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 September 30, 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of October 31, 2018, the registrant had 14,315,410 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

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)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 40,753	$ 76,793
Grant and incentive receivables	2,870	1,608
Restricted cash	51	—
Prepaid expenses and other current assets	1,260	1,129
Total current assets	44,934	79,530
Property and equipment, net	323	421
Restricted cash	543	355
Other assets	101	948
Total assets	$ 45,901	$ 81,254
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,126	$ 1,893
Accrued expenses	3,092	5,779
Unearned income	727	694
Loans payable, net of discount	2,908	2,314
Total current liabilities	8,853	10,680
Loan payable, net of discount and current portion	7,827	9,922
Unearned income	1,318	1,936
Other long-term liabilities	6	9
Total liabilities	18,004	22,547
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 14,315,410 and 14,294,383 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	14	15
Additional paid-in capital	153,667	150,830
Accumulated other comprehensive income (loss)	144	127
Accumulated deficit	(125,928)	(92,265)
Total stockholders' equity	27,897	58,707
Total liabilities and stockholders' equity	$ 45,901	$ 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 9,572	$ 10,601	$ 26,635	$ 18,898
General and administrative	3,275	2,455	9,778	5,629
Total operating expenses	12,847	13,056	36,413	24,527
Loss from operations	(12,847)	(13,056)	(36,413)	(24,527)
Other income (expense):				
Grant and incentive income	2,016	1,618	2,977	3,180
Interest expense	(259)	(343)	(785)	(1,806)
Interest income	196	90	637	90
Change in fair value of warrant liability	—	5	—	16
Change in fair value of derivative liability	—	—	—	762
Loss on extinguishment of debt	—	—	—	(462)
Other income (expense), net	(6)	86	(79)	57
Total other income (expense), net	1,947	1,456	2,750	1,837
Net loss	(10,900)	(11,600)	(33,663)	(22,690)
Accretion of redeemable convertible preferred stock to redemption value	—	(16)	—	(36)
Net loss attributable to common stockholders	$ (10,900)	$ (11,616)	$ (33,663)	$ (22,726)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.76)	$ (22.60)	$ (2.35)	$ (44.22)
Weighted average common shares outstanding—basic and diluted	14,315,410	513,900	14,304,721	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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (10,900)	$ (11,600)	$ (33,663)	$ (22,690)
Other comprehensive income (loss):				
Foreign currency translation gain (loss)	(33)	(212)	17	(591)
Comprehensive loss	$ (10,933)	$ (11,812)	$ (33,646)	$ (23,281)

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)

	Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (33,663)	$ (22,690)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,684	627
Depreciation and amortization expense	121	148
Non-cash interest expense	593	1,575
Non-cash rent expense	—	(17)
Loss on extinguishment of debt	—	462
Change in fair value of warrant liability	—	(16)
Change in fair value of derivative liability	—	(762)
Changes in operating assets and liabilities:		
Grant and incentive receivables	(1,355)	57
Prepaid expenses and other assets	721	958
Accounts payable	270	2,342
Accrued expenses	(2,680)	2,063
Unearned income	(508)	289
Net cash used in operating activities	(33,817)	(14,964)
Cash flows from investing activities:		
Purchases of property and equipment	(34)	(59)
Net cash used in investing activities	(34)	(59)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock	—	40,053
Proceeds from issuance of convertible promissory notes	—	4,935
Proceeds from issuance of loans under funding agreements	—	685
Proceeds from exercise of stock options	152	—
Repayments of loans payable	(1,750)	(1,750)
Payments of issuance costs of convertible promissory notes	—	(17)
Payments of issuance costs of redeemable convertible preferred stock	—	(197)
Payments of initial public offering costs	(43)	(795)
Net cash provided by (used in) financing activities	(1,641)	42,914
Effect of exchange rate changes on cash	(309)	402
Net increase (decrease) in cash, cash equivalents and restricted cash	(35,801)	28,293
Cash, cash equivalents and restricted cash at beginning of period	77,148	3,429
Cash, cash equivalents and restricted cash at end of period	$ 41,347	$ 31,722
Supplemental disclosure of non-cash investing and financing activities:		
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,322
Issuance of redeemable convertible preferred stock upon extinguishment of convertible promissory notes	$ —	$ 11,102
Derivative liability in connection with issuance of convertible promissory notes	$ —	$ 403
Extinguishment of convertible promissory notes	$ —	$ 8,405
Extinguishment of derivative liability in connection with extinguishment of convertible promissory notes	$ —	$ 2,234
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 36

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 possesses a deep understanding of the pathogenesis of infection, paired with access to what the Company believes to be some of the most advanced mAb discovery techniques and platforms available today. The Company's pipeline is comprised of mAbs targeting multiple serious bacterial and viral pathogens, including *Staphylococcus aureus* ("*S. aureus*") and respiratory syncytial virus ("RSV").

On June 28, 2018, the Company announced the discontinuation of its Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients following the completion of a planned interim analysis of unblinded trial data for 118 patients by an independent data review committee ("DRC"). Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued. During the third quarter of 2018, the Company completed follow-up visits on patients dosed in the trial per the study protocol and intends to evaluate the complete dataset from the 154 patients that were enrolled in the trial to better understand the basis for this result. The Company expects to complete this evaluation in the fourth quarter of 2018 and has ceased further clinical development of ASN100, pending the results of this analysis. The Company currently does not expect to incur material costs for this program beyond the fourth quarter of 2018.

In light of the discontinuation of the clinical development of ASN100, the Company is considering strategic options that may potentially result in changes to its business strategy and future operations. Pending any decision to change its strategic direction, the Company's current operating plan provides for its ongoing review of the data from the ASN100 clinical trial, the continued development of its ASN500 program, as well as supporting its collaborators across its ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, the Company's ability to successfully execute on its strategic plans, 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. Any product candidates will require significant 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.

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.

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

The Company had an accumulated deficit of $125.9 million at September 30, 2018. During the nine months ended September 30, 2018, the Company incurred a net loss of $33.7 million and used $33.8 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 $40.8 million as of September 30, 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.

Arsanis is 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 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. All intercompany balances and transactions have been eliminated.

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 GAAP. The accompanying condensed financial statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 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 September 30, 2018 and condensed results of its operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017 have been made. The results of operations for the three and nine months ended September 30, 2018 and 2017 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 and stock options. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

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.

Comprehensive Gain (Loss)

Comprehensive gain (loss) includes net gain (loss) as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. Comprehensive gain (loss) included $(33) thousand and $(0.2) million for the three months ended September 30, 2018 and 2017, respectively, and $17 thousand and $(0.6) million for the nine months ended September 30, 2018 and 2017, respectively, of foreign currency translation gain (loss) adjustments.

Net Income (Loss) per Share

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, options to purchase common stock, redeemable convertible preferred stock, warrants to purchase common stock and warrants to purchase redeemable convertible preferred stock are considered potential dilutive common shares.

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

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes most existing revenue recognition guidance under GAAP. The FASB also issued several amendments and updates to the new revenue standard (collectively, "Topic 606"). The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle, and will require companies to use more judgment and make more estimates than under the current guidance. These judgments and estimates include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. 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.

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

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

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which requires restricted cash to be presented with cash and cash equivalents on the statement of cash flows and disclosure of how the statement of cash flows reconciles to the balance sheet if restricted cash is shown separately from cash and cash equivalents on the balance sheet. The Company adopted this standard on January 1, 2018. The adoption of ASU 2016-18 resulted in the Company's cash, cash equivalents and restricted cash being included in the beginning and ending amounts for the periods shown on the statement of cash flows and was applied retroactively and reflected in the balances presented for any prior periods. The Company believes that the adoption of this guidance did not have a significant impact on its condensed consolidated financial statements and related disclosures.

The restricted cash as of September 30, 2018 and December 31, 2017 is held as 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.

	September 30, 2018	September 30, 2017
Cash and cash equivalents	$ 40,753	$ 26,254
Restricted cash – current	51	5,118
Restricted cash – non-current	543	350
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 41,347	$ 31,722

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 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 March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("ASU 2018-05"). This standard amends ASC 740, Income Taxes ("ASC 740") to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act pursuant to Staff Accounting Bulletin No. 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Act enactment date. This standard was 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.

Recently Issued Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The new standard specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers. ASU 2018-07 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2018-07 will have on its consolidated financial statements.

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 of this new standard on its consolidated financial statements and related disclosures; however, it expects the adoption of this new guidance will result in the Company recording additional assets and corresponding liabilities on its consolidated balance sheets. The Company's assessment will include, but is not limited to, evaluating the impact that this standard has on the lease of its office space in Waltham, Massachusetts, and its office, laboratory, parking and storage space in Vienna, Austria, The Company's leases of its office and laboratory space in Waltham, MA and animal-use facility in Vienna, Austria expire in January 2019 and February 2019, respectively, and as a result will not be evaluated under the scope of ASU 2016-02.

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):

	As of September 30, 2018	
	Level 1	Total
Assets:		
Cash equivalents - Money Market Funds	$ 38,597	$ 38,597
	$ 38,597	$ 38,597

	As of December 31, 2017	
	Level 1	Total
Assets:		
Cash equivalents - Money Market Funds	$ 70,891	$ 70,891
	$ 70,891	$ 70,891

There were no changes to the valuation methods during the nine months ended September 30, 2018 and the year ended December 31, 2017. There were no transfers within the fair value hierarchy during the nine months ended September 30, 2018 and the year ended December 31, 2017.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued clinical trial costs	$ 778	$ 2,317
Accrued compensation and benefits	1,479	2,454
Accrued professional fees	449	510
Accrued other	386	498
	$ 3,092	$ 5,779

Accrued Clinical Trial Costs

In connection with the Company's decision to discontinue the Phase 2 clinical trial for ASN100, spending and activities related to ASN100 significantly declined and the Company does not expect to incur material costs for this program beyond the fourth quarter of 2018.

Restructuring Costs

On August 10, 2018, the Company's board of directors approved a reduction in workforce to reduce operating costs and better align the Company's workforce with the needs of its business following the Company's discontinuation of the clinical development of ASN100. As part of this reduction in workforce, the Company is in the process of eliminating 19 positions across the company, representing approximately 44% of its workforce. The Company anticipates that it will substantially complete the implementation of the reduction in workforce by the end of the fourth quarter of 2018.

Also, in August 2018, the Company's board of directors approved employee retention arrangements to incentivize certain employees to remain with the Company through early 2019.

The Company currently estimates that it will incur total expenses relating to the reduction in workforce of approximately $2.8 million, which is comprised of notice and employee severance and retention payments. The Company records these charges in accordance with ASC 420, *Exit or Disposal Cost Obligations*. During the three and nine months ended September 30, 2018, the Company recorded severance and retention expense of approximately $0.4 million related to the reduction in workforce. The Company expects to record the remaining $2.4 million of severance and retention expense during the fourth quarter of 2018 and first quarter of 2019.

The following table summarizes the Company's restructuring activities for the nine months ended September 30, 2018, which is included in accrued compensation and benefits as a component of accrued expenses on the Company's condensed consolidated balance sheet as of September 30, 2018 (in thousands):

	September 30, 2018
Employee severance benefits	$ 254
Employee retention benefits	260
Payments	(84)
Total	$ 430

5. 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 11) (the "Adimab Option Agreement"). Under the Adimab Option Agreement, Adimab has provided to the Company certain proprietary antibodies against RSV ("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 Bill & Melinda Gates Foundation (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.

The Company recognized research and development expenses of less than $0.1 million and $0 during the three months ended September 30, 2018 and 2017, respectively, and $0.1 million and $0.1 million during the nine months ended September 30, 2018 and 2017, respectively, in connection with the Adimab Option Agreement, which consisted of reimbursement for services performed by Adimab.

February 2017 and August 2018 Amended and Restated Gates Foundation Grant Agreement

In February 2017, the Company entered into the above-referenced grant agreement with the Gates Foundation, under which the Gates Foundation agreed to provide the Company up to $9.3 million to conduct preclinical development of mAbs 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 funds received from the Gates Foundation were incurred on qualifying expenses attributable to the RSV project, and the Company recognized grant income of $1.6 million under the grant agreement during the year ended December 31, 2017.

In August 2018, the Company entered into an amended and restated grant agreement which replaces the February 2017 grant agreement in its entirety. The amended and restated grant agreement includes amendments to conform to current Gates Foundation audit, reporting, and other administrative requirements, as well as to make the perpetual Gates Foundation license grant described below irrevocable.

The Company recognized grant income of $0 million during the three and nine months ended September 30, 2018, and $0.6 million and $1.2 million during the three and nine months ended September 30, 2017, respectively, under the grant agreement with the Gates Foundation upon incurring qualifying expenses. As of September 30, 2018 and December 31, 2017, unearned income under the grant agreement with the Gates Foundation was $0.

August 2018 Gates Foundation Grant Agreement

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

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

The Company recognized grant income of $1.1 million during the three and nine months ended September 30, 2018, under the August 2018 grant agreement with the Gates Foundation upon incurring qualifying expenses. Accordingly, unearned income under the August 2018 grant agreement with the Gates Foundation was $0 as of September 30, 2018.

Gates Foundation Letter Agreement and Investment

In April 2017, the Company entered into a letter agreement with the Gates Foundation. In connection with the letter agreement, the Gates Foundation purchased 2,464,799 shares of the Company’s Series D preferred stock, which converted into 722,179 shares of our common stock in connection with our November 2017 initial public offering after giving effect to a one-for-3.4130 reverse-stock-split. The Company committed to use the proceeds of $8.0 million from the investment by the Gates Foundation solely to advance the development of a specified monoclonal antibody program that involves the monoclonal antibodies ASN-1, ASN-2 and ASN-3 and the Company’s product candidate, ASN100. Under the letter agreement, in addition to the initial project funded by the Gates Foundation with its initial investment, the Company also agreed to conduct up to four additional projects to be proposed and to be funded by the Gates Foundation.

The letter agreement contains certain global access obligations as well as requirements relating to the Company’s use of the funds received from the Gates Foundation investment. In the event that the Company fails to comply with these obligations or requirements or any related U.S. legal obligations set forth in the letter agreement, the Gates Foundation will have the right, after expiration of a specified cure period, to require the Company to redeem all of the shares owned by the Gates Foundation or to locate a third party that will purchase such shares. For any redemption or purchase resulting from such default, the shares of the Company’s stock held by the Gates Foundation will be redeemed at an amount equal to the greater of the original purchase price (plus specified interest) or the fair market value of such stock on the date of such redemption. The term of the letter agreement continues in perpetuity.

In connection with this letter agreement, the Company has granted to the Gates Foundation and/or Gates Foundation-supported entities certain licenses, including a non-exclusive, non-terminable, royalty-free (except as required under the Adimab Collaboration Agreement), sublicensable license to products, technologies, materials, processes and other intellectual property developed using funds provided by the Gates Foundation or a Gates Foundation-supported entity, or developed in connection with the Company’s

conduct of any funded project or additional funded project, as well as all of the Company's background intellectual property, to utilize and exploit products and services directed at pathogens or other targets subject to any funded project or additional funded project.

The proceeds received from the Gates Foundation in connection with the Company's sale and issuance of Series D preferred stock were incurred on qualifying expenses under the letter agreement during the year ended December 31, 2017.

The Company incurred qualifying expenses of $0 during the three and nine months ended September 30, 2018, and $2.6 million and $3.3 million during the three and nine months ended September 30, 2017, respectively, under the letter agreement with the Gates Foundation.

Funding Agreements with FFG

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

FFG Grants

For grants under the funding agreements with FFG, the Company recognized grant income of $0 and $0.1 million during the three months ended September 30, 2018 and 2017, respectively, and $0 and $0.4 million during the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 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 September 30, 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 $0.1million during the three months ended September 30, 2018 and 2017, respectively, and $0.5 million and $0.4 million during the nine months ended September 30, 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 September 30, 2018 and December 31, 2017, respectively, and unearned income (non-current) related to such benefit was $1.3 million and $1.9 million as of September 30, 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 $0.7 million and $0.6 million during the three months ended September 30, 2018 and 2017, respectively, and $1.3 million and $1.1 million during the nine months ended September 30, 2018 and 2017, respectively, in connection with the Austrian research and development incentive program. As of September 30, 2018 and December 31, 2017, the Company recorded receivables for amounts due under the program of $2.8 million and $1.5 million, respectively, which are included in grant and incentive receivables in the condensed consolidated balance sheet.

6. Loans Payable

The aggregate principal amount of debt outstanding as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Term loans under 2012 Loan Agreement	$ 2,917	$ 4,667
FFG loans	9,872	10,225
	$ 12,789	$ 14,892

Current and non-current debt obligations reflected in the condensed consolidated balance sheets as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Current liabilities:		
Term loans under 2012 Loan Agreement	$ 2,917	$ 2,333
FFG loans	—	—
Unamortized debt discount	(9)	(19)
Loans payable, net of discount	2,908	2,314
Non-current liabilities:		
Term loans under 2012 Loan Agreement	$ —	$ 2,334
FFG loans	9,872	10,225
Unamortized debt discount	(2,045)	(2,637)
Loans payable, net of discount and current portion	7,827	9,922
Total loans payable, net of discount	$ 10,735	$ 12,236

2012 Loan Agreement

On December 7, 2012, the Company entered into a loan and security agreement (the "2012 Loan Agreement") with SVB, and borrowed an aggregate of $2.5 million in two separate tranches: $0.5 million in December 2012 (the "2012 Term Loan A Advance"), and $2.0 million in February 2013 (the "2012 Term Loan B Advance").

In connection with the 2012 Loan Agreement, the Company issued a Series A-2 warrant to SVB, which became exercisable with respect to 2,202 shares of Series A-2 preferred stock on December 12, 2012 in connection with the 2012 Term Loan A Advance, and with respect to 8,811 shares of Series A-2 preferred stock on February 25, 2013 in connection with the 2012 Term Loan B Advance. At the time of grant, the Series A-2 warrant was exercisable at a price of $4.54 per share. The Series A-2 warrant expires on December 6, 2022.

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.

In connection with the First Amendment to the 2012 Loan Agreement, the Company issued a Series B warrant to SVB which became exercisable with respect to 7,251 shares of Series B preferred stock on February 29, 2016 in connection with the 2016 Term Loan A Advance, and with respect to 7,251 shares of Series B preferred stock on August 23, 2016 in connection with the 2016 Term Loan B Advance. At the time of grant, the Series B warrant was exercisable at a price of $7.24 per share. The Series B warrant expires on February 18, 2026.

Upon the closing of the IPO in November 2017, the Series A-2 warrant converted into a common stock warrant to purchase up to 3,940 shares of common stock at an exercise price of $12.70 per share. The Series B warrant converted into a common stock warrant to purchase up to 6,474 shares of common stock at an exercise price of $16.22 per share. At September 30, 2018, these warrants to purchase up to 3,940 shares of common stock at an exercise price of $12.70 and 6,474 shares of common stock at an exercise price of $16.22 remained outstanding.

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

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 September 30, 2018 and December 31, 2017, the interest rate applicable to borrowings under the 2016 Term Loan Advance was 5.00% 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 1% to 2% of the outstanding principal if paid prior to February 19, 2018, which was the second anniversary of the First Amendment effective date. The prepayment fee is 0% subsequent to the second anniversary of the First Amendment effective date. 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. The final payment is being accreted to interest expense through the First Amendment Maturity Date. 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 was in compliance with all covenants under the 2012 Loan Agreement as of December 31, 2017. In March 2018, the Company entered into an Option and License Agreement with BB100, LLC, a subsidiary of Bravos Biosciences, LLC, under which BB100, LLC secured an exclusive, worldwide preclinical development license, and an option to a clinical development and commercialization license, to mAbs targeting *E. coli* that were discovered by the Company in its ASN200 program. In June 2018, the Company entered into an Option and License Agreement with BB200, LLC, a portfolio company of Bravos Biosciences, LLC, under which BB200, LLC secured an exclusive, worldwide preclinical development license, and an option to a clinical development and commercialization license to selected mAbs targeting *K. pneumoniae* that were discovered by the Company in its ASN300 program, including lead preclinical development candidate, ASN-5. As a result of entering into such Option and License Agreements without obtaining prior written consent of SVB, and subsequently delivering compliance certificates under the 2012 Loan Agreement that did not disclose these violations, the Company became in default under the 2012 Loan Agreement. On August 8, 2018, the Company and SVB entered into a Forbearance Agreement (the "Forbearance Agreement"), pursuant to which SVB agreed to forbear from exercising its rights and remedies with respect to such default until the earlier to occur of (i) another event of default under the 2012 Loan Agreement or (ii) October 31, 2018.

In addition to the default in connection with the Option and License Agreements, the Company has discussed with SVB whether its decision to discontinue its Phase 2 clinical trial of ASN100 may be considered a material adverse change in the business, operations or condition (financial or otherwise) of the Company and, accordingly, an event of default under the terms of the 2012 Loan Agreement. SVB has not agreed that the discontinuation of the trial does not constitute an event of default as of September 30, 2018. If the trial discontinuation does constitute a material adverse change in the Company's business, operations or condition, SVB would have the right to accelerate the Company's outstanding obligations under the 2012 Loan Agreement.

Because the Company's obligations under the 2012 Loan Agreement could be accelerated at the election of SVB upon the expiration of the Forbearance Agreement, or earlier if another event of default occurs, including but not limited to if the ASN100 Phase 2 clinical trial discontinuation constitutes a material adverse change in the Company's business, operations or condition, the Company has presented the SVB loan payable as current on the consolidated balance sheet as of September 30, 2018.

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 September 30, 2018 and 2017, respectively, and $0.2 million and $0.3 million during the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018 and December 31, 2017, the unamortized debt discount related to the 2012 Loan Agreement was $9,000 and $26,000, respectively.

The Company made aggregate principal payments in connection with the 2012 Loan Agreement of $0.6 million and $0.6 million during the three months ended September 30, 2018 and 2017, respectively, and $1.8 million and $1.8 million during the nine months ended September 30, 2018 and 2017, respectively.

FFG Loans

In connection with the funding agreements with FFG (see Note 5), the Company received loans from FFG. Loans from FFG were made on a project-by-project basis and had an aggregate principal amount outstanding of $9.9 million and $10.2 million as of September 30, 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 September 30, 2018 and December 31, 2017, the unamortized debt discount related to FFG loans was $2.0 million and $2.6 million, respectively.

The Company recognized interest expense of $0.2 million and $0.2 million during the three months ended September 30, 2018 and 2017, respectively, and $0.5 million and $0.5 million during the nine months ended September 30, 2018 and 2017, respectively, related to the FFG loans. There were no principal payments due or paid under the FFG loans during the three and nine months ended September 30, 2018 and 2017.

The Company may be required to return all or a portion of the FFG loans and/or grants (see Note 5) if it does not comply with the terms of the related FFG funding agreements and related guidelines, including specified requirements as to continued operations with respect to certain locations and funded projects. To date, FFG has not requested the return of any amounts received by the Company under the funding agreements.

7. Common Stock

As of September 30, 2018 and December 31, 2017, the Company had reserved 2,738,039 shares and 2,187,252 shares of common stock, respectively, for the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2017 Equity Incentive Plan and 2017 Employee Stock Purchase Plan and the exercise of outstanding warrants to purchase shares of common stock.

8. Stock-Based Compensation

The Company's 2017 Equity Incentive Plan (the "2017 Plan") provides for the grant by the Company of incentive stock options, non-qualified options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Awards other than incentive stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company. Following the adoption of the 2017 Plan, no further grants will be made under the Company's 2010 Special Stock Incentive Plan ("Special Plan") and 2011 Stock Incentive Plan ("2011 Plan").

Upon its adoption, the number of shares of the Company's common stock initially reserved for issuance under the 2017 Plan was the sum of 585,994 shares, plus the number of shares of the Company's common stock available for issuance under the Special Plan and the 2011 Plan immediately prior to the effectiveness of the 2017 Plan. In addition, the number of shares of the Company's common stock subject to outstanding awards under the Special Plan and 2011 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right will be available for future grant under the 2017 Plan. The number of shares of common stock reserved for issuance under this plan will automatically increase on January 1 of each year, through January 1, 2027, in an amount equal to the lowest of 1,025,490 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on January 1 of each year and an amount determined by the Company's board of directors.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses	$ 292	$ 101	$ 1,776	$ 225
General and administrative expenses	774	172	908	402
	$ 1,066	$ 273	$ 2,684	$ 627

As of September 30, 2018 and December 31, 2017, total unrecognized compensation cost related to the unvested stock-based awards was $10.1 million and $4.0 million, respectively, which is expected to be recognized over weighted average periods of 2.87 and 2.76 years, respectively.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	1,403,119	$ 6.26	8.81	$ 9,128
Granted	829,500	17.19		
Exercised	(21,027)	7.25		
Forfeited	(163,383)	10.75		
Outstanding as of September 30, 2018	2,048,209	$ 10.32	8.30	$ —
Options exercisable as of September 30, 2018	610,562	$ 6.41	6.48	$ —
Options unvested as of September 30, 2018	1,437,647	$ 11.79	9.07	$ —

The Company did not grant stock options during the three months ended September 30, 2018. The weighted average grant-date fair value per share of stock options granted during the nine months ended September 30, 2018 was $11.77.

9. 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$ (10,900)	$ (11,600)	$ (33,663)	$ (22,690)
Accretion of redeemable convertible preferred stock to redemption value	—	(16)	—	(36)
Net loss attributable to common stockholders	$ (10,900)	$ (11,616)	$ (33,663)	$ (22,726)
Denominator:				
Weighted average common shares outstanding—basic and diluted	14,315,410	513,900	14,304,721	513,900
Net loss per share attributable to common stockholders — basic and diluted	$ (0.76)	$ (22.60)	$ (2.35)	$ (44.22)

The Company's potentially dilutive securities, which include options to purchase common stock, redeemable convertible preferred stock, warrants to purchase common stock and warrants to purchase redeemable convertible 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:

	For the Three and Nine Months Ended September 30,	
	2018	2017
Options to purchase common stock	2,048,209	1,197,120
Redeemable convertible preferred stock (as converted to common stock)	—	7,180,483
Warrants to purchase common stock	10,414	—
Warrants to purchase redeemable convertible preferred stock (as converted to common stock)	—	10,414
	2,058,623	8,388,017

10. Commitments and Contingencies

Lease Agreements

In November 2010, the Company entered into a lease agreement for office, laboratory, parking and storage space in Vienna, Austria ("Vienna Lease"), which expires on April 30, 2021. The Company has the option to extend the lease agreement for an additional year. The Vienna Lease includes a rent escalation clause based on an inflation index.

In July 2015, the Company entered into a lease agreement for an animal-use facility in Vienna, Austria ("Animal-use Lease"). The lease initially had a one-year noncancelable term, which expired in June 2016, after which the lease became cancelable by either party upon six months' prior written notice. Base rent for the Animal-use Lease is approximately $0.4 million annually, accordingly, rent expense is being recognized on a straight-line basis over the lease term.

On August 31, 2018 and in accordance with the terms of the Animal-use Lease, the Company provided the landlord with written notice that the lease agreement will terminate no later than February 28, 2019.

In November 2015, the Company entered into a lease agreement for office and laboratory space in Waltham, MA ("Waltham Lease"), which expires on January 31, 2019. The Waltham Lease includes a rent escalation clause, and accordingly, rent expense is being recognized on a straight-line basis over the lease term.

In June 2018, the Company entered into a lease agreement for office space in Waltham, MA ("Lease Agreement") with BP Bay Colony LLC (the "Lessor"). The Company amended the Lease Agreement in August 2018 ("Amended Lease Agreement"). Under the terms of the Amended Lease Agreement, the Company will relocate its Waltham, MA premises to a new premises with 5,711 square feet of office space as compared to the 10,290 square feet premises in the original Lease Agreement. The term of the Amended Lease Agreement commences on January 1, 2019 (the "Commencement Date") and expires approximately five years from the Commencement Date. The Company has the option to extend the term for one additional five-year period upon the Company's written notice to the Lessor at least nine months and no more than 12 months in advance of the extension. Base rent is approximately $0.3 million annually, accordingly, rent expense will be recognized on a straight-line basis over the lease term. In addition to the base rent, the Company is also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the Amended Lease Agreement. The Company provided a security deposit of approximately $0.3 million during the nine months ended September 30, 2018, which is included as a component of restricted cash on the Company's condensed consolidated balance sheet as of September 30, 2018.

The Company recognizes rent expense over the respective lease period and has recorded deferred rent for rent expense incurred but not yet paid.

The Company recorded rent expense of $0.3 million and $0.3 million during the three months ended September 30, 2018 and 2017, respectively, and $1.0 million and $0.9 million during the nine months ended September 30, 2018 and 2017.

The following table summarizes the future minimum lease payments due under the Company's operating leases as of September 30, 2018 (in thousands):

Year Ending December 31,		
2018	$	387
2019		823
2020		796
2021		441
2022		263
Thereafter		263
	$	2,973

License Agreements

The Company entered into the Adimab Option Agreement in February 2017 under which it is obligated to make contingent and non-contingent payments should the Company exercise its option to obtain rights to certain RSV antibodies (see Note 5). If the Company chose to exercise its option, it would be obligated to pay Adimab an option fee of $0.3 million and make clinical and regulatory milestone payments of up to $24.4 million, as well as royalty payments on a product-by-product and country-by-country basis of a mid single-digit percentage based on net sales by the Company, its affiliates, licensees or sublicensees of products based on certain RSV antibodies during the applicable term for such product in that country. The Company may choose to exercise its option under the terms of the Adimab Option Agreement at any time on or before August 31, 2019. As of September 30, 2018 and December 31, 2017, the Company had not exercise its option under the Adimab Option Agreement.

Manufacturing Commitments

In July 2016, the Company entered into an agreement with Boehringer Ingelheim International GmbH ("BI"), a contract manufacturing organization, for the manufacture and supply of ASN100 drug product for the Company's completed Phase 1 and discontinued Phase 2 clinical trials. In March 2016, the Company entered into an agreement with Cytovance Biologics, Inc. ("Cytovance") for process development and the manufacture and supply of ASN100 drug product. Under such agreements, the Company is obligated to pay BI and Cytovance development and manufacturing milestones, in addition to reimbursement of certain material production-related costs. Additionally, the Company is required to make prepayments for process development services and manufacture and delivery of ASN100 material. The terms of these agreements require future delivery and formal acceptance of the clinical material upon delivery from BI and Cytovance. Formal acceptance includes validation of the clinical material and that established specifications have been met and good manufacturing practices, or GMP, standards have been followed during the manufacture of the material. It is only after acceptance that title and risks and rewards of ownership pass to the Company and at that time advance payments will be applied to the purchase of clinical materials required to be produced under the agreements. The purchase of the clinical material will, at the point of delivery, be charged to research and development expense. The Company's policy is to expense research and development costs as incurred (i.e., as services are provided by the Company's vendors or as qualifying materials are delivered).

As of September 30, 2018, BI had completed the manufacturer of ASN100 drug product, accordingly, the Company expensed all advance payments previously made to BI and accrued for any final payments owed. All commitments and obligations under the manufacture and supply agreement pertaining to the workorder with BI for the delivery of the clinical materials were met by BI and the Company as of September 30, 2018.

The Company currently expects the development activities and manufacturing of ASN100 drug product under the agreement with Cytovance to be completed in the fourth quarter of 2018. As of September 30, 2018, the Company had committed to minimum payments under this agreement totaling $0.5 million.

11. Related Party Transactions

Agreements with Adimab, LLC

The Company made payments to Adimab of $16,000 and $58,000 during the three months ended September 30, 2018 and 2017, respectively, and $0.1 million and $0.1 million during the nine months ended September 30, 2018 and 2017, respectively, under the Adimab Option Agreement. The Company recognized less than $0.1 million and $0 during the three months ended September 30, 2018 and 2017, respectively, and $0.1 million and $0.1 million during the nine months ended September 30, 2018 and 2017, respectively, of research and development expense under the Adimab Option Agreement. As of September 30, 2018 and December

31, 2017, the Company owed $0 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.

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 former Chief Scientific Officer, serves as Chief Scientific Officer at EveliQure.

On June 28, 2018 and in accordance with the terms of this agreement with EveliQure, the Company provided EveliQure with written notice that the services and facilities agreement will terminate and EveliQure will vacate the sublet space no later than December 31, 2018.

During the three and nine months ended September 30, 2018, the Company received payments from EveliQure under the agreement of less than $0.1 million and $0.1 million, respectively, and less than $0.1 million and less than $0.1 million during the three and nine months ended September 30, 2017, respectively. During the three and nine months ended September 30, 2018 and 2017, the Company recognized other income under the agreement of less than $0.1 million in each period. As of September 30, 2018 and December 31, 2017, amounts due from EveliQure totaled less than $0.1 million and $0.1 million, respectively.

12. Subsequent Events

2012 Loan Agreement with Silicon Valley Bank

On October 31, 2018, the Company voluntarily remitted payment on its outstanding obligations under the 2012 Loan Agreement with SVB. Total outstanding obligations paid to SVB under the 2012 Loan Agreement on October 31, 2018 was approximately $3.1 million. See Note 6 for further discussion.

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. We possess a deep understanding of the pathogenesis of infection, paired with access to what we believe to be some of the most advanced mAb discovery techniques and platforms available today.

On June 28, 2018, we announced the discontinuation of our Phase 2 clinical trial of ASN100 for the prevention of *S. aureus* pneumonia in high-risk, mechanically ventilated patients following the completion of a planned interim analysis of unblinded trial data for 118 patients by an independent data review committee, or DRC. Based on the results of this analysis, the DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued. During the third quarter of 2018, we completed follow-up visits on patients dosed in the trial per the study protocol and intend to evaluate the complete dataset from the 154 patients that were enrolled in the trial to better understand the basis for this result. We expect to complete this evaluation in the fourth quarter of 2018 and have ceased further clinical development of ASN100, pending the results of this analysis. We do not expect to incur material costs for this program beyond the fourth quarter of 2018.

On August 10, 2018, our board of directors approved a reduction in workforce to reduce operating costs and better align our workforce with the needs of our business following our discontinuation of the clinical development of ASN100 pending the completion of our evaluation of the complete dataset from our Phase 2 trial. As part of this reduction in workforce, we are in the process of eliminating 19 positions across our company, representing approximately 44% of our workforce. We anticipate that we will substantially complete the implementation of the reduction in workforce by the fourth quarter of 2018.

In light of the discontinuation of the clinical development of ASN100, we are considering strategic options that may potentially result in changes to our business strategy and future operations.

Pending any decision to change our strategic direction, our current operating plan provides for our ongoing review of the data from the ASN100 clinical trial, the continued development of our ASN500 program, as well as supporting our collaborators across our ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018.

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 September 30, 2018 primarily with proceeds from the following sources:

- net cash proceeds of $75.1 million from sales of our preferred stock;
- net cash proceeds of $39.5 million from sales of our common stock in our initial public offering;
- net cash proceeds of $18.6 million from sales of our common stock in our private placement to New Enterprise Associates 16, L.P., or NEA;
- gross proceeds of $14.4 million from borrowings under convertible promissory notes;
- proceeds of $9.5 million from borrowings under a loan and security agreement with Silicon Valley Bank, or SVB, which, as amended, we refer to as the 2012 Loan Agreement;
- proceeds of $9.2 million and $9.9 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 $2.7 million from grant agreements 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 $10.9 million and $11.6 million for the three months ended September 30, 2018 and 2017, respectively, and $33.7 million and $22.7 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $125.9 million.

We expect that our research and development expenses related to ASN100 will be reduced during the fourth quarter of 2018 due to the discontinuation of our clinical development of ASN100. Pending any change in our strategic direction, we expect to continue the development of our ASN500 program. We also expect to continue to incur additional costs associated with operating as a public 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 the sale 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 product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, as well as the uncertainties regarding the outcomes from our ongoing review of strategic alternatives, if any, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2018, we had cash and cash equivalents of $40.8 million. We believe our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

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 any 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 agreements 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 product candidates. These expenses include:

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

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

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and programs 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
ASN100	$ 7,411	$ 8,294	$ 18,130	$ 12,679
ASN200	6	17	24	47
ASN300	—	118	17	120
ASN400	—	8	3	50
ASN500	146	322	761	603
Unallocated research and development expenses	2,009	1,842	7,700	5,399
Total research and development expenses	$ 9,572	$ 10,601	$ 26,635	$ 18,898

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

- successful enrollment and completion of clinical trials;
- a safety, tolerability and efficacy profile that is satisfactory to the 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 product candidates. We may obtain unexpected results from clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of any product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay 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.

General and administrative expenses incurred during this period include increased accounting, audit, legal, 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.

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 agreements with the Gates Foundation.

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

In April 2017, in connection with the sale of our Series D convertible preferred stock, all of the outstanding principal and accrued interest under the convertible promissory notes that we issued in 2016 and 2017 was automatically converted into shares of

Series D convertible preferred stock. As a result, in periods subsequent to this conversion, we incurred no interest expense related to convertible promissory notes.

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

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

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

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

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

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 9,572	$ 10,601	$ (1,029)
General and administrative	3,275	2,455	820
Total operating expenses	12,847	13,056	(209)
Loss from operations	(12,847)	(13,056)	209
Other income (expense):			
Grant and incentive income	2,016	1,618	398
Interest expense	(259)	(343)	84
Interest income	196	90	106
Change in fair value of warrant liability	—	5	(5)
Change in fair value of derivative liability	—	—	—
Loss on extinguishment of debt	—	—	—
Other income (expense), net	(6)	86	(92)
Total other income (expense), net	1,947	1,456	491
Net loss	$ (10,900)	$ (11,600)	$ 700

Research and Development Expenses.

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
ASN100	$ 7,411	$ 8,294	$ (883)
ASN200	6	17	(11)
ASN300	—	118	(118)
ASN400	—	8	(8)
ASN500	146	322	(176)
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	1,588	1,357	231
Other	421	485	(64)
Total research and development expenses	$ 9,572	$ 10,601	$ (1,029)

Research and development expenses were $9.6 million for the three months ended September 30, 2018, compared to $10.6 million for the three months ended September 30, 2017. The decrease of $1.0 million was primarily due to a decrease of $0.9 million in direct costs for our ASN100 program, a decrease of $0.1 million in direct costs for our ASN300 program, and a decrease of $0.2 million in direct costs for our ASN500 program. These decreases in research and development expenses were partially offset by an increase of $0.2 million in unallocated research and development expenses, including restructuring related expenses related to the reduction in workforce.

On June 28, 2018, we announced that the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion. Based on the DRC recommendation, we decided to discontinue the Phase 2 clinical trial of ASN100. We expect that direct costs for ASN100 will decrease in the fourth quarter of 2018 when compared to the third quarter of 2018 as we and our CMO and CROs complete manufacturing and clinical trial activities.

Our ASN500 program was initiated in March 2017. Direct costs for our ASN500 program during the three months ended September 30, 2018 were primarily due to third-party fees for the oversight and conduct of preclinical research, facility costs and preclinical program expenses associated with internal lab consumables. We expect that our direct costs for our ASN500 program will increase as we advance our ASN500 program through preclinical development.

The increase in unallocated research and development expenses was primarily due to an increase of $0.2 million in fixed research and personnel-related costs.

General and Administrative Expenses. General and administrative expenses were $3.3 million for the three months ended September 30, 2018, compared to $2.5 million for the three months ended September 30, 2017. The increase of $0.8 million was primarily related to additional costs associated with operating as a public company, including increases of $0.9 million in personnel costs (which included increases in salaries and wages of $0.2 million and stock-based compensation of $0.6 million) primarily due to an increase in headcount and employee compensation.

Other Income (Expense), Net. Other income, net was $1.9 million for the three months ended September 30, 2018, compared to $1.5 million for the three months ended September 30, 2017. The increase of $0.5 million in other income, net was primarily due to an increase in grant and incentive income of $0.5 million from our grant agreements with the Gates Foundation.

Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Operating expenses:			
Research and development	$ 26,635	$ 18,898	$ 7,737
General and administrative	9,778	5,629	4,149
Total operating expenses	36,413	24,527	11,886
Loss from operations	(36,413)	(24,527)	(11,886)
Other income (expense):			
Grant and incentive income	2,977	3,180	(203)
Interest expense	(785)	(1,806)	1,021
Interest income	637	90	547
Change in fair value of warrant liability	—	16	(16)
Change in fair value of derivative liability	—	762	(762)
Loss on extinguishment of debt	—	(462)	462
Other income (expense), net	(79)	57	(136)
Total other income (expense), net	2,750	1,837	913
Net loss	$ (33,663)	$ (22,690)	$ (10,973)

Research and Development Expenses.

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
ASN100	$ 18,130	$ 12,679	$ 5,451
ASN200	24	47	(23)
ASN300	17	120	(103)
ASN400	3	50	(47)
ASN500	761	603	158
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	6,124	3,971	2,153
Other	1,576	1,428	148
Total research and development expenses	$ 26,635	$ 18,898	$ 7,737

Research and development expenses were $26.6 million for the nine months ended September 30, 2018, compared to $18.9 million for the nine months ended September 30, 2017. The increase of $7.7 million was primarily due to an increase of $5.5 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 $2.3 million in unallocated research and development expenses.

The increase in direct costs for our ASN100 program was primarily due to CMO and CRO fees for process development and establishment of manufacturing capabilities for the supply of our clinical materials, the oversight and conduct of our Phase 2 clinical trial and investigator fees for that same clinical trial. Based on our decision to discontinue the Phase 2 clinical trial of ASN100, we expect that direct costs for ASN100 will decline in the fourth quarter of 2018 when compared to the first nine months of 2018 as we and our CMO and CROs complete manufacturing and clinical trial activities.

Direct costs for our ASN500 program during the nine months ended September 30, 2018 were primarily due to third-party fees for the oversight and conduct of preclinical research, facility costs and preclinical program expenses associated with internal lab consumables. We expect that our direct costs for our ASN500 program will increase as we advance our ASN500 program through preclinical development.

The increase in unallocated research and development expenses was due primarily to an increase of $2.2 million in personnel-related costs (including increases in salaries and wages of $1.1 million, stock-based compensation of $0.7 million and personnel travel costs of $0.3 million) primarily due to the hiring of new personnel and increased employee compensation.

General and Administrative Expenses. General and administrative expenses were $9.8 million for the nine months ended September 30, 2018, compared to $5.6 million for the nine months ended September 30, 2017. The increase of $4.1 million was primarily related to additional costs associated with operating as a public company, including increases of $2.2 million in personnel costs (which included increases in salaries and wages of $0.5 million, stock-based compensation of $1.4 million and personnel travel costs of $0.2 million) primarily due to an increase in headcount and employee compensation, $0.3 million in Board of Directors fees, $0.5 million in insurance fees and $1.0 million in professional fees primarily due to legal and accounting costs associated with being a public company.

Other Income (Expense), Net. Other income, net was $2.8 million for the nine months ended September 30, 2018, compared to $1.8 million for the nine months ended September 30, 2017. The increase of $0.9 million in other income, net was primarily due to a decrease of $1.0 million in interest expense primarily associated with our convertible promissory notes, a decrease in loss on extinguishment of debt of $0.5 million in connection with the April 2017 conversion of our 2016 and 2017 convertible promissory notes into shares of our Series D convertible preferred stock, and an increase in interest income of $0.5 million, primarily from the bank interest earned on the cash received from the initial public offering and concurrent private placement of our common stock. These increases in other income, net were partially offset by a decrease of $0.8 million in gains recognized as a result of decreases in the fair value of the derivative liability associated with our convertible promissory notes and a decrease in grant and incentive income of $0.1 million primarily associated with our grant agreement with the Gates Foundation.

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 September 30, 2018, we had received net cash proceeds of $75.1 million from sales of our preferred stock, net cash proceeds of $58.1 million from the sale of our common stock, gross proceeds of $14.4 million from borrowings under convertible promissory notes, proceeds of $9.5 million from borrowings under the 2012 Loan Agreement with SVB, $9.2 million and $9.9 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 $2.7 million of proceeds from our grant agreements with the Gates Foundation.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	$ (33,817)	$ (14,964)
Net cash used in investing activities	(34)	(59)
Net cash provided by (used in) financing activities	(1,641)	42,914
Effect of exchange rate changes on cash	(309)	402
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (35,801)	$ 28,293

Operating Activities. During the nine months ended September 30, 2018, operating activities used $33.8 million of cash, resulting from our net loss of $33.7 million and changes in our operating assets and liabilities of $3.6 million, partially offset by net non-cash charges of $3.4 million. We expect the discontinuation of the clinical development of ASN100 to result in a decline in cash used in operating activities in the fourth quarter of 2018 and 2019, as we expect our expenses associated with ASN100 to decline substantially.

Changes in our operating assets and liabilities for the nine months ended September 30, 2018 consisted primarily of a $2.4 million decrease in accounts payable and accrued expenses, a $0.7 million decrease in prepaid expenses and other assets, a $1.4

million increase in grant and incentive receivables and a $0.5 million decrease in unearned income. The decrease in accounts payable and accrued expenses was primarily due to the payment of the 2017 annual bonuses in March 2018 and the timing of vendor invoices and payments. The decreases in prepaid expenses and other assets were primarily due to the receipt of clinical materials during the nine months ended September 30, 2018. The increase in grant and incentive receivables was primarily due to income earned under the Austrian research and development incentive program during the nine months ended September 30, 2018. The decrease in unearned income was primarily due to the amortization of the discount associated with the FFG loans.

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

Investing Activities. During the nine months ended September 30, 2018 and 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 nine months ended September 30, 2018, cash used in financing activities was $1.6 million, consisting primarily of principal repayments under the 2012 Loan Agreement

During the nine months ended September 30, 2017, net cash provided by financing activities was $42.9 million, consisting primarily of net cash proceeds of $39.9 million from our issuances of Series D convertible preferred stock, net proceeds of $4.9 million from our issuance of convertible promissory notes in January 2017 and proceeds of $0.7 million from loans under our funding agreements with FFG, partially offset by $1.8 million of principal repayments under the 2012 Loan Agreement and the payment of $0.8 million of initial public offering costs.

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 September 30, 2018 and December 31, 2017, the outstanding principal amount under the 2012 Loan Agreement was $2.9 million and $4.7 million, respectively.

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

Borrowings under the 2012 Loan Agreement 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 1% to 2% of the outstanding principal if paid prior to February 19, 2018, which was the second anniversary of the First Amendment effective date. The prepayment fee is 0% subsequent to the second anniversary of the First Amendment effective date. 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 6 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 substantially all of our assets other than our intellectual property, including 65% of the outstanding capital stock of our subsidiary in Austria. The 2012 Loan Agreement 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.

We were in compliance with all covenants under the 2012 Loan Agreement as of December 31, 2017. During the nine months ended September 30, 2018, we failed to comply with the covenants under the 2012 Loan Agreement when we entered into separate option and license agreements for our ASN200 and ASN300 programs with subsidiaries of Bravos Biosciences, LLC without obtaining prior written consent of SVB, and then delivered compliance certificates to SVB that did not disclose these violations. As a result, we became in default under the 2012 Loan Agreement and SVB could, at its option, declare all of our obligations under the 2012 Loan Agreement to be immediately due and payable. On August 8, 2018, we and SVB entered into a Forbearance Agreement pursuant to which SVB agreed to forbear from exercising its rights and remedies with respect to such defaults until the earlier to occur of (i) another event of default under the 2012 Loan Agreement or (ii) October 31, 2018.

In addition to the default in connection with the option and license agreements, we have also discussed with SVB whether our decision to discontinue the Phase 2 clinical trial of ASN100 may be considered a material adverse change in our business, operations or condition (financial or otherwise) and, accordingly, an event of default under the terms of the 2012 Loan Agreement. SVB has not agreed that the discontinuation of the trial does not constitute an event of default as of September 30, 2018. If the trial discontinuation does constitute a material adverse change in the Company's business, operations or condition, SVB would have the right to accelerate the Company's outstanding obligations under the 2012 Loan Agreement.

Because our obligations under the 2012 Loan Agreement could be accelerated at the election of SVB upon the expiration of the Forbearance Agreement, or earlier if another event of default occurs, including but not limited to if the ASN100 Phase 2 clinical trial discontinuation constitutes a material adverse change in our business, operations or condition, we have presented the SVB loan payable as current on the consolidated balance sheet as of September 30, 2018.

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 September 30, 2018 and December 31, 2017, the outstanding principal amount under loans from FFG was $9.9 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 September 30, 2018, the funding agreements with FFG are expected to provide us additional loans of approximately $0.1 million and additional grants of approximately $0.1 million if and when we incur specified amounts of qualifying expenditures.

We may be required to return all or a portion of the FFG loans and/or grants if we do not comply with the terms of the related FFG funding agreements and related guidelines, including specified requirements as to continued operations with respect to certain locations and funded projects. To date, FFG has not requested the return of any amounts received by us under the funding agreements.

Convertible Promissory Notes

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

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

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

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

Funding Requirements

Pending any decision to change our strategic direction, our current operating plan provides for the completion of our ongoing review of the cumulative unblinded data from the ASN100 Phase 2 clinical trial, the continued development of our ASN500 program as well as the continued support of our collaborators across our ongoing ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018. We have ceased further clinical development of ASN100 pending the completion of our ongoing review of the cumulative unblinded data from the discontinued ASN100 Phase 2 clinical trial and currently do not expect to incur material costs for this program beyond 2018.

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

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

Based on this current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements and debt service payments into the first quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional funding to complete the clinical development of any successful product candidate from our ASN500 program, commercialize any product candidate, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for any potential future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize such product candidate ourselves. Also, in light of the discontinuation of the Phase 2 clinical trial of our lead product candidate ASN100, we are considering strategic options for our business that may potentially result in changes to our current business strategy and future operations.

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

- our ability to successfully consummate one or more strategic transactions;
- our ability to eliminate all material ASN100-related expenses by the end of the fourth quarter of 2018;
- the scope, progress, results and costs of researching and developing any product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of any product candidates;

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

Collaboration, License and Funding Arrangements

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

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

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

In February 2017, we entered into a grant agreement with the Gates Foundation, under which the Gates Foundation agreed to provide us up to $9.3 million to conduct preclinical development of mAbs for the prevention of RSV infection in newborns, which we refer to as the RSV project. In August 2018, we entered into an amended and restated grant agreement which replaces the February 2017 grant agreement in its entirety, and includes amendments to conform to current Gates Foundation audit, reporting, and other

administrative requirements as well as to make the perpetual license that is granted to the Gates Foundation with respect to any funded developments resulting from the grant agreement irrevocable. In August 2018, we entered into an additional grant agreement with the Gates Foundation pursuant to which the Gates Foundation granted us up to $1.1 million to conduct preclinical development activities for the RSV project that were not included in the February 2017 grant agreement, as amended and restated in August 2018. The Company recognized grant income of $1.1 million during the three and nine months ended September 30, 2018, under the August 2018 grant agreement with the Gates Foundation upon incurring qualifying expenses. Pursuant to both grant agreements, as amended, we have no payment obligations under the Adimab option and license agreement with respect to sales of products based on licensed RSV antibodies to the extent they are sold at cost in developing countries. However, if such products are sold in developing countries for an amount that exceeds cost, then the amount of such excess will be subject to the royalty payment obligations described in the preceding paragraph.

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

Critical Accounting Policies and Significant Judgments and Estimates

Our 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 and nine months ended September 30, 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
- Prepaid and 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.

Contractual Obligations and Commitments

During the nine months ended September 30, 2018, there were no material changes to our contractual obligations and commitments described under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2017 that we filed with the Securities and Exchange Commission on March 9, 2018, other than the Amended Lease Agreement with respect to our office space in Waltham, MA.

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

The annual base rent obligation is approximately $0.3 million, with a total cash obligation for the base rent over the initial five-year term of the Amended Lease Agreement is approximately $1.3 million. In addition to the base rent, we are also responsible for our share of operating expenses, electricity and real estate taxes, in accordance with the terms of the Amended Lease Agreement. We provided a security deposit in the amount of $0.3 million as well as a relocation payment of $0.1 million to the Lessor during the nine months ended September 30, 2018.

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 September 30, 2018, we had $2.9 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 5.00% as of September 30, 2018. Based on the principal amounts outstanding as of September 30, 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 September 30, 2018, we had $38.6 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 and nine months ended September 30, 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 September 30, 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 September 30, 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 $33.7 million and $22.7 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $125.9 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 have devoted a significant portion of our financial resources and efforts to the development of ASN100. On June 28, 2018, we announced that the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion. Based on the DRC recommendation, we decided to discontinue the Phase 2 clinical trial of ASN100 and have taken steps to notify health authorities and clinical investigators participating in the trial. We are in the process of performing analyses of the cumulative unblinded data from the trial to better understand the basis for this outcome. We have ceased further clinical development of ASN100 pending the completion of our ongoing review of the cumulative unblinded data from the trial. We expect to complete our assessment of the ASN100 Phase 2 clinical trial during the fourth quarter of 2018. Our determination as to our next steps will necessarily impact the amount of expenses we incur and the size of our operating losses for the foreseeable future.

Pending any decision to change our strategic direction, we expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter.

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

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 later-stage clinical trials of any product candidates, obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any evaluation of our business to date or predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

Pending any decision to change our strategic direction, we plan to complete our ongoing review of the cumulative unblinded data from the ASN100 Phase 2 clinical trial, continue the development of our ASN500 program as well as support our collaborators across our ongoing ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018. We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities, we believe that our existing cash and cash equivalents at September 30, 2018 will be adequate to satisfy our capital needs into the first quarter of 2020 based on our current operating plans, which do not include material ASN100 expenses beyond the fourth quarter of 2018.

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

- our ability to successfully consummate one or more strategic transactions;
- our ability to eliminate all material ASN100-related expenses by the end of the fourth quarter of 2018;
- the scope, progress, results and costs of researching and developing our ASN500 program and any product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of any product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and necessary inventory to support commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; 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 any are approved, may not achieve commercial success. Our product revenue, if any, and any commercial milestones or royalty payments under our collaboration agreements will be derived from or based on sales of products that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, government funding, grants, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our financing plans or the terms of such financings. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, additional debt financing would result in increased fixed payment obligations.

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

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

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

Under our loans from Österreichische Forschungsförderungsgesellschaft GmbH, or FFG, principal amounts outstanding totaled $9.9 million as of September 30, 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 may be required to return all or a portion of the FFG loans and/or grants if we do not comply with the terms of the related FFG funding agreements and related guidelines, including specified requirements as to continued operations with respect to certain locations and funded projects. To date, FFG has not requested the return of any amounts received by us under the funding agreements.

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

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

- requiring us to dedicate a portion of our cash and cash equivalents resources to the payment of interest and principal, 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. While we currently have sufficient resources to pay our existing debt in the event that repayment was accelerated under the existing FFG loans, that may not be the case in the future.

Risks Related to the Development of Product Candidates

Our business to date has been almost entirely dependent on the success of ASN100, which recently had its Phase 2 clinical trial discontinued in connection with the Data Review Committee, or DRC, determination that the trial had a low probability of meeting its primary end-point upon completion.

On June 28, 2018, we announced that the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion. Based on the DRC recommendation, we decided to discontinue the Phase 2 clinical trial of ASN100 and have taken steps to notify health authorities and clinical investigators participating in the trial. We are in the process of performing analyses of the cumulative unblinded data from the trial to better understand the basis for this outcome. We have ceased further clinical development of ASN100 pending the completion of our ongoing review of the cumulative unblinded data from the trial. We expect to complete our assessment of the ASN100 Phase 2 clinical trial during the fourth quarter of 2018.

In light of the discontinuation of the Phase 2 clinical trial of our lead product candidate ASN100, we are considering strategic options for our business that may potentially result in changes to our current business strategy and future operations. However, we cannot provide any commitment regarding when or if this strategic review process will result in any type of transaction, and there can be no assurance that such activities will result in any agreements or transactions that will enhance stockholder value.

If we determine to pursue an alternative strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our existing business strategy.

Pending any decision to change our strategic direction, our current operating plan provides for the completion of our ongoing review of the cumulative unblinded data from the ASN100 Phase 2 clinical trial, the continued development of our ASN500 program as well as the continued support of our collaborators across our ongoing ASN200 and ASN300 programs, both of which were outlicensed to subsidiaries of Bravos Biosciences, LLC during the first half of 2018.

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

We are focused on the discovery, development and commercialization of monoclonal antibody, or mAb, immunotherapies to address serious infectious diseases. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates, including those that we are directly developing and those being developed under collaboration with subsidiaries of Bravos Bioscience, LLC, in future clinical trials or in obtaining marketing approval thereafter. For example, we have not yet advanced a product candidate beyond Phase 2 clinical development. In June 2018 we discontinued our Phase 2 clinical trial of ASN100, based on the results of a planned interim analysis of unblinded trial data conducted by the DRC. The DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued.

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

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

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

In order to obtain FDA approval to market a new biological product we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug application, or IND, in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. As a result, we cannot be

sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

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

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

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

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

We currently have no products approved for sale and historically we invested a significant portion of our efforts and financial resources in the development of ASN100. In June 2018, we discontinued our Phase 2 clinical trial of ASN100, based on the results of a planned interim analysis of unblinded trial data conducted by the DRC. The DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued.

While we are exploring strategic options, we are continuing to develop our ASN500 program, which is currently in preclinical development. The success of any product candidates we may develop will depend on several factors, including the following:

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

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

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

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

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

- delays in reaching a consensus with regulatory authorities or collaborators on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board or independent ethics committee approval at each clinical trial site;
- delays in recruiting suitable subjects to participate in clinical trials;
- imposition of a clinical hold by regulatory authorities, including as a result of a serious adverse event or after an inspection of our clinical trial operations or trial sites;
- failure by us, any CROs we engage, clinical investigators, our collaborators or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with good clinical practices, or GCP, or applicable regulatory requirements in the European Union, the United States, or in other countries;

- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- delays or failures in demonstrating the comparability of product manufactured at one facility or with one process to product manufactured at another facility or with another process, including clinical trials to demonstrate such comparability;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or subjects dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

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

We could encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted or ethics committees, by the 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. In June 2018, we discontinued our Phase 2 clinical trial of ASN100, based on the results of a planned interim analysis of unblinded trial data conducted by the DRC. The DRC determined that the trial was futile, meaning that it was not likely to meet its primary end-point upon completion, and recommended that trial enrollment be discontinued.

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

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

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

There can be no assurance that the success we achieved in preclinical studies and early clinical trials ultimately will result in success in potential future clinical trials of product candidates. For example, on June 28, 2018, we announced that the DRC for our ASN100 Phase 2 clinical trial recommended that trial enrollment be discontinued based on the DRC's conclusion that the trial was not likely to meet its primary end-point upon completion. Based on the DRC recommendation, we decided to discontinue the Phase 2 clinical trial of ASN100. In addition, we cannot assure you that we or our collaborators will be able to achieve success in our preclinical studies or any future clinical trials of any 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 clinical trials, which could delay or prevent our collaborators and us from proceeding with clinical trials of any product candidates.

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

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

- coordination between us, CROs and any future collaborators in our efforts to enroll and administer the clinical trial;
- size of the patient population and process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- time of year in which the trial is initiated or conducted;
- variations in the seasonal incidence of the target indication;
- severity of the disease under investigation;
- ability to obtain and maintain subject consent;
- ability to enroll and treat patients in a timely manner;
- risk that enrolled subjects will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

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

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

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

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

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct clinical trials;

- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange fluctuations; and
- diminished protection of intellectual property in some countries.

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

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

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

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

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

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

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

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

All of our mAbs are manufactured by starting with cells that are stored in a cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP and multiple working cell banks and believe we would have adequate backup should any cell bank be lost in a catastrophic event. However, it is possible that we or our third-party manufacturers could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks. We cannot assure you that

any stability or other issues relating to the manufacture of any product candidates or products will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

Risks Related to Dependence on Third Parties

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

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

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

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

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

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

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

We may seek additional collaborations to advance the development of product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed

collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate.

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

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

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

We do not expect to independently conduct any future clinical trials of any product candidates. We expect to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct any future clinical trials. In addition, we currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur in our product development activities. Although we seek to carefully manage our relationships with 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 clinical, non-clinical and preclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. As a result, our results of operations and the commercial prospects for our products would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to the Commercialization of Product Candidates

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

We do not currently have a sales and marketing organization and have never commercialized a product. To successfully commercialize any products that may result from our development programs such as our ASN500 program, we will need to develop these capabilities, either on our own or with others. The establishment and development of our own commercial and medical science liaison teams or the engagement of a contract sales force to discuss any products we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with entities regarding product candidates to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many well-funded and profitable pharmaceutical and biotechnology companies that currently have extensive and experienced medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of product candidates. Without an internal team or the support of a third party to perform marketing, sales and medical affairs functions, we may be unable to compete successfully against these more established companies.

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

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

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

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

There is significant uncertainty related to hospital formulary approval, insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. It is difficult to predict what third-party payors will decide with respect to the insurance coverage and reimbursement for product candidates.

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

Moreover, increasing efforts by hospital, government and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for product candidates. We expect to experience pricing pressures in connection with the sale of any product candidates due to the trend toward reducing hospital costs, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

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

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

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

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

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

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

- different regulatory requirements for approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

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

Risks Related to Our Business Operations

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 key 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 is 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 (such as the discontinuation of our Phase 2 clinical trial of ASN100) or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The reduction in workforce we undertook in August 2018 may yield unintended consequences, such as attrition beyond our ongoing reduction and poor employee morale, which may cause our remaining employees to seek alternate employment. 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.

We may experience difficulties in managing reductions in force.

In August 2018, we undertook a reduction in workforce to reduce our workforce by approximately 44%. Effecting any reductions in workforce places significant strains on management, our employees and our operational, financial and other resources. Furthermore, reductions in force involve certain additional costs, including severance and benefits payments to terminated employees, and we may also incur liabilities from early termination or assignment of contracts, potential litigation or other effects from such reduction in workforce. Such effects from the reduction in workforce could have a material adverse effect on our ability to execute on our business plan. There can be no assurance that we will be successful in implementing our reduction in workforce.

Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to develop our product candidates, including ASN500, or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

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

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

- decreased demand for any product candidates that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;

- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

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

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

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

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

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

- comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions;
- provide accurate information to the FDA, the EMA and other regulatory authorities;
- comply with healthcare fraud and abuse laws and regulations in the United States and abroad;
- comply with the 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 have adopted a code of conduct and implemented other internal controls applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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

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

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

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

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

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

As of December 31, 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 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 product candidates and technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to product candidates and technology that are important to our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of 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 product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, and these decisions have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future decisions by the U.S. Congress, the federal courts and the USPTO, as well as similar bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or any collaborators may obtain in the future.

Patent reform legislation enacted in the United States in 2011 could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first to invent" system to a "first inventor to file" system. The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor to file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

We are a party to several intellectual property license and option agreements, including agreements with the 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 any product candidates that we may develop. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize 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, which would have a material adverse impact on our business. Further, under our agreements with Adimab, under certain circumstances, Adimab is permitted to transfer to third parties antibody libraries that may include antibodies that we have licensed from Adimab, as well as certain information regarding certain attributes of such antibodies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our commercial success depends upon our ability and the ability of any collaborators to develop, manufacture, market and sell product candidates and use 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 any product candidates that we develop approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights 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 product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

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

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

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

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

Trade secrets and know-how can be difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the

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

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

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

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

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

- FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any product candidates for which we, or any future collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, or any future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

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

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

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

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

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

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

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

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

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

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

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in

the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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

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

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

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

In March 2010, then-President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale, are the following:

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

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

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 and commercialize product candidates. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions.

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

In addition, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services (HHS) will: take steps to end the gaming of regulatory

and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

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

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

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

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

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

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

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

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

damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

Risks Related to Ownership of Our Common Stock

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

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

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

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

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

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

acquisition of 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 compliance with applicable securities law. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

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

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

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

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

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

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

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

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

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

- 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 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 September 30, 2018, we estimate that we have used approximately $32.5 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: November 9, 2018

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

Date: November 9, 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: November 9, 2018

By: /s/ René Russo
René Russo, PharmD
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: November 9, 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 September 30, 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: November 9, 2018

By: /s/ René Russo
René Russo, PharmD
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 September 30, 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: November 9, 2018

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