (if not previously deducted in calculating the amount invoiced), all in compliance with applicable accounting standards, consistently applied by the Selling Party:

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NGO Sales shall not be deemed sales or other dispositions of Products for purposes of this definition of “Net Sales” or for purposes of Article 4 (*Financial Terms*) hereof except to the extent set forth in Section 1.77 (*NGO Sales*’).

For clarity, sale of a Product by a Selling Party to another Selling Party for resale by such entity to a Third Party (other than a Selling Party) shall not be deemed a sale for purposes of this definition of “Net Sales;” provided, however, that the first sale thereafter by a Selling Party to a Third Party (other than a Selling Party) shall be included in the computation of Net Sales. If a Selling Party sells or disposes of a Product to a Third Party (other than a Selling Party) in a country in a transaction that is not an arm’s-length sale (defined below), the gross amount invoiced for such Product for purposes of calculating Net Sales for such transaction shall be deemed to equal the weighted (by sales volume) average sale price of such Product in such country to arm’s-length purchasers during the calendar quarter in which such sale or disposition occurs. For purposes of the foregoing, an “arm’s-length sale” is a sale of Product solely for cash consideration to a Third Party that is unaffiliated with the Selling Party.

Further, transfers or dispositions of Products as free promotional samples in commercially reasonable amounts, consistent with prevailing pharmaceutical industry standards, or in any patient assistance, test marketing program, named-patient program or compassionate use program (so long as such Products are provided without charge or at or below the Selling Party’s cost), donated to non-profit institutions or government agencies, or used in research, development or regulatory activities, including, without limitation, clinical trials, shall be disregarded in determining Net Sales.

On a country-by-country basis, if a Product under this Agreement is sold in the form of a Combination Product in a country, Net Sales for the purpose of determining royalties due hereunder shall be calculated as follows:

(i) Where both Product containing the applicable Licensed Antibody as its sole active therapeutic ingredient (“**Single-Agent Product**”) and all Other Active(s) in such Combination Product are sold separately in such country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product in such country (as determined

without the application of this paragraph) by the fraction  $A/(A+B)$ , where A is the weighted average sale price (by sales volume) of Single-Agent Product in such country, and B is the weighted average sale price (by sales volume) of the Other Active(s) in the Combination Product when sold separately, in each case in the same dosage and dosage form and in the same country as the Combination Product during the applicable reporting period.

(ii) If Single-Agent Product is sold in such country, but none of the Other Active(s) is sold separately in such country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product in such country (as determined without the application of this paragraph) by the fraction  $A/C$ , where A is the weighted average sale price (by sales volume) of such Single-Agent Product in such country, and C is the weighted average sale price (by sales volume) of the Combination Product in such country.

(iii) If Single-Agent Product is not sold in such country, but the Other Active(s) are sold separately in such country, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product in such country (as determined without the application of this paragraph) by the fraction  $(C-D)/C$ , where C is the weighted average sale price (by sales volume) of the Combination Product in such country, and D is the sum of the weighted average sale price (by sales volume) of the Other Active(s) in the Combination Product when sold separately in such country.

(iv) If neither Single-Agent Product nor the Other Active(s) are sold separately in such country, Net Sales for the purpose of determining royalties due hereunder for the Combination Product shall be determined by mutual agreement of the Parties in good faith based on the relative value contributions of the Licensed Antibody and the Other Active(s), such agreement not to be unreasonably withheld. If the Parties are unable to reach mutual agreement as to the relative value contributions of the Licensed Antibody and the Other Active(s), such relative value contributions shall be determined in accordance with Section 10.4 (*Dispute Resolution*).

**1.77 “NGO Sales”** means sales and dispositions of Products (including Companion Diagnostics) by or on behalf of the Selling Parties in fulfillment of the Global Access Commitment, to the extent that the gross amounts invoiced and the fair market value of non-cash consideration received by the Selling Parties for such sales and dispositions of Products does not exceed the sum of: (a) the Selling Party’s fully-burdened cost of goods of such Products; (b) excise taxes, use taxes, tariffs, sales taxes and customs duties and/or other government charges or fees imposed on the sale of such Products (including VAT); and (c) outbound freight, shipment, insurance and other distribution costs for such Products. For clarity, to the extent that the gross amounts invoiced and the fair market value of non-cash consideration received by the Selling Parties for sales and dispositions of Products (including Companion Diagnostics) in fulfillment of the Global Access Commitment exceed the sum of (a), (b) and (c) in the foregoing sentence, the amount of such excess shall be included in the calculation of “Net Sales” (and shall not be considered “NGO Sales”).

**1.78 “Option”** has the meaning set forth in Section 2.2(b) (*Option*).

**1.79 “Option Fee”** has the meaning set forth in Section 4.1(b) (*Option Fee*).



**1.80 “Other Active”** means any active therapeutic ingredient other than a Licensed Antibody.

**1.81 “Other Arsanis Patents”** means all Arsanis Patents (other than Blocking Arsanis Patents) that claim inventions actually practiced by or on behalf of Arsanis in the manufacture, use, sale, offer for sale or import of any RSV Antibody prior to termination of this Agreement.

**1.82 “Party”** means Adimab or Arsanis.

**1.83 “Patent”** means any patent application or patent anywhere in the world, including all of the following categories of patents and patent applications, and their foreign equivalents: provisional, utility, divisional, continuation, continuation-in-part, and substitution applications; and utility, re-issue, re-examination, renewal and extended patents; and any rights associated with extended patent terms, including Patent Term Adjustment (PTA), Patent Term Extension (PTE), Supplementary Protection Certificates (SPC); and other similar rights.

**1.84 “Phase I Trial”** means a human clinical trial conducted in any country that would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a) (or any amended or successor regulations).

**1.85 “Phase II Trial”** means a human clinical trial conducted in any country that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or any amended or successor regulations).

**1.86 “Phase III Trial”** means a human clinical trial conducted in any country that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations).

**1.87 “PMDA”** shall mean the Japanese Pharmaceuticals and Medical Devices Agency or any successor agency thereto in Japan having substantially the same function.

**1.88 “Post-Exercise Term”** means the portion of the Term beginning upon Arsanis’ exercise of the Option in accordance with Section 2.2(b) (*Option*).

**1.89 “Product”** means any pharmaceutical product (whether or not such product has received Marketing Approval) that comprises or contains one or more Licensed Antibodies (whether or not as the sole active ingredient(s)), including, without limitation, any Companion Diagnostic.

**1.90 “Receiving Party”** has the meaning set forth in Section 6.2 (*Exclusions from Nondisclosure Obligation*).

**1.91 “Regulatory Authority”** shall mean any national, supranational or other regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction, including the FDA in the U.S., the EMA in the European Union, and the PMDA in Japan.

1.92 “**Research License**” has the meaning set forth in Section 2.2(a) (*Research License to Arsanis*).

1.93 “**Research Plan**” has the meaning set forth in Section 2.3 (*Delivery of Adimab RSV Antibodies*).

1.94 “**Royalty Payment**” has the meaning set forth in Section 4.3(a) (*Royalty Payments*).

1.95 “**Royalty Term**” means, on a Product-by-Product and country-by-country basis, the term beginning on First Commercial Sale of a Product in a country and ending at the later of twelve (12) years after the First Commercial Sale of such Product in such country and (b) the expiration of the last Valid Claim of an RSV Antibody Patent listed on **Exhibit B** hereto (or a Patent claiming priority to an RSV Antibody Patent listed on **Exhibit B** hereto) Covering such Product in such country.

1.96 “**RSV**” means respiratory syncytial virus.

1.97 “**RSV Antibodies**” means, collectively, Adimab RSV Antibodies and Arsanis Derived Antibodies.

1.98 “**RSV Antibody Patents**” means those Patents that Cover Adimab RSV Antibodies, including those Patents set forth on **Exhibit B** hereto. RSV Antibody Patents exclude: (a) Adimab Platform Patents; and (b) those Patents that Cover Arsanis Derived Antibodies (except to the extent any claim of any such Patent claims priority to any of the Patents set forth on **Exhibit B** hereto).

1.99 “**Rules**” has the meaning set forth in Section 10.4(b)(i) (*Arbitration*).

1.100 “**Sale Transaction**” has the meaning set forth in Section 10.7 (*Assignment*).

1.101 “**Second Product**” has the meaning set forth in Section 4.2(a) (*Milestone Events*).

1.102 “**Selected Antibody**” has the meaning set forth in Section 2.2(b) (*Option*).

1.103 “**Selling Party**” has the meaning provided in Section 1.766 (*Net Sales*).

1.104 “**Senior Executive Discussions**” has the meaning set forth in Section 10.4(a) (*Initial Dispute Resolution*).

1.105 “**Sequence**” means, with respect to any Antibody, the amino acid sequence of such Antibody and the corresponding nucleic acid sequences encoding such Antibody.

1.106 “**Single Agent Product**” has the meaning set forth in Section 1.76 (*Net Sales*).

1.107 “**Term**” shall have the meaning set forth in Section 9.1 (*Term*).

1.108 “**Third Party**” means an entity other than a Party or a Party’s Affiliates.

**1.109 “Third Party Acquirer”** has the meaning set forth in Section 10.7 (*Assignment*).

**1.110 “Third Party Claims”** has the meaning set forth in Section 8.1 (*Indemnification by Adimab*).

**1.111 “Third Party Patent License”** means a license under a Patent of a Third Party that Arsanis determines in good faith is reasonably required for the manufacture, use, sale, offer for sale or import of a Licensed Antibody or Product in order to avoid potential Third Party claims of patent infringement based on the way in which Adimab discovered an Adimab RSV Antibody using Adimab Platform Technology. For clarity, Third Party Patent Licenses explicitly excludes (a) licenses to any Patent other than a Patent Covering the way in which an Adimab RSV Antibody was discovered using Adimab Platform Technology and (b) licenses to Excluded Technology.

**1.112 “Unrestricted RSV Antibody”** means any RSV-specific antibody that is not an RSV Antibody.

**1.113 “Valid Claim”** means a claim of a Patent, which claim (a) is issued and unexpired and has not been found to be unpatentable, invalid or unenforceable by a court or other authority having jurisdiction, from which decision no appeal is taken, will be taken or can be taken; or (a) is pending and has not been finally abandoned or finally rejected and has been pending for no more than seven (7) years.

**1.114** References in the body of this Agreement to “Sections” or “Articles” refer to the sections or articles of this Agreement. The terms “include,” “includes,” “including” and derivative forms of them shall be deemed followed by the phrase “without limitation” regardless of whether such phrase appears there (and with no implication being drawn from its inconsistent inclusion or non-inclusion) and the term “or” has the inclusive meaning represented by the phrase “and/or” (regardless of whether it is actually written and drawing no implication from the actual use of the phrase “and/or” in some instances but not in others).

## ARTICLE 2

### RESEARCH LICENSE AND OPTION; EVALUATION OF RSV ANTIBODIES.

**2.1 Alliance Managers.** Each Party shall designate in writing within [\*\*] days after the Effective Date an “Alliance Manager” to be the primary contact for such Party. A Party may replace its Alliance Manager at any time upon written notice to the other Party. The Alliance Managers shall be responsible for managing communications between the Parties with respect to this Agreement.

#### 2.2 Grants to Arsanis During Evaluation Term.

**(a) Research License to Arsanis.** Subject to the terms and conditions of this Agreement, Adimab hereby grants Arsanis, during the Evaluation Term, an exclusive, fully-paid, royalty-free, non-sublicensable license under the Adimab Platform Patents, Adimab Platform Technology, and RSV Antibody Patents, to create, research, optimize, make, have made and use RSV Antibodies, including Arsanis Derived Antibodies, in the Field for the purposes of (i) determining whether to exercise the Option and (ii) identifying the Adimab RSV Antibodies (if any) with respect to which Arsanis wishes to exercise the Option (the “**Research License**”). For the avoidance of doubt, the Research License specifically excludes the right to use the Adimab Platform Technology to discover or optimize antibodies.

**(b) Option.** Adimab hereby grants to Arsanis, during the Evaluation Period, the exclusive option (the “**Option**”) to obtain the Assignment and License for up to [\*\*] Adimab RSV Antibodies selected by Arsanis in its sole discretion. Arsanis may exercise the Option at any time on or before the expiry of the Evaluation Term by delivering written notice to Adimab identifying the Adimab RSV Antibodies with respect to which Arsanis is exercising the Option (each, a “**Selected Antibody**”), not to exceed [\*\*] Selected Antibodies, no later than the expiry of the Evaluation Term, and paying the Option Fee to Adimab within [\*\*] days after delivery of such notice.

**2.3 Delivery of Adimab RSV Antibodies.** As promptly as practicable (and in any event within [\*\*] days) after the Effective Date, Adimab shall deliver to Arsanis: (a) [\*\*]. It is understood and agreed that [\*\*] and [\*\*], the [\*\*] an Adimab RSV Antibody. In addition, as promptly as reasonably practicable after the Effective Date, [\*\*], and the [\*\*], by mutual agreement of the Parties. [\*\*] a written research plan for the [\*\*] (the “**Research Plan**”), which shall set forth the [\*\*] described therein, and each Party shall [\*\*]. Adimab shall [\*\*]. If [\*\*], Adimab will [\*\*].

**2.4 Reports.** During the Evaluation Period, Arsanis shall provide [\*\*] written reports to Adimab summarizing the research and development activities conducted by or on behalf of Arsanis with respect to RSV Antibodies during the preceding [\*\*] period. In addition, such report shall identify any stage completion milestone of the Funded Project that was achieved during such [\*\*] period. For the avoidance of doubt, in no event shall Arsanis have any obligation to disclose to Adimab the Sequence of any Arsanis Derived Antibody.

## **2.5 Adimab Materials.**

**(a) Use of Adimab Materials During Evaluation Term.** During the Evaluation Term, Arsanis shall use the Adimab Materials solely within the scope of the Research License. Arsanis shall not use Adimab Materials for any other purposes. During the Evaluation Term, Arsanis shall not sell, transfer, disclose or otherwise provide access to the Adimab Materials, other Confidential Information of Adimab, or RSV Antibodies to any Third Party, except as expressly permitted by Section 2.5(b) (*Access to Adimab Materials Within Arsanis*) and 2.5(c) (*Third Party Access to Adimab Materials*).

**(b) Access to Adimab Materials Within Arsanis.** Arsanis may allow access to Adimab Materials, other Confidential Information of Adimab, and RSV Antibodies to those employees, officers and consultants of Arsanis who require such access in order to enable Arsanis to conduct activities with respect to the RSV Antibodies within the scope of the Research License for the purpose of determining whether to exercise the Option and identifying the Adimab RSV Antibodies (if any) with respect to which Arsanis wishes to exercise the Option; *provided, however*, that: (i) each such employee, officer or consultant is bound by obligations of confidentiality and non-use regarding Confidential Information of Adimab,

ownership, use and disposition of RSV Antibodies, including Adimab Materials, that, in each case, are no less protective of Adimab than the terms of this Agreement; and (ii) Arsanis shall at all times be fully responsible for its employees', officers' and consultants' compliance with this Agreement.

**(c) Third Party Access to Adimab Materials.** Arsanis may engage Third Party contractors to perform activities within the scope of the Research License on behalf of Arsanis; *provided, however*, that: (i) none of Adimab's rights hereunder are diminished or otherwise adversely affected as a result of such contracting; (ii) each such contractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information of Adimab, ownership, disposition, and use of RSV Antibodies, including Adimab Materials, that, in each case, are no less protective of Adimab than the terms of this Agreement; (iii) prior to initiating performance of any such activities on behalf of Arsanis, each such contractor has signed a binding agreement or instrument assigning, and agreeing to assign, to Arsanis all data and other work product relating to Adimab Materials and RSV Antibodies generated by such contractor; and (iv) Arsanis shall at all times be fully responsible for each such contractor's compliance with this Agreement.

**(d) Limits on Use of Adimab Materials.** Arsanis understands and agrees that Adimab Materials may have unpredictable and unknown chemical properties, that they are to be used with caution, and that, except as expressly permitted by Article 3 (*License and Assignment; Development & Commercialization*) following exercise of the Option, they are not to be used [\*\*]. At no time shall the physical Adimab Materials delivered by Adimab to Arsanis be [\*\*] for any purpose. Arsanis shall use Adimab Materials in compliance with all applicable laws and regulations.

**2.6 Title to Adimab Materials.** During the Evaluation Term, Adimab shall retain title to the Adimab Materials, including all quantities of Adimab RSV Antibodies delivered to Arsanis.

## **2.7 Adimab Retained Rights.**

**(a) Adimab Platform Technology.** Adimab will at all times retain the exclusive and absolute right to practice and license the Adimab Platform Technology and the Adimab Platform Patents for any and all purposes; *provided, however*, that during the Evaluation Term and the Post-Exercise Term, Adimab shall not deliver Adimab RSV Antibodies to any Third Party. For clarity, during the Evaluation Term, Adimab may use the Adimab Platform Technology to discover, optimize, develop, manufacture, and commercialize Unrestricted RSV Antibodies on behalf of itself or Third Parties without limitation. Except as set forth in this Section 2.7(a) (*Adimab Platform Technology*), nothing herein shall prevent Adimab from licensing or transferring some or all of the Adimab Platform Technology to a Third Party (including technical support in connection therewith) nor shall anything herein require Adimab to in any way limit the use of the Adimab Platform Technology by Adimab or a Third Party for purposes of generating antibodies against RSV.

**(b) Antibodies within Libraries.** Notwithstanding anything to the contrary in this Agreement, nothing herein shall require Adimab to physically remove from its antibody libraries any RSV Antibody that is included in any antibody library it has generated or will generate. Arsanis acknowledges that Adimab has transferred antibody libraries to numerous partners and may transfer additional antibody libraries to partners in the future, and that although statistically unlikely, it is theoretically possible that such antibody libraries contain antibodies with the same Sequence as an RSV Antibody. Adimab hereby reserves the right for Adimab to license or transfer any antibody library to Third Parties (including the transfer of physical possession of such antibody libraries, which may contain samples of an RSV Antibody included therein, to a Third Party as part of the transfer of libraries).

**(c) Clarifications.** For clarity, nothing contained in this Agreement shall be construed to prohibit or restrict Adimab from:

**(i)** using the Adimab Platform Technology to discover, optimize, develop, manufacture, and commercialize Unrestricted RSV Antibodies on behalf of itself or Third Parties;

**(ii)** licensing or transferring any Unrestricted RSV Antibody (including the transfer of physical possession of samples of any Unrestricted RSV Antibody) to any Third Party;

**(iii)** using or generating libraries which may include RSV Antibodies, subject to Adimab's compliance with Section 2.8(a) (*Adimab Negative Covenants*); or

**(iv)** licensing or transferring antibody libraries to any Third Party (including samples of any RSV Antibody contained in such libraries, but solely as contained in such libraries), subject to Adimab's compliance with Section 2.8(a) (*Adimab Negative Covenants*).

**2.8 Certain Negative Covenants.** The following covenants are in addition to any express covenants of the parties contained elsewhere in this Agreement.

**(a) Adimab Negative Covenants.** During the Evaluation Term, Adimab and its Affiliates shall not grant to any Third Party any license, option or other right under or with respect to any RSV Antibody Patent and shall not deliver any isolated Adimab RSV Antibody to any Third Party. Adimab further covenants that, during the Evaluation Term, if any Third Party to which Adimab or its Affiliate has transferred any antibody library that includes any Adimab RSV Antibody requests, or inquires as to the availability of, any license, option or other rights to any Adimab RSV Antibody, or requests the nucleic acid sequence or amino acid sequence of any Adimab RSV Antibody, or requests additional physical material of any Adimab RSV Antibody, Adimab or its Affiliate shall:

**(i)** inform such Third Party that rights to such Adimab RSV Antibody are not available and that Adimab's contractual obligations to another Adimab partner prohibit it from providing the sequence information for, or any additional physical material of, such Adimab RSV Antibody;

**(ii)** not disclose to such Third Party the Sequence information (to the extent that such sequence has not been published) for such Adimab RSV Antibody (it being understood that such Third Party may determine the Sequence of such Adimab RSV Antibody on its own initiative, and the same shall not constitute a breach of this Agreement by Adimab); and

(iii) not deliver any additional physical material of such Adimab RSV Antibodies to a Third Party.

**(b) Arsanis Negative Covenants.** Arsanis and its Affiliates shall not file any IND with respect to or conduct any clinical trial of any RSV Antibody during the Evaluation Term prior to Option exercise. Arsanis further covenants not to practice, and not to permit or cause any of its Affiliates or any Licensee or other Third Party to practice, any Adimab Platform Patents, Adimab Platform Technology or RSV Antibody Patents or Evaluation Term Patents for any purpose outside the express scope of the Research License during the Evaluation Term prior to Option exercise.

**2.9 Effect of Expiration of Option Without Exercise.** If the Evaluation Term expires without Arsanis having exercised the Option, then:

**(a)** effective as of such expiration, (i) the Research License and the Option shall terminate and be of no further force or effect, and (ii) [\*\*]; and

**(b)** within [\*\*] days after expiration of the Evaluation Term, Arsanis shall (i) either return to Adimab or destroy (at Adimab's direction) all quantities of Adimab RSV Antibodies (including Adimab Materials) remaining in the possession of Arsanis, (ii) destroy all quantities of Arsanis Derived Antibodies remaining in the possession of Arsanis, and (iii) deliver to Adimab [\*\*].

Additional consequences of expiration of the Evaluation Term without Arsanis having exercised the Option are set forth in Article 9 (*Term; Termination*) hereof.

### ARTICLE 3

#### LICENSE AND ASSIGNMENT; DEVELOPMENT & COMMERCIALIZATION

##### 3.1 Development and Commercialization License and Assignment.

**(a) Assignment.** Subject to the terms and conditions of this Agreement, effective on Arsanis' exercise of the Option, Adimab hereby assigns to Arsanis all right, title and interest in and to all Selected Antibodies and all RSV Antibody Patents (the "**Assignment**").

**(b) License.** Subject to the terms and conditions of this Agreement, effective on Arsanis' exercise of the Option, Adimab hereby grants to Arsanis a non-exclusive, worldwide license, including the right to sublicense through multiple tiers of sublicense in accordance with Section 3.2 (**Licensees and Sublicensees**), under the Adimab Platform Patents and Adimab Platform Technology, to research, develop, have developed, make, have made, use, sell, have sold, offer for sale, import and export Licensed Antibodies and Products in the Field (the "**License**") during the Term. For the avoidance of doubt, the License specifically excludes the right to use the Adimab Platform Technology to discover or optimize antibodies.

**3.2 Licensees and Sublicensees.** Arsanis shall have the right to grant licenses or sublicenses, through multiple tiers of sublicense, under the License and/or the RSV Antibody Patents, in each case solely with respect to any Licensed Antibody or Product. Any license or sublicense (or option to license or sublicense) of any Licensed Antibody or Product granted to any Licensee, and any direct or indirect license or sublicense (or option to license or sublicense) under the License and/or the RSV Antibody Patents granted to any Licensee, shall be made solely pursuant to a written agreement (a “**Licensee Agreement**”) that is consistent with all relevant terms and conditions of this Agreement and that includes the applicable Licensee’s express agreement to comply with all applicable terms of this Agreement, including, for clarity, Section 9.4 (*Commitments Regarding RSV Antibodies*). Arsanis shall remain responsible for all payments and other performance obligations due under this Agreement, notwithstanding any license or sublicense that it may grant.

**3.3 Additional Covenants.** The provisions of Section 2.8(a) (*Adimab Negative Covenants*) shall apply, *mutatis mutandis*, during the Post-Exercise Term. Arsanis covenants not to practice, and not to permit or cause any of its Affiliates or any Licensee or other Third Party to practice: (a) any Adimab Platform Patents or Adimab Platform Technology for any purpose outside the express scope of the License; or (b) the RSV Antibody Patents, and Arsanis Patents that Cover Arsanis Derived Antibodies (and solely with respect to the claims of such Arsanis Patents that Cover Arsanis Derived Antibodies), for the purpose of researching, developing, manufacturing or commercializing RSV Antibodies that are not Licensed Antibodies.

**3.4 Acknowledgment Regarding Arsanis Derived Antibodies.** Arsanis hereby acknowledges and agrees that, regardless of whether or not any of the manufacture, use, sale, offer for sale and import of an Arsanis Derived Antibody is Covered by, or would require the practice of, or a license under, any Adimab Platform Technology, Adimab Platform Patents or RSV Antibody Patents, all Arsanis Derived Antibodies, and all Products comprising or containing any Arsanis Derived Antibody, developed or commercialized by or on behalf of Arsanis or any of its Affiliates or Licensees, whether during or after the Term, and whether or not any such Arsanis Derived Antibody is a Licensed Antibody, are milestone- and royalty-bearing to Adimab in accordance with Article 4 of this Agreement; *provided, however*, that the foregoing shall not be construed as granting to Arsanis any license or other right under any Adimab Platform Technology, Adimab Platform Patents or RSV Antibody Patents, or any other Patents or Know-How Controlled by Adimab, to develop or commercialize any RSV-specific antibody other than as expressly permitted by this Agreement.

**3.5 Diligence.** During the Post-Exercise Term, Arsanis (directly or through its Affiliates or Licensees) shall use Commercially Reasonable Efforts: (a) to [\*\*]; (b) to [\*\*]; (c) to [\*\*]; and (d) following [\*\*].

**3.6 Regulatory.** During the Post-Exercise Term, Arsanis (itself or with or through its Affiliates or Licensees) shall be solely responsible for preparing and submitting all INDs, NDAs and other regulatory filings for Licensed Antibodies and Products in the Field (collectively, “**Arsanis Regulatory Filings**”), and for obtaining and maintaining all Marketing Approvals for Products in the Field (“**Arsanis Approvals**”), at Arsanis’ sole expense. All Arsanis Regulatory Filings and Arsanis Approvals shall be submitted in the name of, and owned by, Arsanis (or its Affiliate or Licensee, as applicable).



**3.7 Disclosure Regarding Arsanis Efforts.** After Arsanis' exercise of the Option: (a) prior to [\*\*] of a Product, Arsanis shall provide [\*\*] written reports to Adimab in [\*\*] of each year summarizing the [\*\*]; and (b) after [\*\*] of a Product, Arsanis shall provide [\*\*] written reports to Adimab in [\*\*] of each year summarizing the [\*\*]. In addition, any such report shall identify any stage completion milestone of the Funded Project that was achieved during the applicable [\*\*]month period.

**3.8 Acknowledgment of Foundation Rights.** Adimab acknowledges that Arsanis' activities under Article 2 and, if Arsanis exercises the Option, certain activities of Arsanis under this Article 3 constitute part of the Funded Project. Adimab further acknowledges that the funding provided by the Foundation to Arsanis for the Funded Project entitles the Foundation to the Foundation Rights and makes the Funded Developments and any Background Technology incorporated into a Funded Development or required to use a Funded Development subject to the Global Access Commitment both during and after the Term, regardless of whether or not Arsanis exercises the Option and notwithstanding the expiration or any termination of this Agreement.

## ARTICLE 4

### FINANCIAL TERMS.

#### 4.1 Pre-Clinical Fees

**(a) Research Funding.** Arsanis shall compensate Adimab on a calendar quarterly basis for Adimab's performance of its obligations under, and in accordance with, the Research Plan, in an amount determined by multiplying the actual FTEs expended by Adimab in the performance of such obligations during such calendar quarter by the FTE Rate. Adimab shall issue quarterly written invoices to Arsanis setting forth the actual FTEs expended by Adimab in performing such Research Plan obligations, which invoice shall describe the Research Plan activities performed, and Arsanis shall pay the invoiced amount within [\*\*] days of receipt.

**(b) Option Fee.** In order to exercise the Option under Section 2.2(b) (*Option*), Arsanis shall pay to Adimab a non-creditable, nonrefundable option exercise fee of [\*\*] dollars (\$[\*\*]) (the "*Option Fee*").

#### 4.2 Milestone Payments.

**(a) Milestone Events.** Subject to Section 4.2(b) (*Maximum Milestone Payments*) and Section 4.2(c) (*Catch-Up Payments*), Arsanis shall report in writing to Adimab the first achievement of each event set forth in the table below (each, a "**Milestone Event**") by (i) the first Product (excluding any Companion Diagnostic) to achieve such Milestone Event ("**First Product**") and (ii) the first Product (excluding any Companion Diagnostic) containing or incorporating a Licensed Antibody other than the Licensed Antibody contained or incorporated in the First Product ("**Second Product**"), and, in each case, pay the corresponding milestone payment set forth in the table below (each, a "**Milestone Payment**") to Adimab, each within [\*\*] days after the first achievement of the corresponding Milestone Event by such Product:

Milestone Event	Milestone Payment	
	First Product	Second Product
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

**(b) Maximum Milestone Payments.** For clarity, the maximum aggregate amount of Milestone Payments payable under this Section 4.2 (*Milestone Payments*) for any and all Products is twenty four million three hundred seventy five thousand dollars (\$24,375,000) (*i.e.*, a maximum aggregate of [\*\*] dollars (\$[\*\*]) for the first achievement of all Milestone Events by the First Product, and a maximum aggregate of [\*\*] dollars (\$[\*\*]) for the first achievement of all Milestone Events by a Second Product).

**(c) Catch-Up Payments.** If a later-stage clinical Milestone Event is achieved for any Product without one or more earlier-stage clinical Milestone Events having been achieved for that Product, then Arsanis shall pay the Milestone Payment(s) for such previous clinical Milestone Event(s) along with the payment for the most recently achieved clinical-stage Milestone Event. If a Milestone Event related to [\*\*] for any Product is achieved without one or more of the clinical Milestone Events being achieved for that Product, then Arsanis shall pay the Milestone Payment(s) for such previous clinical Milestone Event(s) along with the payment for the first Milestone Event related to filing of an NDA for such Product.

#### 4.3 Royalties.

**(a) Royalty Payments.** Subject to the remainder of Section 4.3 (*Royalties*), Arsanis shall pay Adimab, on a Product-by-Product and country-by-country basis, a royalty of [\*\*] percent ([\*\*]%) of Net Sales of a Product in a country during the applicable Royalty Term for such Product in such country (“**Royalty Payments**”). On a Product-by-Product and country-by-country basis, upon expiration of the Royalty Term with respect to a Product in a country, the License with respect to such Product in such country shall become royalty-free, fully-paid, irrevocable and perpetual.

**(b) Adjustment for Third Party IP.** If Arsanis enters into any Third Party Patent License, then [\*\*] percent ([\*\*]%) of the royalties actually paid to the Third Party under such Third Party Patent License with respect to sales of any given Product in any given calendar quarter in any given country may be offset against the Royalty Payment, if any, that would otherwise have been payable to Adimab with respect to Net Sales of such Product in such calendar quarter in such country; *provided, however*, that in no event shall the royalty owed to Adimab be reduced by more than [\*\*] percent ([\*\*]%) of the payment which would otherwise be due hereunder by reason of any and all such offsets in the aggregate. It is understood, agreed and acknowledged that Adimab’s allowing Arsanis to claim the credit of this Section 4.3(b)

(Adjustments for Third Party IP) as to any particular Third Party Patent License: (i) does not mean Adimab believes that the licensed Patents of the Third Party were infringed by or Cover any aspect of the discovery or optimization work by Adimab; and (ii) is not, will not be, and shall not be under any circumstances construed as an admission of any kind. Adimab may have many reasons not to challenge any given assertion of the credit of this Section 4.3(b) (Adjustment for Third Party IP) by Arsanis, including: (1) maintaining good relations with a counterparty; (2) an assessment that the costs of the credit are outweighed by the benefits of Arsanis having a license in place that makes it feel comfortable to proceed with the Product (resulting in a greater likelihood of milestones and royalties being paid to Adimab); (3) resource limitations that make it impracticable to challenge Arsanis' assertion of such credit even though Adimab may disagree whether this is proper; and (4) other reasons other than thinking that the relevant Patents Cover or were infringed by any aspect of the discovery or optimization work.

**(c) Biosimilar Competition.** On a Product-by-Product and country-by-country basis, if, during the Royalty Term for a Product in a country, sales of Biosimilars of such Product account for [\*\*]% or more of aggregate unit sales of such Product and such Biosimilars in such country in a calendar quarter, as determined by reference to applicable sales data obtained from a reputable independent source (e.g., IMS Health), then for the remainder of the Royalty Term for such Product in such country, the royalties that would otherwise be payable by Arsanis under Section 4.3(a) (Royalty Payments) (as adjusted pursuant to Section 4.3(b) (Adjustment for Third Party IP), to the extent applicable), with respect to Net Sales of such Product in such country shall be reduced by [\*\*] percent ([\*\*]%).

**(d) Compulsory Licensing.** If a Compulsory License is granted to a Third Party with respect to a Product in a country, and the royalty rate payable by such Third Party to Arsanis or its Affiliate or Licensee for such Compulsory License does not equal or exceed the royalty rate provided by Section 4.3(a) (Royalty Payments) (as adjusted pursuant to Section 4.3(b) (Adjustment for Third Party IP) and 4.3(c) (Biosimilar Competition), to the extent applicable), then in lieu of Royalty Payments with respect to such Third Party's Net Sales of such Product in such country, Arsanis shall pay to Adimab [\*\*] percent ([\*\*]%) of the royalties paid by such Third Party to Arsanis or its Affiliate or Licensee with respect to such Third Party's sales of such Product in such country for the period during which such Compulsory License is in effect, but only with respect to sales or other dispositions of that Product in that country by that Third Party compulsory licensee.

**(e) Royalty Floor.** Except as expressly set forth in Section 4.3(d) (Compulsory Licensing), in no event shall the effective royalty rate applicable to Net Sales of a Product in a country (excluding NGO Sales) for purposes of Royalty Payments hereunder be reduced, by reason of any and all applicable adjustments in the aggregate, to less than [\*\*] percent ([\*\*]%) of Net Sales of such Product in such country.

**(f) No Royalty on NGO Sales.** For clarity, no Royalty Payments, royalties or other payments of any kind shall be payable to Adimab with respect to NGO Sales.

**(g) [\*\*].**

**4.4 Quarterly Payment Timing.** All Royalty Payments due under Section 4.3 (*Royalties*) shall be paid quarterly within [\*\*] days after the end of the relevant calendar quarter for which royalties are due.

**4.5 Royalty Payment Reports.** With respect to each calendar quarter, within [\*\*] days after the end of the calendar quarter, Arsanis shall provide to Adimab a written report stating the number and description of all Products sold during the relevant calendar quarter; the gross sales associated with such sales; and the calculation of Net Sales on such sales, including the amount of any deduction provided for in the definition of Net Sales. The report shall provide all such information on a country-by-country and Product-by-Product basis.

**4.6 Payment Method.** All payments due under this Agreement to Adimab shall be made by bank wire transfer in immediately available funds to an account designated by Adimab. All payments hereunder shall be made in the legal currency of the United States of America, and all references to “\$” or “dollars” shall refer to United States dollars (*i.e.*, the legal currency of the United States).

**4.7 Taxes.** Adimab will pay any and all taxes levied on account of any payments made to it under this Agreement. The parties shall reasonably cooperate in good faith to achieve legally-available tax efficiencies related to payments under this Agreement. To the extent that Arsanis is required to deduct and withhold taxes on any payment to Adimab, Arsanis shall deduct and withhold such taxes and pay the amounts of such taxes to the proper government authority in a timely manner and promptly submit to Adimab an official tax certificate or other evidence of such withholding sufficient to enable Adimab to claim such payment of taxes. Arsanis shall provide Adimab with reasonable assistance in order to allow Adimab to recover, as permitted by applicable law, withholding taxes, value added taxes or similar obligations resulting from payments made hereunder or to obtain the benefit of any present or future treaty against double taxation which may apply to such payments. Adimab shall provide Arsanis with any tax forms that may be reasonably necessary in order for Arsanis not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax income treaty. Adimab shall use reasonable efforts to provide any such tax forms to Arsanis at least [\*\*] days prior to the due date identified by Arsanis for any payment for which Adimab desires that Arsanis apply a reduced withholding rate. Arsanis shall make all payments due hereunder from the United States.

**4.8 Records; Audit.** Arsanis shall keep (and shall cause its Affiliates and Licensees to keep) complete and accurate records pertaining to the sale or other disposition of Products in sufficient detail to permit Adimab to confirm the accuracy of all royalty payments due hereunder for at least [\*\*] full calendar years following the end of the calendar year to which they pertain. Adimab shall have the right, [\*\*], to cause an independent, certified public accountant of international standing and reasonably acceptable to Arsanis to audit such records solely to confirm Net Sales and royalties for a period covering not more than the preceding [\*\*] full calendar years. No calendar year shall be subject to audit under this section more than [\*\*]. Such audits may be exercised during normal business hours upon at least [\*\*] days' prior written notice to Arsanis in the location where the records are maintained. The auditor will execute a reasonable written confidentiality agreement with Arsanis and will disclose to Adimab only such information as is reasonably necessary to provide Adimab with information regarding any actual or potential discrepancies between amounts reported and actually paid and amounts payable

under this Agreement. The auditor will send a copy of the report to Arsanis at the same time it is sent to Adimab. The report sent to both Parties will include the methodology and calculations used to determine the results. If the audit reveals an underpayment, Arsanis shall promptly pay to Adimab the amount of such underpayment plus interest in accordance with Section 4.11 (*Late Payments*). If the audit reveals that the monies owed by Arsanis to Adimab have been understated by more than [\*\*] percent ([\*\*]%) for the period audited, Arsanis shall, in addition, pay the costs of such audit. If such audit discloses an overpayment by Arsanis, then Arsanis shall have the right to deduct the amount of such overpayment from any amount owed to Adimab under this Agreement.

**4.9 Foreign Exchange.** If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the rate of exchange for such currency used throughout Arsanis' accounting system for financial reporting purposes for the calendar quarter for which payment is due. With any payment in relation to which a currency conversion is performed to calculate the amount of payment due, Arsanis shall provide to Adimab a copy of the exchange rates used in such calculation.

**4.10 Non-refundable, non-creditable payments.** Each payment that is required under this Agreement is non-refundable and non-creditable except to the extent set forth in Section 4.3(b) (*Adjustment for Third Party IP*).

**4.11 Late Payments.** Any amount owed by Arsanis to Adimab under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the rate of [\*\*] percent ([\*\*]%) above the then-applicable short-term three-month London Interbank Offered Rate (LIBOR) as quoted in the Wall Street Journal (or if it no longer exists, a similarly authoritative source) calculated on a daily basis, or, if lower, the highest rate permitted under applicable law.

## ARTICLE 5

### INTELLECTUAL PROPERTY.

#### 5.1 Ownership and Inventorship.

**(a) Adimab Platform Patents.** Adimab shall at all times remain the sole and exclusive owner of the Adimab Platform Patents.

**(b) RSV Antibody Patents.** Prior to Option exercise, Adimab shall be the sole and exclusive owner of all RSV Antibody Patents. From and after Arsanis' exercise of the Option in accordance with Section 2.2(b) (*Option*), Arsanis shall be the sole and exclusive owner of all RSV Antibody Patents.

**(c) Other Patents.** Except as expressly set forth in Section 2.9 (*Effect of Expiration of Option Without Exercise*), Section 5.1(b) (RSV Antibody Patents) and Section 9.5(b)(i)(2)(B) (*Assignment of RSV Antibody Patents*), nothing in this Agreement shall alter the ownership of the Parties' Patents.

**(d) Inventorship.** For purposes of this Agreement, inventorship of any invention, whether or not patentable, shall be determined in accordance with United States patent law.

**5.2 Assignment.** Each Party shall promptly execute and deliver, or require its employees or contractors to execute and deliver, all documents and instruments necessary or reasonably requested by the other Party to effectuate, evidence, record and perfect the Assignment and the ownership of RSV Antibody Patents set forth in Section 5.1(b) (*RSV Antibody Patents*) and Section 9.5(b)(i)(2)(B) (*Assignment of RSV Patent Rights*), and to enable the other Party to apply for and prosecute such RSV Antibody Patents in any country. In addition, [\*\*\*]. Each Party hereby designates and appoints the other Party and its duly authorized officers and agents as its agent and attorney-in-fact to act for and on behalf of such Party solely to execute, deliver and file the foregoing documents and instruments, with the same legal force and effect as if executed by such Party if a Party is unable for any reason to secure the other Party's or its representatives' signature on any such document or instrument. Each Party acknowledges that this appointment is coupled with an interest. Each Party shall make its relevant personnel (and their assignments and signatures on such documents and instruments) reasonably available to the other Party for assistance in accordance with this Article 5 (*Intellectual Property*) at no charge.

### **5.3 Patent Prosecution and Maintenance.**

**(a) Adimab Platform Technology.** Adimab shall have the sole right (but not the obligation) to file, prosecute, maintain, defend and enforce all Patents directed to Adimab Platform Technology and all Adimab Platform Patents, all at its own expense.

#### **(b) RSV Antibody Patents, Evaluation Term Patents and Arsanis Patents.**

**(i) Prior to Option Exercise.** During the Evaluation Term prior to Option exercise:

(1) Adimab shall file additional RSV Antibody Patents and prosecute, maintain, defend and enforce all RSV Antibody Patents, in accordance with instructions from Arsanis and at Arsanis' expense;

(2) Arsanis and its Affiliates shall not file, and shall not cause to be filed, any additional RSV Antibody Patents, including patent applications that Cover any Adimab RSV Antibody;

(3) Adimab shall provide Arsanis with drafts of proposed patent office submissions with respect to Adimab RSV Antibodies and RSV Antibody Patents, including draft patent applications and related correspondence, no less than [\*\*\*] business days in advance of filing;

(4) Adimab shall consider in good faith the requests and comments of Arsanis with respect to such drafts;

(5) Adimab shall keep Arsanis reasonably informed of progress with regard to the prosecution and maintenance of RSV Antibody Patents and shall provide Arsanis with copies of all correspondence received from patent offices relating thereto (including office actions and the like) promptly after receipt; and

(6) Arsanis may, in its sole discretion and at its sole expense, file or cause to be filed applications for Evaluation Term Patents, [\*\*].

**(ii) During the Post-Exercise Term.** During the Post-Exercise Term:

(1) Arsanis shall have the sole right to prosecute, maintain, enforce and defend all RSV Antibody Patents, Evaluation Term Patents, and Arsanis Patents, all at its own expense;

(2) Adimab and its Affiliates shall not file, and shall not cause to be filed, any additional RSV Antibody Patents;

(3) Adimab shall have the right to review and comment on prosecution of RSV Antibody Patents, and Arsanis shall consider in good faith the requests and comments of Adimab with respect thereto;

(4) Arsanis shall provide Adimab with drafts of proposed patent office submissions with respect to RSV Antibody Patents, including draft patent applications and related correspondence, no less than [\*\*] business days in advance of filing; and

(5) Arsanis shall keep Adimab reasonably informed of progress with regard to the prosecution and maintenance of RSV Antibody Patents and shall provide Adimab with copies of all correspondence received from patent offices relating thereto (including office actions and the like) promptly after receipt.

**(c) Responsibility.** It is understood and agreed that searching for, identification and evaluation of Third-Party Patents that may Cover Excluded Technology, including the Sequence of, or any method of using or making, any Licensed Antibody, is the responsibility of Arsanis, and that Adimab shall have no responsibility for the foregoing nor liability if any such Third Party Patents exist.

**5.4 Cooperation of the Parties.** At the reasonable request of the responsible (as provided for in this Article 5 (*Intellectual Property*)) Party, the other Party agrees to cooperate fully in the preparation, filing, prosecution, enforcement and maintenance of any RSV Patents under this Agreement. Such cooperation includes executing all papers and instruments (or causing its personnel to do so) reasonably useful to enable the other Party to apply for and to prosecute patent applications in any country; and promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, enforcement or maintenance of any such Patents. Notwithstanding the foregoing, Adimab shall not be required pursuant hereto to disclose Adimab Platform Technology to Arsanis or to participate in any action against another Adimab customer.

## ARTICLE 6

### CONFIDENTIALITY; PUBLICITY.

#### 6.1 General Confidentiality Obligations.

**(a) Confidential Information.** Any and all confidential or proprietary information disclosed to one Party by the other Party under this Agreement is the “**Confidential Information**” of the disclosing Party; *provided, however*, that, notwithstanding the foregoing:

(i) information embodied in Adimab Materials is Adimab’s Confidential Information;

(ii) information embodied in the Arsanis Materials is Arsanis’ Confidential Information;

(iii) prior to exercise of the Option, Sequence information (whether as to amino acid sequence or nucleic acid sequence) with respect to RSV Antibodies shall be deemed the Confidential Information of both Parties; and

(iv) from and after the date of Option exercise: (A) the Sequence information as to the CDRs of RSV Antibodies shall be Confidential Information of Arsanis; and (B) the Sequence information as to the non-CDR portions (*i.e.*, the framework) of RSV Antibodies may be disclosed by either Party; *provided, however*, that this clause (B) shall not be construed to require Arsanis to disclose to Adimab any Sequence information with respect to any Arsanis Derived Antibody.

**(b) Limits on Use and Disclosure of Confidential Information.** Each Party shall receive and maintain the other Party’s Confidential Information in strict confidence. Neither Party shall disclose any Confidential Information of the other Party to any Third Party. Neither Party shall use the Confidential Information of the other Party for any purpose other than as required to perform its obligations or exercise its rights hereunder. Each Party may disclose the other Party’s Confidential Information to the receiving Party’s employees and contractors requiring access thereto for the purposes of this Agreement, *provided, however*, that prior to making any such disclosures, each such person shall be bound by written agreement to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Each Party agrees to take all steps necessary to ensure that the other Party’s Confidential Information shall be maintained in confidence including such steps as it takes to prevent the disclosure of its own proprietary and confidential information of like character. Each Party agrees that this Agreement shall be binding upon its employees and contractors involved in the activities contemplated hereby and that it shall be liable for any breach by its employees or contractors. The foregoing obligations of confidentiality and non-use shall survive, and remain in effect for a period of [\*\*] years from, the termination or expiration of this Agreement in accordance with Article 9 (*Term; Termination*).

**6.2 Exclusions from Nondisclosure Obligation.** Information shall not be considered Confidential Information of a Party (the “**Disclosing Party**”) and the nondisclosure and nonuse obligations in Section 6.1 (*General Confidentiality Obligations*) shall not apply to the extent that the other Party (the “**Receiving Party**”) can establish by competent written proof that such



information: (a) was publicly known at the time of disclosure (or generation, as applicable); (b) after disclosure (or generation, as applicable), becomes publicly known by publication or otherwise, except by breach of this Agreement by the Receiving Party; (c) was in the Receiving Party's possession at the time of disclosure hereunder; (d) is received by the Receiving Party from a Third Party who has the lawful right to disclose the Confidential Information and who shall not have obtained the Confidential Information either directly or indirectly from the Disclosing Party; or (e) is independently developed by the Receiving Party (*i.e.*, without reference to Confidential Information of the disclosing Party); *provided, however*, that Adimab shall not be permitted to avail itself of: (i) the exceptions set forth in the foregoing clauses (c) and (e) during the Evaluation Term with respect to Sequence information as to Adimab RSV Antibodies; (ii) the exception set forth in the foregoing clause (c) during the Post-Exercise Term with respect to Sequence information with respect to the CDRs of Adimab RSV Antibodies; or (iii) the exception set forth in the foregoing clause (e) during the Post-Exercise Term with respect to Sequence information with respect to the CDRs of Adimab RSV Antibodies except to the extent that such Sequences are independently rediscovered by Adimab without use of any Confidential Information of Arsanis or any Arsanis Materials.

**6.3 Authorized Disclosures.** If either Party is required, pursuant to a governmental law, regulation or order, to disclose any Confidential Information of the other Party, the receiving Party (a) shall give advance written notice to the disclosing Party, (b) shall make a reasonable effort to assist the other Party to obtain a protective order requiring that the Confidential Information so disclosed be used only for the purposes for which the law, regulation or order required and (c) shall disclose the Confidential Information solely to the extent required by the law, regulation or order. In addition, and notwithstanding the provisions of Section 6.1 (*General Confidentiality Obligations*), the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances: (i) filing or prosecuting Patent Rights as permitted by this Agreement; (ii) enforcing such party's rights under this Agreement and in performing its obligations under this Agreement; (iii) prosecuting or defending litigation as permitted by this Agreement; and (iv) in the case of Arsanis as the Receiving Party, (A) disclosure in submissions to or filings with any Regulatory Authority (including, without limitation, in INDs and NDAs) with respect to any Product, and in correspondence with any Regulatory Authority regarding any Product or any of the foregoing submissions or filings, and (B) disclosures to the Foundation required by the Grant Documents; *provided, however*, that in no event may Arsanis disclose Adimab Platform Technology without the prior written consent of Adimab, which consent may be withheld in Adimab's sole discretion.

**6.4 Terms of Agreement.** The terms of this Agreement are the Confidential Information of both Parties. However, each Party shall be entitled to disclose the terms of this Agreement under legally binding obligations of confidence and limited use to: legal, financial and investment banking advisors; and potential and actual investors and acquirers, and, in the case of Arsanis, potential and actual Licensees, doing diligence and counsel for the foregoing. In addition, if legally required, a copy of this Agreement may be filed by either Party with the SEC (or relevant ex-U.S. counterpart). In that case, the filing Party will if requested by the other Party diligently seek confidential treatment for terms of this Agreement for which confidential treatment is reasonably available, and shall provide the non-filing Party reasonable advance notice of the terms proposed for redactions and a reasonable opportunity to request that the filing Party make additional redactions to the extent confidential treatment is reasonably available under the law. The filing Party shall seek and diligently pursue such confidential treatment requested by the non-filing Party.

**6.5 Return of Confidential Information.** Promptly after the termination or expiration of this Agreement for any reason (but specifically excluding expiration of the Term in accordance with clause (b) of Section 9.1 (*Term*)), each Party shall return to the other Party all tangible manifestations of such other Party's Confidential Information at that time in the possession of the receiving Party; *provided, however*, that: (a) a Party may retain one (1) copy of the Confidential Information of the other Party in its files for the sole purpose of ascertaining and complying with its confidentiality obligations hereunder; (b) a Party shall not be required to destroy any computer files stored securely by such Party only on centralized storage servers (and not on personal computers or devices) that are created during automatic system back up, so long as such computer files are not readily accessible by such Party's personnel (other than its information technology specialists who are responsible for maintaining such Party's electronic backup services; and (c) the obligation of the receiving Party to return Confidential Information pursuant to this Section 6.5 (*Return of Confidential Information*) shall not apply to Confidential Information of the other Party or copies thereof which must be retained pursuant to mandatory applicable law. Any Confidential Information retained will continue to be subject to the terms of this Agreement.

#### **6.6 Publicity.**

**(a) Press Releases.** The Parties shall issue joint press release announcing the execution of this Agreement in substantially the form attached hereto as **Exhibit C**. It is further acknowledged that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder, all of which shall be made in accordance with the terms of this Section 6.6(a) (*Press Releases*).

**(i) Disclosure of Significant Achievements.** During the Post-Exercise Term: (A) Adimab may, without the prior review or approval of Arsanis, issue public statements or press releases announcing the exercise of the Option and the achievement of any Milestone Event for which a Milestone Payment is payable hereunder; *provided, however*, that no such statement or release shall disclose any Sequence information as to the CDR of the Licensed Antibody contained in the Product that achieved such Milestone Event or otherwise specifically identify such Licensed Antibody or Product (except that Adimab may identify such Licensed Antibody or Product by the Arsanis product designation used by Arsanis in its public disclosures); and (B) Arsanis may, without the prior review or approval of Adimab, issue public statements or press releases regarding Products being developed or commercialized by or on behalf of Arsanis, its Affiliates or Licensees, including, without limitation, announcements regarding initiation or completion of clinical trials, clinical trial results, regulatory filings and approvals, entry into License Agreements, and receipt of payments under License Agreements, and where not unreasonably cumbersome, Arsanis shall include in such statement a recognition of Adimab as the source of the Adimab RSV Antibodies.

**(ii) Other Disclosures.** Except as expressly set forth in Section 6.6(a)(i) (*Disclosure of Significant Achievements*), the Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of subsequent press releases prior to the issuance thereof; provided, however, that a Party may not withhold consent to such releases that the other Party may determine, based on advice of counsel, are reasonably necessary to comply with applicable laws, including disclosure requirements of the U.S. Securities and Exchange Commission, or with the requirements of any stock exchange on which securities issued by a Party or its Affiliates are traded. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text. Each Party may make public statements regarding this Agreement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as the contents of any such public statement or press release are contained in a prior public disclosure or public statement approved by the other Party pursuant to this Section 6.6(a)(ii) (*Other Disclosures*) or permitted by Section 6.6(a)(i) (*Disclosure of Significant Achievements*) or Section 6.3 (*Authorized Disclosures*) and does not reveal Confidential Information of the other Party.

**(b) Bundled Press Releases.** It is understood and agreed that a Party may sometimes issue press releases that group multiple achievements of such Party. It is understood and agreed that a Party may choose to group text from a previously-approved press release with other accomplishments or events not relating to this Agreement and, in such event, the only portions of the press release to which Section 6.6(a) (*Press Releases*) shall apply shall be those portions that relate to this Agreement or the other Party.

**6.7 Certain Data.** The Parties recognize the need for Adimab to disclose the general capabilities of the Adimab Platform Technology. In connection therewith, and provided that Adimab does not disclose the identity of Arsanis, any Adimab RSV Antibody, the target thereof (*i.e.*, RSV) or any Sequence information as to the CDRs of Adimab RSV Antibodies, Adimab shall have the right to disclose generally Adimab RSV Antibody attributes, including the following: [\*\*]. For clarity, Adimab has already published the article by Gilman et al., entitled “Rapid profiling of RSV antibody repertoires from the memory B cells of naturally infected adult donors”, *Sci Immunol.*, Vol. 1(6), December 16, 2016 (Epublished December 9, 2016), which article includes the sequences of certain Adimab RSV Antibodies.

## ARTICLE 7

### REPRESENTATIONS AND WARRANTIES.

**7.1 Mutual Representations.** Each of Adimab and Arsanis hereby represents and warrants to the other of them that the representing and warranting Party is duly organized in its jurisdiction of incorporation; that the representing and warranting Party has the full power and authority to enter into this Agreement; that this Agreement is binding upon the representing and warranting Party; that this Agreement has been duly authorized by all requisite corporate action within the representing and warranting Party; and that the execution, delivery and performance by the representing and warranting Party of this Agreement and its compliance with the terms and conditions hereof does not and shall not conflict with or result in a breach of any of the terms and conditions of or constitute a default under (a) any agreement or other instrument binding or affecting it or its property, (b) the provisions of its bylaws or other governing documents or (c) any order, writ, injunction or decree of any governmental authority entered against it or by which any of its property is bound.

**7.2 Representations of Adimab.** Adimab hereby represents and warrants to Arsanis that, as of the Effective Date:

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**7.3 DISCLAIMER OF WARRANTIES.** OTHER THAN THE EXPRESS WARRANTIES SET FORTH IN THIS ARTICLE 7 (REPRESENTATIONS AND WARRANTIES), EACH PARTY DISCLAIMS ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

**7.4 Limitation of Liability.** EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 6 (CONFIDENTIALITY; PUBLICITY), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; PROVIDED, HOWEVER, THAT THIS SECTION 7.4 (LIMITATION OF LIABILITY) SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 8 (INDEMNIFICATION).

## ARTICLE 8

### INDEMNIFICATION

**8.1 Indemnification by Adimab.** Adimab hereby agrees to indemnify, defend and hold harmless (collectively, "**Indemnify**") Arsanis, its Affiliates and its and their directors, officers, agents and employees (collectively, "**Arsanis Indemnitees**") from and against any and all liability, loss, damage or expense (including without limitation reasonable attorneys' fees) (collectively, "**Losses**") they may suffer as the result of any claim, demand, action or other proceeding by any Third Party (collectively, "**Third-Party Claims**") arising out of or relating to (a) the breach by Adimab of any warranty, representation, covenant or agreement made by Adimab in this Agreement, or (b) the gross negligence or intentional misconduct of any Adimab Indemnitee; except, in each case, to the extent such Losses result from (i) [\*\*].

**8.2 Indemnification by Arsanis.** Arsanis hereby agrees to Indemnify Adimab, its Affiliates and its and their directors, officers, agents and employees (collectively, "**Adimab Indemnitees**") from and against any and all Losses they may suffer as the result of Third-Party Claims arising out of or relating to (a) the breach by Arsanis of any warranty, representation, covenant or agreement made by Arsanis in this Agreement, (b) the gross negligence or intentional misconduct of any Arsanis Indemnitee, (c) the research, testing, development, manufacture, use, handling, storage, sale, offer for sale, import or other disposition by or on behalf of Arsanis or any of its Affiliates or Licensees or the Foundation of any Licensed Antibody or Product, or (d) the use by Arsanis or its Affiliates or Licensees or the Foundation of any Excluded Technology; except, in each case, to the extent such Losses result from (i) [\*\*].

**8.3 Indemnification Procedures.** The obligation of a Party (the “**Indemnifying Party**”) under Section 8.1 (*Indemnification By Adimab*) or Section 8.2 (*Indemnification By Arsanis*) (as applicable) to Indemnify the other Party (the “**Indemnified Party**”) and its associated indemnitees – i.e., the Adimab Indemnitees or Arsanis Indemnitees, as applicable (the “**Indemnitees**”) – is conditioned on: (a) the Indemnified Party providing the Indemnifying Party prompt written notice of any Third-Party Claim giving rise to an indemnification obligation hereunder, (b) the Indemnified Party and its Indemnitees permitting the Indemnifying Party to assume direction and control of the defense of the Third-Party Claim (including the right to settle the Third-Party Claim solely for monetary consideration) using counsel reasonably satisfactory to the Indemnified Party, (c) the Indemnified Party and its Indemnitees cooperating as requested (at the expense of the Indemnifying Party) in the defense of the Third-Party Claim, and (d) the Indemnified Party and its Indemnitees not compromising or settling such Third-Party Claim without the Indemnifying Party’s prior written consent. The Indemnifying Party shall not agree to any settlement of such Third-Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party and its Indemnitees from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or its Indemnitees or that acknowledges fault by the Indemnified Party or any Indemnitee, without the prior written consent of the Indemnified Party or such Indemnitee, as applicable. If the Parties cannot agree as to the application of the foregoing Sections 8.1 (*Indemnification by Adimab*) and 8.2 (*Indemnification by Arsanis*), each may conduct separate defenses of the Third-Party Claim, and each Party reserves the right to claim indemnity from the other in accordance with this Article 8 (*Indemnification*) upon the resolution of the underlying Third-Party Claim.

## ARTICLE 9

### TERM; TERMINATION.

**9.1 Term.** The term (the “**Term**”) of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated as set forth below in this Article 9 (*Term; Termination*), shall expire upon (a) the expiration of the Evaluation Term in the event that the Option is not exercised prior to expiration of the Evaluation Term; or (b) in the event that the Option is exercised, on the expiration of the last-to-expire Royalty Term for any and all Products. Upon expiration of the Term pursuant to clause (b) of this Section 9.1 (*Term*), the License shall become royalty-free, fully-paid, irrevocable and perpetual.

### 9.2 Termination for Material Breach.

**(a) Material Breach Other Than Breach of Diligence Obligation.** Subject to Section 9.2(c) (*Dispute Regarding Breach*), and except in the case of a material breach covered by Section 9.2(b) (*Material Breach of Diligence Obligations*), each Party shall have the right, in the event of material breach of this Agreement by the other Party, to terminate this Agreement upon written notice to the other Party if such other Party is in material breach of this

Agreement and has not cured such breach within [\*\*] days (or [\*\*] days with respect to any payment breach) after notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of such [\*\*] day period (or [\*\*] day period with respect to any payment breach) unless the breaching Party has cured such breach prior to the end of such period. Notwithstanding the foregoing or Section 9.5 (*Effect of Expiration or Termination*) to the contrary, but without limiting Adimab's rights under Section 9.2(b) (*Material Breach of Diligence Obligations*), after initiation of the first clinical trial of a Product, Adimab may not terminate this Agreement pursuant to this Section 9.2(a) (*Material Breach Other Than Breach of Diligence Obligations*), except in the case of uncured material payment breach by Arsanis, but for clarity, Adimab may pursue any and all remedies that may be available to it at law or in equity as a result of such breach by Arsanis.

**(b) Material Breach of Diligence Obligation.** If Adimab in good faith believes that Arsanis has failed to comply with its obligations under Section 3.5 (*Diligence*), Adimab shall so notify Arsanis and, within [\*\*] days thereafter, Arsanis and Adimab will meet and discuss the matter in good faith and attempt to reach mutual agreement as to whether or not Arsanis is in material breach of Section 3.5 (*Diligence*) and, if so, to agree upon a mutually acceptable plan for Arsanis to regain compliance with Section 3.5 (*Diligence*) within a reasonable period. Following such meeting, if either (i) the Parties do not reach mutual agreement within such [\*\*] day period, or (ii) the Parties mutually agree on a plan for Arsanis to regain compliance with Section 3.5 (*Diligence*) but Arsanis fails to regain such compliance within the agreed period, then subject to Section 9.2(c) (*Dispute Regarding Breach*) below, Adimab will have the right, at its sole discretion, to terminate this Agreement.

**(c) Dispute Regarding Breach.** Any right to terminate this Agreement under this Section 9.2 (*Termination For Material Breach*) shall be stayed and the cure period tolled in the event that, during any cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Section 10.4 (*Dispute*) with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 10.4 (*Dispute*).

**9.3 Termination for Convenience.** Arsanis may terminate this Agreement for any reason or for no reason upon sixty (60) days' written notice to Adimab.

**9.4 Commitments Regarding RSV Antibodies.** The Parties agree that if Arsanis or any of its Licensees develops or commercializes any RSV Antibody or Product, then Arsanis shall pay to Adimab the fees set forth in Article 4 (*Financial Terms*), including the Option Fee (if not previously paid), Milestone Payments and Royalty Payments, as applicable, on all RSV Antibodies developed or commercialized by Arsanis or any of its Licensees as (or as if) a Product under this Agreement. Arsanis shall include in each Licensee Agreement an obligation on the part of the applicable Licensee, in the event that Arsanis is unwilling or unable to pay to Adimab any Milestone Payments and Royalty Payments that become due hereunder with respect to RSV Antibodies developed or commercialized by such Licensee (because, for example, of the dissolution of Arsanis for bankruptcy or other reasons), to make such payments directly to Adimab; *provided, however*, that: (a) if such Licensee achieves a Milestone Event for which a Milestone Payment is payable by Arsanis hereunder and pays to Arsanis a milestone payment with respect to such Milestone Event, but Arsanis fails to remit to Adimab the corresponding

Milestone Payment, then such Licensee shall have no liability to Adimab for such Milestone Payment; and (b) if such Licensee pays royalties to Arsanis on particular Net Sales of Products by such Licensee, but Arsanis fails to remit to Adimab the corresponding Royalty Payment with respect to those Net Sales, then such Licensee shall have no liability to Adimab for such Royalty Payment.

#### **9.5 Effect of Expiration or Termination.**

**(a) Any Termination.** Upon any termination of this Agreement prior to its expiration, all licenses and rights granted by either Party to the other Party pursuant to this Agreement (including the Research License, the Option and the License) shall automatically terminate and revert to the granting Party, and all other rights and obligations of the Parties under this Agreement shall terminate; in each case, except as expressly provided below in this Section 9.5 (*Effect of Expiration or Termination*) or elsewhere in this Article 9 (*Term; Termination*).

**(b) Expiration Without Option Exercise, or Termination by Adimab For Material Breach or by Arsanis For Convenience.** Solely in the event of expiration of this Agreement pursuant to clause (a) of Section 9.1 (*Term*), or termination of this Agreement by Adimab pursuant to Section 9.2 (*Termination for Material Breach*), or by Arsanis pursuant to Section 9.3 (*Termination for Convenience*), the following provisions shall apply, subject, in all cases, to Section 9.5(c) (*Survival of Licensee Agreements*) and Section 9.5(d) (*Foundation Rights*):

**(i) Termination of Licenses.** As applicable:

**(1) Prior to Option Exercise.** In the case of expiration of this Agreement pursuant to clause (a) of Section 9.1 (*Term*), or termination of this Agreement during the Evaluation Term either by Adimab pursuant to Section 9.2 (*Termination for Material Breach*) or by Arsanis pursuant to Section 9.3 (*Termination for Convenience*), the Research License and the Option shall terminate and be of no further force or effect.

**(2) After Option Exercise.** In the case of or termination of this Agreement during the Post-Exercise Term either by Adimab pursuant to Section 9.2 (*Termination for Material Breach*) or by Arsanis pursuant to Section 9.3 (*Termination for Convenience*):

**(A) Termination But For Fully-Paid Products.** The License shall terminate and be of no further force or effect; *provided, however*, that if the License with respect to a particular Product in a particular country had become royalty-free, fully-paid, irrevocable and perpetual by virtue of the expiration of the Royalty Term for such Product in such country prior to such termination (such Product in such country, a “Fully-Paid Product”), then the License with respect to such Fully-Paid Product shall survive such termination; and

**(B) Assignment of RSV Antibody Patents.** Effective as of such termination, Arsanis shall, and it hereby does, assign to Adimab all right, title and interest in and to all RSV Antibody Patents;

**(ii) Adimab Materials and RSV Antibodies.** Within [\*\*] days after such termination, Arsanis shall (1) either return to Adimab or destroy (at Adimab's direction and expense) all Adimab Materials and all Adimab RSV Antibodies remaining in the possession of Arsanis (other than Fully-Paid Products), and (2) except as otherwise mutually agreed by the Parties in writing, destroy all quantities of Arsanis Derived Antibodies in the possession of Arsanis (other than Fully-Paid Products);

**(iii) Non-Exclusive Unblocking License to Adimab.** Effective as of such termination, Arsanis shall, and it hereby does, grant to Adimab, a non-exclusive, worldwide, royalty-free, fully-paid license, with the right to sublicense through multiple tiers, under Blocking Arsanis Patents solely to make, have made, use, sell, have sold, offer for sale and import Adimab RSV Antibodies and products comprising or containing Adimab RSV Antibodies (but excluding Fully-Paid Products, if any) in the Field. For clarity, the sole purpose of the license that may be granted pursuant to this Section 9.5(b)(iii) (*Non-Exclusive Unblocking License to Adimab*) is to provide Adimab with freedom to operate under Blocking Arsanis Patents solely with respect to the manufacture, use, sale, offer for sale and import of Adimab RSV Antibodies and products comprising or containing Adimab RSV Antibodies (excluding Fully-Paid Products) in the Field, and this Section 9.5(b)(iii) (*Non-Exclusive Unblocking License to Adimab*) does not, and shall not be construed to, obligate Arsanis to disclose any Blocking Arsanis Patent or the Arsanis Invention(s) claimed therein to Adimab;

**(iv) Right of Negotiation for Exclusive License and Product Transfer to Adimab.** Effective as of such termination, Arsanis shall, and it hereby does, grant to Adimab, a right of first negotiation, exercisable within [\*\*] days after termination, to obtain, upon commercially reasonable terms and conditions to be negotiated in good faith by the Parties:

**(1) Exclusive License.** An exclusive, worldwide, royalty-bearing license, with the right to sublicense through multiple tiers, under the Blocking Arsanis Patents, Other Arsanis Patents and Arsanis Know-How, in each case, solely to develop, make, have made, use, sell, have sold, offer for sale and import RSV Antibodies and Products (excluding Fully-Paid Products) in the Field; *provided, however*, that, to the extent that Blocking Arsanis Patents, Other Arsanis Patents or Arsanis Know-How includes Patents or Know-How licensed to Arsanis by a Third Party that is subject to royalty or milestone payment obligations to such Third Party with respect to any RSV Antibody or Product, then Arsanis shall so notify Adimab, together with a true, complete and correct description of such royalty and milestone payment obligations, and the inclusion of such Patents or Know-How in the Blocking Arsanis Patents, Other Arsanis Patents or Arsanis Know-How (as applicable) shall be subject to Adimab's agreeing in writing to pay, and promptly paying, all royalty and milestone payments that become due to such Third Party by reason of the development, manufacture, use, sale, offer for sale or import of RSV Antibodies and Products by or on behalf of Adimab or its Affiliates, licensees or sublicensees (in addition to the mutually agreed compensation payable to Arsanis for the grant of rights described in this Section 9.5(b)(iv) (*Exclusive Unblocking License and Regulatory Transfer to Adimab*));

**(2) Regulatory Filings and Approvals.** The transfer and assignment to Adimab of all Arsanis Regulatory Filings, including INDs and NDAs, and all Arsanis Approvals, including Marketing Approvals, in each case for RSV Antibodies and Products (other than Fully-Paid Products) in the Field controlled by Arsanis or any of its Affiliates; and



**(3) Other Transfers.** The transfer and assignment or sublicense of such other elements as may be necessary or useful for Adimab to continue the development and commercialization of RSV Antibodies and Products as conducted by Arsanis prior to such termination, including, for example, transferring (to the extent requested by Adimab) formal relationships with manufacturing organizations, patient groups and payors that, in each case, are specific to RSV Antibodies and Products, as well as other Product-specific items such as pharmacovigilance databases, and data related to indication, use, risks, and benefits.

**(v) Prohibition on Further Use.** Arsanis and its Affiliates shall not, and shall not grant any license or other right to, or otherwise cause or permit, any Third Party to, develop, manufacture or commercialize any RSV Antibody or Product (other than Fully-Paid Products).

**(c) Survival of License Agreements.** In the event that (i) Arsanis has entered into a Licensee Agreement consistent with the terms of this Agreement (including the provisions of Section 3.2 (*Licensees and Sublicensees*)), (ii) this Agreement is terminated, and (iii) such Licensee Agreement is in effect at the time of such termination, then such Licensee Agreement will survive such termination of this Agreement; *provided, however*, that the Licensee assumes all of Arsanis' obligations hereunder with respect to the Licensed Antibodies and Products covered by such Licensee Agreement (including those obligations set forth in Section 3.5 (*Diligence*), Section 3.7 (*Disclosure Regarding Arsanis Efforts*), and Section 9.4 (*Commitments Regarding RSV Antibodies*), and pays to Adimab all amounts that would have been due to Adimab from Arsanis as a result of Licensee's activities (including those obligations set forth in Article 4 (*Financial Terms*)).

**(d) Foundation Rights.** Notwithstanding any other provision of this Agreement to the contrary, the Parties acknowledge and agree that any and all Foundation Rights that have accrued or become effective prior to any expiration of this Agreement pursuant to clause (a) of Section 9.1 (*Term*) or the effective date of any termination of this Agreement prior to its expiration pursuant to clause (b) of Section 9.1 (*Term*) shall survive such expiration or termination of this Agreement and remain in full force and effect in accordance with the terms of the Grant Documents. Adimab further acknowledges and agrees that, to the extent that (i) the RSV Antibody Patents are assigned back to Adimab, (ii) the Evaluation Term Patents (if any) are assigned to Adimab, (iii) Evaluation Term Data and Sequence information for Arsanis Derived Antibodies created during the Evaluation Term are disclosed to Adimab, and/or (iv) any Blocking Arsanis Patents, Other Arsanis Patents or Arsanis Know-How are licensed to Adimab, the foregoing shall remain subject to the Foundation Rights to the same extent as they were immediately prior to such expiration or termination, and Adimab shall be bound by the Global Access Commitment with respect thereto.

**9.6 Accrued Obligations; Survival.** Neither expiration nor any termination of this Agreement shall relieve either party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the parties' rights and obligations under Sections 2.9 (*Effect of Expiration of Option Without Exercise*), 3.4 (*Acknowledgment Regarding Arsanis Derived Antibodies*), 3.8 (*Acknowledgment of Foundation Rights*), 4.4 (*Quarterly Payment Timings*) through 4.11 (*Late Payments*) (with respect to payment obligations outstanding or having accrued as the effective date of termination or expiration), 5.1 (*Ownership and Inventorship*), 5.2 (*Assignment*), 6.1 (*General Confidentiality Obligations*), 6.2 (*Exclusions from Nondisclosure Obligation*), 6.3 (*Authorized Disclosures*), 6.4 (*Terms of Agreement*), 6.5 (*Return of Confidential Information*), 6.7 (*Certain Data*), 7.3 (*Disclaimer of Warranties*), 7.4 (*Limitation of Liability*), 9.4 (*Commitments Regarding RSV Antibodies*), 9.5 (*Effect of Expiration or Termination*) and 9.6 (*Accrued Obligations; Survival*), and Articles 1 (*Definitions*), 8 (*Indemnification*) and 10 (*Miscellaneous*) shall survive any expiration or termination of this Agreement.

## **ARTICLE 10 MISCELLANEOUS.**

**10.1 No Implied Licenses.** No right or license under any Patent, Know-How or other intellectual property of either Party is granted or shall be deemed to have been granted under this Agreement by implication. All such rights or licenses are or shall be granted only as expressly provided in this Agreement.

**10.2 Bankruptcy Code.** All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the US (collectively, the "**Bankruptcy Laws**"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

**10.3 Independent Contractors.** The Parties shall perform their obligations under this Agreement as independent contractors. Nothing contained in this Agreement shall be construed to be inconsistent with such relationship or status. This Agreement and the Parties' relationship in connection with it shall not constitute, create or in any way be interpreted as a joint venture, fiduciary relationship, partnership, or agency of any kind.

## 10.4 Dispute Resolution.

**(a) Initial Dispute Resolution.** Subject to Section 10.4(c) (*Court Actions*), either Party may refer any dispute in connection with this Agreement (“**Dispute**”) not resolved by discussion of the Alliance Managers to senior executives of the Parties (for Adimab, its CEO or his designee and for Arsanis, its CEO or his designee) for good-faith discussions over a period of not less than [\*\*] days (the “Senior Executives Discussions”). Each Party will make its executives reasonably available for such discussions.

### **(b) Disputes Not Resolved Between the Parties.**

**(i) Arbitration.** Subject to Section 10.4(c) (*Court Actions*) below, any Dispute that is not resolved under Section 10.4(a) (*Initial Dispute Resolution*) within the period specified above shall be resolved by final and binding arbitration administered by JAMS (the “**Administrator**”) in accordance with its then-effective Comprehensive Arbitration Rules and Procedures (the “**Rules**”), except to the extent any such Rule conflicts with the express provisions of this Section 10.4(b) (*Arbitration*). (Capitalized terms used but not otherwise defined in this Agreement shall have the meanings provided in the Rules.) The Arbitration shall be conducted by three (3) neutral arbitrators, each of whom shall be a lawyer with at least fifteen (15) years of experience with a law firm or corporate law department and at least ten (10) years representing (either as outside counsel or in-house counsel) companies in the pharmaceutical or biotechnology industry in connection with licensing transactions; *provided, however*, that no such individual shall be a current or former employee or director, or a current stockholder, of either party or any of their respective Affiliates. Each party shall appoint one arbitrator, and the two so-appointed arbitrators shall jointly nominate the third arbitrator. The arbitration and all associated discovery proceedings and communications shall be conducted in English, and the arbitration shall be held in New York, New York.

**(ii) Hearing; Decision.** The Hearing shall commence within [\*\*] days after the discovery cutoff. The arbitrators shall require that each party submit concise written statements of position and shall permit the submission of rebuttal statements, subject to reasonable limitations on the length of such statements to be established by the arbitrators. The Hearing shall be no longer than [\*\*] business days in duration. The arbitrators shall also permit the submission of expert reports. The arbitrators shall render the Award within [\*\*] days after the arbitrators declares the Hearing closed, and the Award shall include a written statement describing the essential findings and conclusions on which the Award is based, including the calculation of any damages awarded. The arbitrators will, in rendering their decision, apply the substantive law of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law. The arbitrators’ authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Section 7.4 (*Limitations on Liability*). The Award rendered by the arbitrators shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

**(iii) Costs.** Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees or arbitration, unless in each case the arbitrators order otherwise, which they are hereby empowered, authorized and instructed to do if they determine that to be fair and appropriate.

**(iv) Confidentiality of Process and Awards.** Except to the extent necessary to confirm an award or as may be permitted by Section 6.3 (*Authorized Disclosures*) or Section 6.6(a) (*Press Releases*), neither Party shall disclose the existence, content or results of an arbitration under this Agreement without the prior written consent of the other Party.

**(v) Statute of Limitations.** In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the subject matter of the Dispute would be barred by the applicable statute of limitations under New York law.

**(c) Court Actions.** Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 10.4(b) (*Disputes Not Resolved Between the Parties*).

**10.5 Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

**10.6 Entire Agreement.** This Agreement (including its Exhibits) set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements and understandings between the Parties with respect to such subject matter. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

**10.7 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however*, that:

**(a)** either party may assign this Agreement and its rights and obligations hereunder without the other party's consent:

(i) in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party (“**Third Party Acquirer**”), whether by merger, sale of stock, sale of assets or otherwise (each, a “**Sale Transaction**”); *provided, however*, that in the event of a Sale Transaction (whether this Agreement is actually assigned or is assumed by the Third Party Acquirer or the surviving corporation resulting from such Sale Transaction by operation of law (*e.g.*, in the context of a reverse triangular merger)), intellectual property rights of the Third Party Acquirer that existed prior to the Sale Transaction shall not be included in the technology licensed or assigned hereunder or otherwise subject to this Agreement; or

(ii) to an Affiliate; *provided, however*, that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate; and

(b) Adimab may assign or transfer its rights to receive payments under this Agreement (but none of its obligations or liabilities), without Arsanis’ consent, to an Affiliate or to a Third Party in connection with the sale of, monetization of, transfer of, or obtaining financing on the basis of the payments due to Adimab under this Agreement or debt or project financing in connection with this Agreement.

This Agreement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assigns. Any assignment of this Agreement not made in accordance with this Agreement is prohibited hereunder and shall be null and void.

**10.8 Severability.** If one or more of the provisions in this Agreement are deemed unenforceable by law, then such provision shall be deemed stricken from this Agreement and the remaining provisions shall continue in full force and effect, and the Parties shall substitute for the unenforceable provision an enforceable provision that conforms as nearly as possible with the original intent of the Parties.

**10.9 Force Majeure.** A Party shall be excused from liability for the failure or delay in performance of such Party’s obligations under this Agreement to the extent that such performance is prevented by a Force Majeure. Such excuse from liability shall be effective only to the extent and duration of the Force Majeure event(s) causing the failure or delay in performance. The affected Party shall notify the other Party of such Force Majeure event(s) as soon as reasonably practicable and shall use reasonable efforts to resume performance of its obligations under this Agreement as soon as reasonably practicable.

**10.10 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, postage prepaid, delivered by express delivery service or personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

If to Adimab:

Adimab, LLC  
7 Lucent Drive  
Lebanon, NH 03766  
Attention: General Counsel

with a required copy to:

Attention: Head, Business Development at the same address.

In the case of Arsanis:

Arsanis Inc.  
890 Winter Street  
Suite 230  
Waltham, MA 02451-1472  
Attention: CEO

**10.11 Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**10.12 Headings.** The headings for each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on, nor to be used to interpret, the meaning of the language contained in the particular Article or Section.

**10.13 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the subsequent enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time executed by an authorized officer of the waiving Party.

**10.14 Performance by Affiliates.** A Party may perform some or all of its obligations under this Agreement through Affiliate(s) or may exercise some or all of its rights under this Agreement through Affiliates. However, each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance as if such Party were performing such obligations itself, and references to a Party in this Agreement shall be deemed to also reference such Affiliate. In particular and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in Article 6 (*Confidentiality; Publicity*), and shall (to avoid doubt) be subject to the intellectual property assignment and other intellectual property provisions of Article 5 (*Intellectual Property*) as if they were the original Party to this Agreement (and be deemed included in the actual Party to this Agreement for purposes of all intellectual property-related definitions).

**10.15 Counterparts.** This Agreement may be executed in one or more identical counterparts, each of which shall be deemed to be an original, and which collectively shall be deemed to be one and the same instrument. In addition, signatures may be exchanged by facsimile or PDF.

*[Remainder of Page Left Intentionally Blank; Signature Page Follows]*

IN WITNESS WHEREOF, the Parties have by duly authorized persons executed this Agreement to be effective as of the Effective Date.

**ARSANIS INC.:**

By: /s/ Michael P. Gray  
Title: Chief Financial Officer  
Date: February 24, 2017

**ADIMAB, LLC:**

By: /s/ Tillman Gerngross  
Title: Tillman Gerngross  
Date: 2/25/2017

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**EXHIBITS LIST**

**A –ADIMAB RSV ANTIBODIES**

**B –RSV ANTIBODY PATENTS**

**C –PRESS RELEASE**



**EXHIBIT A**  
**Adimab RSV Antibodies**

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of 3 pages were omitted. [\*\*]

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**Exhibit B**  
**RSV Antibody Patents**

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**DRAFT- NOT FOR IMMEDIATE RELEASE**

**Arsanis and Adimab Enter Into License Agreement to Target Respiratory Syncytial Virus (RSV) With Monoclonal Antibodies**

*Arsanis awarded up to \$9.3 million from the Bill & Melinda Gates Foundation to advance RSV antibody program towards the clinic*

**WALTHAM, MA., US, VIENNA, Austria, and LEBANON, NH., US – [February \_\_, 2017]** – Arsanis, Inc., a clinical-stage biopharmaceutical company developing targeted monoclonal antibodies for pre-emptive and post-infection treatment of serious infectious diseases, and Adimab, LLC, the global leader in the discovery and optimization of fully human monoclonal and bispecific antibodies, announced today they have entered into an agreement under which Arsanis has secured the exclusive, worldwide license to antibodies targeting respiratory syncytial virus (RSV) that were discovered by Adimab. Arsanis will initially focus on the selection of a lead RSV antibody candidate and has received a grant of up to \$9.3 million from the Bill & Melinda Gates Foundation to advance the selected antibody to IND filing.

“Arsanis’ partnerships with Adimab and the Gates Foundation will allow us to apply our deep expertise in the discovery and development of anti-infective antibodies to advance highly potent human monoclonal antibodies for the prevention of RSV infection,” said Rene Russo, Pharm.D., BCPS, President and Chief Executive Officer, Arsanis. “We believe this approach has the potential to address a significant global need for effective and accessible RSV therapeutics in both developed and developing countries.”

Under the agreement with Adimab, Arsanis has exclusively licensed a panel of RSV antibodies for the purpose of evaluating and selecting the best therapeutic leads under an exclusive global development and commercialization license. Adimab will be entitled to receive license fees and development milestones, as well as a royalty on net sales.

“We are very pleased that Arsanis and the Gates Foundation are collaborating on this important program. Through our B cell isolation approach, Adimab has identified highly potent antibodies against a number of infectious disease targets. The RSV antibodies licensed to Arsanis include some of the most potent RSV neutralizers reported to date,” said Guy Van Meter, VP of Business Development at Adimab. “This new agreement expands an already successful relationship with Arsanis, under which Arsanis’ lead program ASN100 for *S. aureus* pneumonia, currently in a Phase 2 clinical study, was discovered.”

## About Respiratory Syncytial Virus (RSV)

RSV is a highly contagious virus that causes infections in both the upper and lower respiratory tract. RSV infects nearly every child at least once by the age of two years and is a major cause of hospitalization due to respiratory infection in children, the elderly, and immunocompromised patients. RSV infection typically results in cold-like symptoms but can lead to more serious respiratory illnesses such as croup, pneumonia, bronchiolitis, and in extreme cases, death. RSV infection in the pediatric and adult populations account for more than 300,000 hospitalizations per year in the U.S. In the developing world, RSV is responsible for 30 million cases of acute respiratory tract infection and 200,000 deaths per year. As a result, there is a significant need for novel therapeutics to prevent RSV infection.

## About Arsanis, Inc.

Arsanis is a clinical-stage biotechnology company leading the development of targeted monoclonal antibodies (mAbs) for pre-emptive therapy and treatment of serious infectious diseases. The company's current programs address pathogenic processes selectively, aiming to preserve the healthy microbiome and potentially allowing Arsanis to address critical infections without contributing to the problem of resistance. The company is building a broad product pipeline addressing the most important infectious diseases that threaten patients globally. Its lead clinical program, ASN100, is aimed at serious *Staphylococcus aureus* infections and is being evaluated in a Phase 2 clinical study for the prevention of *S. aureus* pneumonia in high-risk patients.

Arsanis is a U.S. company headquartered in Waltham, Massachusetts, with European research and preclinical development operations headquartered in Vienna, Austria (Arsanis Biosciences GmbH). For more information, please visit the Arsanis website at [www.arsanis.com](http://www.arsanis.com).

## About Adimab

Adimab has established antibody discovery collaborations with many leading pharmaceutical companies, such as Merck, Novo Nordisk, Biogen, GSK, Roche, Novartis, Eli Lilly, Genentech, Celgene, Gilead, Kyowa Hakko Kirin, Takeda and Sanofi. In addition, Adimab has partnered with several smaller publicly traded companies, such as Acceleron, Merrimack Pharmaceuticals, Kite, Five Prime, as well as leading venture-backed companies including Jounce, Mersana, Alector, Surface Oncology, Potenza, Tizona, Tusk and several academic institutions such as Memorial Sloan Kettering and MD Anderson. The Adimab antibody discovery and optimization platform has also been internalized by several large pharma partners; *Adi-inside* partners include Merck, Novo Nordisk, Biogen and GSK.

Adimab's integrated antibody discovery and optimization platform provides unprecedented speed from antigen to purified, full-length human IgGs. Adimab offers fundamental advantages by delivering diverse panels of therapeutically relevant antibodies that meet the most aggressive standards for affinity, epitope coverage, species cross-reactivity and developability. Adimab enables its partners to rapidly expand their biologics pipelines through a broad spectrum of technology access arrangements. For more information, please visit the Adimab website at <http://www.adimab.com>.

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