UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38295

ARSANIS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-3181608**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
890 Winter Street, Suite 230 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a small reporting company)	Small reporting company	☐
		Emerging growth Company	☒

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

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

As of April 30, 2018, the registrant had 14,294,421 shares of common stock, $0.001 par value per share, outstanding.

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We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. Other trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Quarterly Report on Form 10-Q 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 63,999	$ 76,793
Grant and incentive receivables	1,926	1,608
Restricted cash	51	—
Prepaid expenses and other current assets	2,549	1,129
Total current assets	68,525	79,530
Property and equipment, net	384	421
Restricted cash	312	355
Other assets	—	948
Total assets	$ 69,221	$ 81,254
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,108	$ 1,893
Accrued expenses	5,141	5,779
Unearned income	730	694
Loans payable, net of discount	2,318	2,314
Total current liabilities	9,297	10,680
Loan payable, net of discount and current portion	9,698	9,922
Unearned income	1,796	1,936
Other long-term liabilities	7	9
Total liabilities	20,798	22,547
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized as of March 31, 2018 and December 31, 2017; 14,294,421 and 14,294,383 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	15	15
Additional paid-in capital	151,396	150,830
Accumulated other comprehensive income (loss)	(93)	127
Accumulated deficit	(102,895)	(92,265)
Total stockholders' equity	48,423	58,707
Total liabilities and stockholders' equity	$ 69,221	$ 81,254

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

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

	Three Months Ended March 31,	
	2018	2017
Operating expenses:		
Research and development	$ 8,133	$ 4,391
General and administrative	2,817	1,436
Total operating expenses	10,950	5,827
Loss from operations	(10,950)	(5,827)
Other income (expense):		
Grant and incentive income	445	700
Interest expense	(267)	(1,019)
Interest income	216	—
Change in fair value of derivative liability	—	762
Other income (expense), net	(74)	(1)
Total other income (expense), net	320	442
Net loss	(10,630)	(5,385)
Accretion of redeemable convertible preferred stock to redemption value	—	(7)
Net loss attributable to common stockholders	$ (10,630)	$ (5,392)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.74)	$ (10.49)
Weighted average common shares outstanding—basic and diluted	14,294,421	513,900

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

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

	Three Months Ended March 31,	
	2018	2017
Net loss	$ (10,630)	$ (5,385)
Other comprehensive loss:		
Foreign currency translation gain (loss)	(220)	(82)
Comprehensive loss	$ (10,850)	$ (5,467)

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

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

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (10,630)	$ (5,385)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	566	182
Depreciation and amortization expense	46	48
Non-cash interest expense	200	941
Non-cash rent expense	(7)	(5)
Change in fair value of derivative liability	—	(762)
Changes in operating assets and liabilities:		
Grant and incentive receivables	(277)	(535)
Prepaid expenses and other assets	(465)	(1,952)
Accounts payable	(788)	1,339
Accrued expenses	(654)	1,144
Unearned income	(168)	1,474
Net cash used in operating activities	(12,177)	(3,511)
Cash flows from investing activities:		
Purchases of property and equipment	—	(17)
Net cash used in investing activities	—	(17)
Cash flows from financing activities:		
Proceeds from issuance of convertible promissory notes	—	4,935
Repayments of loans payable	(583)	(582)
Payments of issuance costs of convertible promissory notes	—	(17)
Payment of initial public offering costs	(43)	—
Net cash provided by (used in) financing activities	(626)	4,336
Effect of exchange rate changes on cash	17	12
Net increase (decrease) in cash, cash equivalents and restricted cash	(12,786)	820
Cash, cash equivalents and restricted cash at beginning of period	77,148	3,429
Cash, cash equivalents and restricted cash at end of period	$ 64,362	$ 4,249
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 19
Derivative liability in connection with issuance of convertible promissory notes	$ —	$ 403
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 7

The accompanying unaudited notes are an integral part of these condensed 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, or mAb, immunotherapies to address serious infectious diseases. The Company's deep understanding of the pathogenesis of infection, paired with access to what the Company believes to be some of the most advanced mAb discovery techniques and platforms available today, has positioned the Company to further its goal of building and advancing a pipeline of novel mAbs with multiple mechanisms of action and high potency against their intended targets. The Company's lead clinical program, ASN100, is aimed at serious *Staphylococcus aureus* infections and is being evaluated in a Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. In addition to ASN100, the Company's preclinical pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including respiratory syncytial virus, or RSV.

Arsanis was incorporated under the laws of the State of Delaware and is headquartered in Waltham, Massachusetts, with a wholly-owned subsidiary that is primarily focused on discovery research 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 condensed 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.

Reverse Stock Split

On November 3, 2017, the Company effected a one-for-3.4130 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

Initial Public Offering

On November 20, 2017, the Company closed an initial public offering of its common shares, in which the Company issued and sold 4,000,000 common shares at a price to the public of $10.00 per share. Concurrent to the initial public offering, (i) the Company issued an additional 600,000 common shares at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option and (ii) New Enterprise Associates 16, L.P., or NEA, purchased 2,000,000 shares of our common stock at the initial per share public offering price of $10.00 in a private placement. The aggregate net proceeds to the Company from the initial public offering, inclusive of the over-allotment exercise, and the private placement were $58.1 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the initial public offering, all of the outstanding redeemable convertible preferred stock of the Company automatically converted into 7,180,483 shares of the Company's common stock.

Going Concern

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the condensed consolidated financial statements are issued. As of March 31, 2018, the Company had an accumulated deficit of $102.9 million. During the three months ended March 31, 2018, the Company incurred a net loss of $10.6 million and used $12.2 million of cash in operations. The Company expects to continue to generate operating losses for the foreseeable future. Based on its current operating plan, the Company expects that its cash and cash equivalents of $64.0 million as of March 31, 2018, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months from the issuance date

of these condensed consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Statements

The condensed balance sheet at December 31, 2017 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America ("GAAP"). The accompanying condensed financial statements as of March 31, 2018 and for the three months ended March 31, 2018 are unaudited. The accompanying unaudited interim financial statements have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K as filed with the SEC on March 9, 2018. In the opinion of management, all adjustments, consisting only of normal recurring adjustments as necessary, for the fair statement of the Company's condensed financial position as of March 31, 2018 and condensed results of its operations and cash flows for the three months ended March 31, 2018 have been made. The results of operations for the three months ended March 31, 2018 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2018.

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.

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 balance sheets 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.

Cash and Cash Equivalents

All unrestricted highly liquid investments purchased with an original maturity date of 90 days or less at the date of purchase are considered to be cash equivalents.

The Company's cash equivalents, which are money market funds held in a sweep account, are measured at fair value on a recurring basis. As of March 31, 2018 and December 31, 2017, the carrying amount of cash equivalents was $62.6 million and $70.9 million, respectively, which approximates fair value and was determined based upon Level 1 inputs. The sweep account is valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1.

Restricted Cash

In March 2017, the Company received a payment of $1.6 million under a grant agreement with the Bill & Melinda Gates Foundation (the "Gates Foundation"). 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 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. Such funds received from the Gates Foundation were classified as restricted cash (current) until the Company incurred qualifying expenses under the letter agreement and the restrictions no longer apply. As of March 31, 2018 and December 31, 2017, none of the proceeds 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 funds imposed by the agreement.

The Company maintains letters of credit for the benefit of the landlords in connection with the Company's office leases.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the statement of cash flows.

	March 31,		December 31,	
	2018	2017	2017	2016
Cash and cash equivalents	$ 63,999	$ 2,282	$ 76,793	$ 3,035
Restricted cash – current	51	1,595	—	—
Restricted cash – non-current	312	372	355	394
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 64,362	$ 4,249	$ 77,148	$ 3,429

Fair Value Measurements

Certain assets of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of cash equivalents, other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's loan and security agreement with Silicon Valley Bank ("SVB") 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 Österreichische Forschungsförderungsgesellschaft mbH ("FFG") approximates their fair value because the Company records imputed interest expense based on rates that approximate market rates of interest as of the issuance date of each FFG loan. The carrying value of the Company's convertible promissory notes approximated their fair value due to the short term of the notes.

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, facility costs, depreciation, third-party license fees, and external costs of outside vendors engaged to conduct clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Research Contract Costs and Accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. These agreements are cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and

contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

The Company measures stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance-based vesting conditions.

For stock-based awards granted to consultants and non-employees, compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. Prior to November 20, 2017, the Company had been a private company and lacked company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the three months ended March 31, 2018 and 2017, comprehensive loss included $0.2 million and $0.1 million of foreign currency translation loss adjustments, respectively.

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 entitled the holders of such shares to participate in dividends but contractually did not require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Adopted Accounting Pronouncements

In March 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-05, *Income Taxes (Topic 740) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("ASU 2018-05"). This standard amends ASC 740, Income Taxes ("ASC 740") to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act pursuant to Staff Accounting Bulletin No. 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Act enactment date. This standard is effective upon issuance. The Company will continue to assess the impact that various provisions will have on its business. Any subsequent adjustment to these amounts will be recorded to current tax expense in the quarter of 2018 when the analysis is complete.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In January 2017, FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"). The amendments in this update clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill and consolidation. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which requires restricted cash to be presented with cash and cash equivalents on the statement of cash flows and disclosure of how the statement of cash flows reconciles to the balance sheet if restricted cash is shown separately from cash and cash equivalents on the balance sheet. The Company adopted the standard retrospectively to all periods presented on the required effective date of January 1, 2018, and its adoption impacted the presentation of restricted cash in the cash flow. See "—Restricted Cash" for a reconciliation of cash and cash equivalents and restricted cash presented in the consolidated balance sheets and consolidated statements of cash flows.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* ("ASU 2016-16"), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted the standard retrospectively to all periods presented on the required effective date of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes most existing revenue recognition guidance under GAAP. The FASB also issued several amendments and updates to the new revenue standard (collectively, "Topic 606"). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle, and will require companies to use more judgment and make more estimates than under the current guidance. These judgments and estimates include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The Company adopted this guidance, effective January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows as the Company does not currently have any revenue-generating arrangements.

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 ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2017-11 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.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets 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 March 31, 2018 Using:	
	Level 1	Total
Assets:		
Cash equivalents - Money Market Funds	62,598	62,598
	$ 62,598	$ 62,598

	Fair Value Measurements as of December 31, 2017 Using:	
	Level 1	Total
Assets:		
Cash equivalents - Money Market Funds	$ 70,891	$ 70,891
	$ 70,891	$ 70,891

During the three months ended March 31, 2018 and 2017, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of Cash Equivalents

The cash equivalents in the table above are composed of money market funds held in a sweep account. The fair value of the cash equivalents was determined based on quoted market prices with no valuation adjustments applied, which represents a Level 1 measurement within the fair value hierarchy.

Valuation of Warrant Liability

The Company's warrant liability in prior periods was 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 in prior periods included 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 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 estimated 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 was 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 prior periods 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.

There was no warrant liability or derivative liability as of March 31, 2018 and December 31, 2017.

4. Prepaid Expenses and Other Current Assets

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

	March 31, 2018	December 31, 2017
Prepaid clinical trial costs	$ 1,839	$ 257
Prepaid directors' and officers' and other corporate insurance	372	524
Other	338	348
	$ 2,549	$ 1,129

5. Property and Equipment, Net

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

	March 31, 2018	December 31, 2017
Laboratory and office equipment	$ 1,782	$ 1,739
Furniture and fixtures	429	419
Leasehold improvements	303	297
Computer equipment and software	194	189
	2,708	2,644
Less: Accumulated depreciation and amortization	(2,324)	(2,223)
	$ 384	$ 421

Depreciation and amortization expense for the three months ended March 31, 2018 and 2017 was $46,000 and $48,000, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2018	December 31, 2017
Accrued clinical trial costs	$ 2,888	$ 2,317
Accrued compensation and benefits	1,465	2,454
Accrued professional fees	381	510
Other	407	498
	$ 5,141	$ 5,779

7. Collaboration, License and Funding Arrangements

Adimab Option and License Agreement

In February 2017, the Company entered into an option and license agreement with Adimab, LLC ("Adimab"), a related party (see Note 15) (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.

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 certain royalty payment obligations described in the agreement.

During the three months ended March 31, 2018 and 2017, the Company recognized research and development expense of $0.1 million and $13,000, respectively, 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 15), 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 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. Such funds received from the Gates Foundation were no longer classified as restricted cash once the Company incurred qualifying expenses under the grant agreement and the restrictions no longer applied.

During the three months ended March 31, 2018 and 2017, the Company recognized grant income of $0 and $44,000, respectively, under the grant agreement with the Gates Foundation upon incurring qualifying expenses. As of March 31, 2018 and December 31, 2017, unearned income under the grant agreement with the Gates Foundation was $0.

Funding Agreements with FFG

Between September 2011 and March 2017, the Company entered into a series of funding agreements with FFG that provided for loans and grants to fund between 50% and 70% of qualifying research and development expenditures of the Company's subsidiary in Austria on a project-by-project basis, as approved by FFG.

FFG Grants

For grants under the funding agreements with FFG, the Company recognized grant income of $0 and $0.1 million during the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018 and December 31, 2017, the Company recorded grant receivables from FFG of $0.1 million and $0.1 million, respectively, for qualifying expenses incurred that were reimbursable under the funding agreements. As of March 31, 2018 and December 31, 2017, there were no amounts recorded as unearned income in connection with the FFG grants.

FFG Loans

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

The Company recognized grant income of $0.2 million and $0.1 million during the three months ended March 31, 2018 and 2017, respectively, related to the recognition of the unearned income recorded for the imputed benefit of FFG loans at below-market interest rates. Unearned income (current) related to the imputed benefit of FFG loans at below-market interest rates was $0.7 million and $0.7 million as of March 31, 2018 and December 31, 2017, respectively, and unearned income (non-current) related to such benefit was $1.8 million and $1.9 million as of March 31, 2018 and December 31, 2017, respectively.

Research and Development Incentive

The Company participates in a research and development incentive program provided by the Austrian government whereby the Company is entitled to reimbursement by the Austrian government for a percentage of qualifying research and development expenses incurred by the Company's subsidiary in Austria. Under the program, the reimbursement rate for qualifying research and development expenses incurred by the Company through its subsidiary in Austria was 12% for the year ended December 31, 2017, and is 14% for the year ended December 31, 2018.

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 $0.3 million and $0.4 million during the three months ended March 31, 2018 and 2017, respectively, in connection with the Austrian research and development incentive program. As of March 31, 2018 and December 31, 2017, the Company recorded receivables for amounts due under the program of $1.8 million and $1.5 million, respectively, which amounts were included in grant and incentive receivables in the condensed consolidated balance sheet.

8. Loans Payable

The aggregate principal amount of debt outstanding as of March 31, 2018 and December 31, 2017 consisted of the following (in thousands):

	March 31, 2018	December 31, 2017
Term loans under 2012 Loan Agreement	$ 4,083	$ 4,667
FFG Loans	10,478	10,225
	$ 14,561	$ 14,892

Current and non-current debt obligations reflected in the condensed consolidated balance sheets as of March 31, 2018 and December 31, 2017 consisted of the following (in thousands):

	March 31, 2018	December 31, 2017
Current liabilities:		
Term loans under 2012 Loan Agreement	$ 2,333	$ 2,333
FFG loans	—	—
Unamortized debt discount	(15)	(19)
Loans payable, net of discount	2,318	2,314
Non-current liabilities:		
Term loans under 2012 Loan Agreement	$ 1,750	$ 2,334
FFG loans	10,478	10,225
Unamortized debt discount	(2,530)	(2,637)
Loans payable, net of discount and current portion	9,698	9,922
Total loans payable, net of discount	$ 12,016	$ 12,236

2012 Loan Agreement

On December 7, 2012, the Company entered into a loan and security agreement (the "2012 Loan Agreement") with 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"). 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 March 31, 2018 and December 31, 2017, the interest rate applicable to borrowings under the 2016 Term Loan Advance was 4.50% and 4.25%, 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 balance sheet and is being amortized to interest expense over the term of the loan using the effective interest method.

The Company recognized interest expense under the 2012 Loan Agreement, as amended, of $0.1 million and $0.1 million during the three months ended March 31, 2018 and 2017, respectively, including interest expense related to the amortization of the debt discount and final payment of $33,000 and $49,000 during the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018 and December 31, 2017, the unamortized debt discount was $19,000 and $26,000, respectively.

During the three months ended March 31, 2018 and 2017, the Company made aggregate principal payments in connection with the 2012 Loan Agreement of $0.6 million and $0.6 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 $10.5 million and $10.2 million as of March 31, 2018 and December 31, 2017, 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 March 31, 2018 and December 31, 2017, the unamortized debt discount related to FFG loans was $2.5 million and $2.6 million, respectively.

The Company recognized interest expense of $0.2 million and $0.1 million during the three months ended March 31, 2018 and 2017, respectively, related to the FFG loans, which included interest expense related to the amortization of debt discount of $0.2 million and $0.1 million during the three months ended March 31, 2018 and 2017, respectively. There were no principal payments due or paid under the FFG loans during the three months ended March 31, 2018 and 2017.

9. Convertible Promissory Notes

There were no convertible promissory notes outstanding as of March 31, 2018 and December 31, 2017.

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 April 2017, in connection with the Company's issuance and sale of its Series D redeemable convertible preferred stock (the "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 recognized interest expense of $0.7 million, including amortization of debt discount of $0.6 million, during the three months ended March 31, 2017 in connection with the 2016 Notes.

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 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 recognized interest expense of $0.1 million, including amortization of debt discount of $0.1 million, during the three months ended March 31, 2017, in connection with the 2017 Notes.

10. Preferred and Common Stock Warrants

As of March 31, 2018 and December 31, 2017, outstanding warrants to purchase shares of common stock consisted of the following:

Date Exercisable	Number of Shares Issuable	Exercise Price	Exercisable for	Classification	Expiration
December 12, 2012	788	$ 12.70	Common	Equity	December 6, 2022
February 25, 2013	3,152	$ 12.70	Common	Equity	December 6, 2022
February 29, 2016	3,237	$ 16.22	Common	Equity	February 18, 2026
August 23, 2016	3,237	$ 16.22	Common	Equity	February 18, 2026
	10,414				

In connection with the 2012 Loan Agreement and the First Amendment to the 2012 Loan Agreement, the Company issued to SVB warrants for the purchase of Series A-2 and Series B preferred stock.

The Company classified the warrants as a liability on its consolidated balance sheet (included in other long-term liabilities) as the warrants were free-standing financial instruments that may require the Company to transfer assets upon exercise. The liability associated with each portion of the warrants that became exercisable was recorded at fair value on the dates they became exercisable and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were 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 were recognized until the warrants qualified for equity classification. The Company recognized a gain (loss) of $0 for the three months ended March 31, 2017 related to the change in fair value of the warrants.

In November 2017, in connection with the closing of the initial public offering, the warrants for the purchase of redeemable convertible preferred stock converted into warrants for the purchase of common stock. Upon the conversion, the Company reclassified the warrants as equity, recorded at fair value on the date of the reclassification on its consolidated balance sheets (included in additional paid-in capital).

11. Common Stock

As of March 31, 2018 and December 31, 2017, the Company had reserved 2,759,028 and 2,187,252 shares of common stock, respectively, for the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2017 Equity Incentive Plan and 2017 Employee Stock Purchase Plan (see Note 12) and the exercise of outstanding warrants to purchase shares of common stock (see Note 10).

On November 3, 2017, the Company effected a one-for-3.4130 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's then-existing redeemable convertible preferred stock (see Note 1).

12. Stock-Based Compensation

2017 Equity Incentive Plan

The Company's 2017 Equity Incentive Plan (the "2017 Plan") provides for the grant by the Company of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Awards other than incentive stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company.

As of March 31, 2018 and December 31, 2017, the number of shares of common stock reserved for issuance under the 2017 Plan was the sum of (i) 1,331,747 shares and 759,971 shares, respectively, plus (ii) the number of shares of our common stock subject to outstanding awards under our 2010 Special Stock Incentive Plan and our 2011 Stock Incentive Plan, each as amended to date, 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 (iii) an annual increase, to be added on January 1 of each year, beginning on January 1, 2018 and continuing through January 1, 2027, in an amount equal to the lowest of 1,025,490 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on January 1 of each year and an amount determined by the Company's board of directors. As of March 31, 2018 and December 31, 2017, 422,747 shares and 553,971 shares, respectively, remained available for future grant.

Shares that are expired, terminated, surrendered or canceled under the 2017 Plan without having been fully exercised will be available for future awards. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

Stock Option Grants During the Three Months Ended March 31, 2018 and 2017

During the three months ended March 31, 2018, the Company granted options to purchase 703,000 shares of common stock to employees and directors. The Company did not grant any such options to purchase shares of common stock during the three months ended March 31, 2017. The Company recorded stock-based compensation expense for options granted to employees and directors of $0.6 million and $0.2 million during the three months ended March 31, 2018 and 2017, respectively.

The Company did not grant options to purchase shares of common stock to non-employees during either of the three month-periods ended March 31, 2018 and 2017. The Company recorded stock-based compensation expense for options granted to non-employees of $6,000 and $3,000 during the three months ended March 31, 2018 and 2017, 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:

	Three Months Ended March 31,	
	2018	2017
Risk-free interest rate	2.71%	*
Expected term (in years)	6.08	*
Expected volatility	77.3%	*
Expected dividend yield	0%	*

* Not applicable as no stock options were granted during the three months ended March 31, 2017.

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2017 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	1,403,119	$ 6.26	8.81	$ 9,128
Granted	703,000	17.16		
Exercised	—	—		
Forfeited	—	—		
Outstanding as of March 31, 2018	2,106,119	$ 9.90	9.02	$ 27,365
Options exercisable as of March 31, 2018	372,600	$ 6.84	7.02	$ 5,981
Options unvested as of March 31, 2018	1,733,519	$ 10.55	9.45	$ 21,384

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 three months ended March 31, 2018 was $11.79. There were no options granted during the three months ended March 31, 2017.

The total fair value of options vested during the three months ended March 31, 2018 and 2017 was $0.2 million and $0.2 million, respectively.

Stock-Based Compensation

Stock-based compensation expense was classified in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development expenses	$ 178	$ 62
General and administrative expenses	388	120
	$ 566	$ 182

As of March 31, 2018 and December 31, 2017, total unrecognized compensation cost related to the unvested stock-based awards was $11.7 million and $4.0 million, respectively, which is expected to be recognized over weighted average periods of 3.46 and 2.76 years, respectively.

13. Income Taxes

The Company did not record a federal or state income tax benefit for its losses for the three months ended March 31, 2018 and 2017 due to the conclusion that a full valuation allowance is required against the Company's deferred tax assets.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act ("Tax Reform Legislation"), which made significant changes to U.S. federal income tax law. On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Legislation. The ultimate impact of the Tax Reform Legislation may differ from this estimate, possibly materially, due to changes in interpretations and assumptions, guidance that may be issued and actions the Company may take in response to the Tax Reform Legislation. The Tax Reform Legislation is highly complex and the Company will continue to assess the impact that various provisions will have on its business. Income tax provision for the three months ended March 31, 2018, did not reflect any adjustment to the previously assessed Tax Reform Legislation enactment effect.

14. 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):

	Three Months Ended March 31,	
	2018	2017
Numerator:		
Net loss	$ (10,630)	$ (5,385)
Accretion of redeemable convertible preferred stock to redemption value	—	(7)
Net loss attributable to common stockholders	$ (10,630)	$ (5,392)
Denominator:		
Weighted average common shares outstanding—basic and diluted	14,294,421	513,900
Net loss per share attributable to common stockholders — basic and diluted	$ (0.74)	$ (10.49)

The Company's potentially dilutive securities, which include stock options, warrants to purchase shares of Preferred Stock and common stock, unvested restricted stock, convertible promissory notes and Preferred Stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2018	2017
Options to purchase common stock	2,106,119	544,411
Redeemable convertible preferred stock (as converted to common stock)	—	1,789,704
Warrants to purchase common stock	10,414	—
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	—	7,475
	2,116,533	2,341,590

15. Related Party Transactions

Agreements with Adimab, LLC

During the three months ended March 31, 2018 and 2017, the Company made payments to Adimab of $21,000 and $0, respectively, and recognized $0.1 million and $13,000 of research and development expense under the Adimab Option Agreement. As of March 31, 2018 and December 31, 2017, the Company owed $0.1 million and $21,000, respectively, to Adimab under the Adimab Option Agreement. The chairman of the Company's board of directors is a co-founder of Adimab and currently serves as Adimab's Chief Executive Officer.

Agreements with the Gates Foundation

During the three months ended March 31, 2018 and 2017, the Company recognized grant income of $0 and $44,000, respectively, under the grant agreement upon incurring qualifying expenses. As of March 31, 2018 and December 31, 2017, unearned income under the grant agreement was $0. The Gates Foundation is a principal stockholder of the Company.

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, serves as Chief Scientific Officer at EveliQure.

During the three months ended March 31, 2018 and 2017, the Company received payments from EveliQure under the agreement of $0.1 million and less than $0.1 million, respectively. During the three months ended March 31, 2018 and 2017, the Company recognized other income under the agreement of less than $0.1 million in each period. As of March 31, 2018 and December 31, 2017, amounts due from EveliQure totaled less than $0.1 million and $0.1 million, respectively.

16. Geographic Information

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

	March 31, 2018	December 31, 2017
United States	$ 27	$ 35
Austria	357	386
Total property and equipment, net	$ 384	$ 421

Item 2. 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 condensed consolidated financial statements and the related notes and the other financial information included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission on March 9, 2018.

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. 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. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. 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 Quarterly Report on Form 10-Q, particularly in the section entitled "Risk Factors" in Part II, Item 1A that could cause actual results or events to differ materially from the forward-looking statements that we make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Overview

We are a clinical-stage biopharmaceutical company focused on applying monoclonal antibody, or mAb, immunotherapies to address serious infectious diseases. Our deep understanding of the pathogenesis of infection, paired with access to what we believe to be some of the most advanced mAb discovery techniques and platforms available today, has positioned us to further our goal of building and advancing a pipeline of novel mAbs with multiple mechanisms of action and high potency against their intended targets. Our lead clinical program, ASN100, is aimed at serious *Staphylococcus aureus* infections and is being evaluated in a Phase 2 clinical trial for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients. 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 building our business to support discovery, research and development activities for our programs. We do not have any products approved for sale and have not generated any revenue from product sales.

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

- net cash proceeds of $75.1 million from sales of our preferred stock;
- net cash proceeds of $39.5 million from sales of our common stock in our initial public offering;
- net cash proceeds of $18.6 million from sales of our common stock in our private placement to New Enterprise Associates 16, L.P., or NEA;
- gross proceeds of $14.4 million from borrowings under convertible promissory notes;
- proceeds of $9.5 million from borrowings under a loan and security agreement with Silicon Valley Bank, or SVB, which, as amended, we refer to as the 2012 Loan Agreement;
- proceeds of $9.2 million and $10.5 million of grant and loan proceeds, respectively, from our funding agreements with Österreichische Forschungsförderungsgesellschaft mbH, or FFG;
- proceeds of $4.9 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.

On November 20, 2017, we closed an initial public offering of our common shares, in which we issued and sold 4,000,000 common shares at a price to the public of $10.00 per share. Concurrent with the initial public offering, (i) we issued an additional 600,000 common shares at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option and (ii) NEA

purchased 2,000,000 shares of our common stock at the initial per share public offering price of $10.00 in a private placement. The aggregate net proceeds to us from the initial public offering, inclusive of the over-allotment exercise, and the private placement were $58.1 million after deducting underwriting discounts and commissions and offering expenses payable by us.

Since our inception, we have incurred significant operating losses. 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 $10.6 million and $5.4 million for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of $102.9 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, 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 business 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. 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 March 31, 2018, we had cash and cash equivalents of $64.0 million. We believe our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the second half of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

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.

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.

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

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
ASN100	$ 5,237	$ 2,482
ASN200	15	7
ASN300	16	2
ASN400	3	17
ASN500	271	28
Unallocated research and development expenses	2,591	1,855
Total research and development expenses	$ 8,133	$ 4,391

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 continue our Phase 2 clinical trial of ASN100 as well as potentially conduct subsequent clinical trials of ASN100, seek to advance one or more additional product candidates, advance our preclinical programs, prepare associated regulatory filings for our product candidates and increase personnel costs, including stock-based compensation.

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.

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, director, 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 remain reasonably consistent with expenses incurred for the three-month period ended March 31, 2018. General and administrative expenses incurred during this period include increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with our becoming a public company in November 2017. 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.

Interest Income. Interest income primarily consists of interest earned on cash equivalents in our sweep account.

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 classified the warrants as a liability on our consolidated balance sheet. We remeasured this warrant liability to fair value at each reporting date using the Black-Scholes option-pricing model and recognized changes in the fair value of the warrant liability as a component of other income (expense), net in our consolidated statement of operations.

In November 2017, in connection with the closing of our initial public offering, the warrants for the purchase of preferred stock converted into warrants for the purchase of common stock. Upon the conversion, we reclassified the warrants as equity, recorded at fair value on the date of the reclassification on our consolidated balance sheets (included in additional paid-in capital).

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 and as a result, we no longer have a derivative liability recorded on our consolidated balance sheet and therefore, 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, 2017, we had U.S. federal and state net operating loss carryforwards of $24.2 million and $20.4 million, respectively, which begin to expire in 2031 and 2036, respectively. In addition, as of December 31, 2017, we had foreign net operating loss carryforwards of $56.3 million, which do not expire. As of December 31, 2017, we also had U.S. federal and state research and development tax credit carryforwards of $0.3 million and $0.1 million, respectively, which begin to expire in 2032 and 2031, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the Three Months Ended March 31, 2018 and 2017

The following table summarizes our results of operations for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		
	2018	2017	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 8,133	$ 4,391	$ 3,742
General and administrative	2,817	1,436	1,381
Total operating expenses	10,950	5,827	5,123
Loss from operations	(10,950)	(5,827)	(5,123)
Other income (expense):			
Grant and incentive income	445	700	(255)
Interest expense	(267)	(1,019)	752
Interest income	216	—	216
Change in fair value of derivative liability	—	762	(762)
Other income (expense), net	(74)	(1)	(73)
Total other income (expense), net	320	442	(122)
Net loss	$ (10,630)	$ (5,385)	$ (5,245)

Research and Development Expenses.

	Three Months Ended March 31,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
ASN100	$ 5,237	$ 2,482	$ 2,755
ASN200	15	7	8
ASN300	16	2	14
ASN400	3	17	(14)
ASN500	271	28	243
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	2,017	1,354	663
Other	574	501	73
Total research and development expenses	$ 8,133	$ 4,391	$ 3,742

Research and development expenses were $8.1 million for the three months ended March 31, 2018, compared to $4.4 million for the three months ended March 31, 2017. The increase of $3.7 million was primarily due to an increase of $2.8 million in direct costs for our ASN100 program, an increase of $0.2 million in direct costs for our ASN500 program, and an increase of $0.7 million in unallocated research and development expenses.

The increase in direct costs for our ASN100 program was primarily due to CMO and CRO fees for process development and establishment of manufacturing capabilities for the supply of our clinical materials, the oversight and conduct of our Phase 2 clinical trial and investigator fees for that same clinical trial.

Our ASN500 program was initiated in March 2017. Direct costs for our ASN500 program during the three months ended March 31, 2018 were primarily due to third-party fees for the oversight and conduct of preclinical research, facility costs and preclinical program expenses associated with internal lab consumables.

The increase in unallocated research and development expenses was due primarily to an increase of $0.7 million in personnel-related costs (including an increase in stock-based compensation of $0.1 million) primarily due to the hiring of new personnel and increased employee compensation.

General and Administrative Expenses. General and administrative expenses were $2.8 million for the three months ended March 31, 2018, compared to $1.4 million for the three months ended March 31, 2017. The increase of $1.4 million was primarily

related to additional costs associated with operating as a public company, including an increase of $0.6 million in personnel costs (which included an increase in stock-based compensation of $0.3 million) primarily due to an increase in headcount and employee compensation and an increase of $0.6 million in professional fees primarily due to legal and accounting costs associated with being a public company.

Other Income (Expense), Net. Other income, net was $0.3 million for the three months ended March 31, 2018, compared to $0.4 million for the three months ended March 31, 2017. The decrease of $0.1 million in other income, net was primarily due to a decrease of $0.8 million in gains recognized as a result of decreases in the fair value of the derivative liability associated with our convertible promissory notes and a decrease in grant and incentive income of $0.3 million primarily associated with our FFG grants and loans and the Austrian research and development incentive program. These decreases were partially offset by a decrease of $0.8 million in interest expense primarily associated with our convertible promissory notes and an increase in interest income of $0.2 million, primarily from the bank interest earned on the cash received from the initial public offering and concurrent private placement of our common stock.

Liquidity and Capital Resources

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

Since our inception, we have not generated any revenue from 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 our initial public offering and concurrent private placement, the sale of preferred stock, borrowings under convertible promissory notes, borrowings under the 2012 Loan Agreement, proceeds received from loans and grants under funding agreements with FFG, research and development incentive payments received from the Austrian government and proceeds from a grant agreement with the Gates Foundation. Through March 31, 2018, we had received net cash proceeds of $75.1 million from sales of our preferred stock, net cash proceeds of $58.1 million from the sale of our common stock, gross proceeds of $14.4 million from borrowings under convertible promissory notes, proceeds of $9.5 million from borrowings under the 2012 Loan Agreement with SVB, $9.2 million and $10.5 million of grant and loan proceeds, respectively, from our funding agreement with FFG, $4.9 million of research and development incentive payments received from the Austrian government and $1.6 million of proceeds from our grant agreement with the Gates Foundation.

Cash Flows

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

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	$ (12,177)	$ (3,511)
Net cash used in investing activities	—	(17)
Net cash provided by (used in) financing activities	(626)	4,336
Effect of exchange rate changes on cash	17	12
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (12,786)	$ 820

Operating Activities. During the three months ended March 31, 2018, operating activities used $12.2 million of cash, resulting from our net loss of $10.6 million and changes in our operating assets and liabilities of $2.4 million, partially offset by net non-cash charges of $0.8 million. Changes in our operating assets and liabilities for the three months ended March 31, 2018 consisted primarily of a $1.4 million decrease in accounts payable and accrued expenses, a $0.5 million increase in prepaid expenses and other assets, a $0.3 million increase in grant and incentive receivables and a $0.2 million decrease in unearned income. The decrease in accounts payable and accrued expenses was primarily due to the payment of the 2017 annual bonuses in March 2018 and the timing of vendor invoices and payments. The increases in prepaid expenses and other assets were primarily due to prepayments for the supply of clinical materials. The increase in grant and incentive receivables was primarily due to income earned under the Austrian research and development incentive program during the three months ended March 31, 2018. The decrease in unearned income was primarily due to the amortization of the discount associated with the FFG loans.

During the three months ended March 31, 2017, operating activities used $3.5 million of cash, resulting from our net loss of $5.4 million, partially offset by net non-cash charges of $0.4 million and net cash provided by changes in our operating assets and liabilities of $1.5 million. Net cash provided by changes in our operating assets and liabilities for the three months ended March 31, 2017 consisted primarily of a $1.5 million increase in unearned income, a $1.3 million increase in accounts payable and a $1.1 million increase in accrued expenses, partially offset by a $1.9 million increase in prepaid expenses and other assets and a $0.5 million increase in grant and incentive receivables. 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, which is recognized as grant income as we incur qualifying expenses under the agreement. The increases in accounts payable and accrued expenses were primarily due to increases in clinical trial costs associated with our Phase 2 clinical trial of ASN100. The increase in prepaid expenses and other 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.

Investing Activities. During the three months ended March 31, 2018, no cash was used in investing activities.

During the three months ended March 31, 2017, we used less than $0.1 million of cash in investing activities, consisting primarily of purchase of property and equipment.

Financing Activities. During the three months ended March 31, 2018, cash used by financing activities was $0.6 million, consisting primarily of principal repayments under the 2012 Loan Agreement

During the three months ended March 31, 2017, net cash provided by financing activities was $4.3 million, consisting primarily of proceeds of $4.9 million from our issuance of convertible promissory notes in January 2017, partially offset by $0.6 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 March 31, 2018 and December 31, 2017, the outstanding principal amount under the 2012 Loan Agreement was $4.1 million and $4.7 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. In November 2017, in connection with the closing of the initial public offering, the warrants for the purchase of convertible preferred stock converted into warrants for the purchase of common stock. See Note 10 to our condensed consolidated financial statements appearing in this Quarterly Report on Form 10-Q for additional information on the conversion of the warrants.

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 March 31, 2018 and December 31, 2017, the outstanding principal amount under loans from FFG was $10.5 million and $10.2 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 March 31, 2018, 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, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- leverage our programs to advance other product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the second half of 2019, including the completion of our ongoing Phase 2 clinical trial of ASN100 and initiation of a subsequent pivotal Phase 3 clinical trial, assuming a successful outcome in our Phase 2 clinical trial. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional funding to complete the clinical development of ASN100, commercialize ASN100, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for ASN100 or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize ASN100 ourselves.

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government funding, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, additional debt financing would result in increased fixed payment obligations.

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

Contractual Obligations and Commitments

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

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
	(in thousands)				
Manufacturing commitments (1)	4,514	4,514	—	—	—
Debt obligations (2)	15,389	2,561	7,612	5,216	—
Operating lease commitments (3)	2,175	1,033	1,096	46	—
Total	$ 22,078	$ 8,108	$ 8,708	$ 5,262	$ —

(1) 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.

(2) Amounts in the table reflect the contractually required principal and interest payable as of March 31, 2018 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 4.50%, which was the applicable interest rate as of March 31, 2018. In the event that the underlying program research results in a scientific or technical failure, the principal then outstanding under the FFG loan obligation related to that program may be forgiven by FFG and converted into non-repayable grant funding on a project-by-project basis.

(3) Amounts in the table reflect minimum payments due for our leases of office, laboratory and other space under operating leases that expire between January 2019 and April 2021. Amounts in the table also reflect noncancelable payments due for our lease of an animal-use facility, which is cancelable by either party upon six months' written notice.

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

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

During the three months ended March 31, 2018, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 9, 2018 and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- Government contracts, grant agreements and incentive programs
- Accrued research and development expenses
- Determination of the fair value of common stock prior to the initial public offering
- Valuation of derivative liability

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 condensed consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2018, we had $4.1 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 an applicable interest rate of 4.50% as of March 31, 2018. Based on the principal amounts outstanding as of March 31, 2018, 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 March 31, 2018, we had $62.6 million of cash equivalents consisting of money market funds held in our sweep account. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Because of the short-term nature of the instruments in our portfolio, we would not expect an immediate 10% change in market interest rates to have a material impact on our financial position or results of operations.

Foreign Currency Exchange Risk

We are also exposed to foreign exchange rate risk. Our headquarters are located in the United States, where the majority of our general and administrative expenses are incurred in U.S. dollars. Research and development costs are incurred by our subsidiary in Austria, whose functional currency is the Euro. During the three months ended March 31, 2018 and 2017, we recognized a foreign currency transaction loss of less than $0.1 million in each period. This loss primarily related to unrealized and realized foreign currency losses as a result of transactions entered into by our U.S. entity in currencies other than the U.S. dollar. These foreign currency transaction losses were recorded as a component of other income (expense), net in our condensed consolidated statements of operations. We believe that a 10% change in the exchange rate between the U.S. dollar and the Euro would not have a material impact on our financial position or results of operations.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports we file and submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

Our business is subject to numerous risks. The following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the Securities and Exchange Commission, press releases, communications with investors, and oral statements. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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 $10.6 million and $5.4 million for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of $102.9 million. We have funded our operations to date primarily with proceeds from our initial public offering and concurrent private placement, the sale of preferred stock, convertible debt financings, borrowings under a loan agreement, proceeds received from governmental loans and grants and proceeds received under a non-governmental grant. To date, we have devoted substantially all of our resources to building our business to support discovery, research and development activities for our programs. We 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 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 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.

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, 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 our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the second half of 2019, including the completion of our ongoing Phase 2 clinical trial of ASN100 and initiation of a subsequent pivotal Phase 3 clinical trial, assuming a successful outcome in our Phase 2 clinical trial. To

finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. See Note 1 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q 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 cash equivalents 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;
- 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.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government funding, grants, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. 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 $4.1 million as of March 31, 2018. 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 $10.5 million as of March 31, 2018. 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 2023. 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 and cash equivalents 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 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, 2017, we had U.S. federal and state net operating loss carryforwards of $24.2 million and $20.4 million, respectively, which begin to expire in 2031 and 2036, respectively. In addition, as of December 31, 2017, we had foreign net operating loss carryforwards of $56.3 million, which do not expire. As of December 31, 2017, we also had U.S. federal and state research and development tax credit carryforwards of $0.3 million and $0.1 million, respectively, which begin to expire in 2032 and 2031, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, 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, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

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

Risks Related to 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 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.

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;
- 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;
- 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 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.

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 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 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 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, more frequent dosing regimens or lower doses than we expect for ASN100. Furthermore, in the currently ongoing Phase 2 clinical trial, ASN100 is being studied in mechanically ventilated patients at high risk for 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 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.

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

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of these collaborations may not be successful;
- collaborators may not pursue development and/or commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by any collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

Furthermore, third parties on whom we rely may also have relationships with other entities, some of which may be our competitors. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our 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.

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. 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;

- 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;
- 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.

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 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.

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.

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 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. 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. Our agreements with Adimab impose specified diligence, milestone payment, royalty, asset transfer payment, acquisition payment, prosecution, insurance and other obligations on us. If we fail to comply with our obligations under the licenses, Adimab may have the right to terminate the license agreements, in which event we might not be able to market, and may be required to transfer to Adimab our rights in, any product that is covered by the Adimab agreements, including ASN100. Termination of the license agreements may also result in our having to negotiate a new or reinstated license with less favorable terms 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, sublicensable licenses to research, develop, manufacture, seek regulatory approval for and commercialize antibodies that we or our research contractors discover in specified areas of global health that the Gates Foundation has identified as underinvested or disproportionately impacting poor and vulnerable populations, including ASN100, for the treatment of neonatal sepsis caused by *S. aureus*. Two of these non-exclusive licenses will only be granted upon request from the Gates Foundation, and the third, although it has already been granted, would only be exercisable by the Gates Foundation upon certain "trigger events," as described further in the agreement.

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

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, 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 evidentiary standards required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of a biologics license application, or BLA, to the FDA or other submission or to obtain regulatory approval in the United States;
- FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA Fast Track designation. 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.

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.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as "Brexit." On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of 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.

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 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;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals, including license revocation;
- refusal to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

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;

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

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

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

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

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

The collection 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;
- 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.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare 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 or other government programs may result in a similar reduction in payments from private payors. Since enactment of the

ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 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. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

More recently, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA during the next Congressional session.

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

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

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

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

Our operations are subject to anti-corruption laws, including the Bribery Act, the FCPA and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially own shares representing more than a majority of our outstanding common stock. In addition, three of our directors are affiliated with stockholders who each own more than 5% of our outstanding common stock. If these stockholders were to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of 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 eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to 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. As of March 31, 2018, we had 14,294,421 shares of common stock outstanding.

Of these shares, 7,694,421 shares of common stock outstanding are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the expiration of the applicable lock-up period. For example, the expiration date for the lock-up agreements entered into between our officers, directors, employees and stockholders and the representatives of our initial public offering expires on May 14, 2018. Moreover, beginning 180 days after the completion of our initial public offering, holders of an aggregate of approximately 7,180,483 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. In November 2017, we registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements entered into in connection with our initial public offering.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Provisions in our corporate charter and our by-laws 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.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by our directors, officers, other employees or stockholders to the company or our stockholders, any action asserting a claim against us arising pursuant to the 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Initial Public Offering

On November 20, 2017, we closed our initial public offering, in which we issued and sold 4,000,000 shares of common stock at a public offering price of $10.00 per share, and issued an additional 600,000 shares of common stock at a price of $10.00 per share pursuant to the exercise of the underwriters' over-allotment option. The aggregate gross proceeds to us from our initial public offering, inclusive of the over-allotment exercise, were $46.0 million. The offering commenced on November 15, 2017, and did not terminate until the sale of all shares offered.

All of the shares of common stock issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-221050), which was declared effective by the SEC on November 15, 2017. Citigroup Global Markets Inc., Cowen and Company, LLC and Piper Jaffray & Co. were joint book-running managers for the initial public offering. The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise, were approximately $39.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us of approximately $6.5 million.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

As of March 31, 2018, we estimate that we have used approximately $14.5 million of our existing cash and cash equivalents at the time of the initial public offering, together with the net proceeds from our initial public offering, to advance our product candidates through clinical trial programs and for working capital and general corporate purposes. There have been no material changes in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on November 17, 2017 pursuant to Rule 424(b).

Item 6. Exhibits

Exhibit No.	Description	Incorporation by Reference			Filed with this 10-Q
		Form	SEC Filing Date	Exhibit Number	
3.1	Restated Certificate of Incorporation of the Company	8-K	11/20/2017	3.1	
3.2	Amended and Restated By-laws of the Company	8-K	11/20/2017	3.2	
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Arsanis, Inc.

Date: May 10, 2018

By: /s/ René Russo
René Russo
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2018

By: /s/ Michael Gray
Michael Gray
Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, René Russo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arsanis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2018

By: /s/ René Russo
René Russo
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Gray, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Arsanis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2018

By: /s/ Michael Gray
Michael Gray
Chief Operations Officer and
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arsanis, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, René Russo, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 10, 2018

By: /s/ René Russo
René Russo
President and Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Arsanis, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Gray, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 10, 2018

By: /s/ Michael Gray
Michael Gray
Chief Operating Officer and
Chief Financial Officer
(principal financial and accounting officer)