UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2019

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: 001-35005

ASSEMBLY BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**20-8729264**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11711 N. Meridian St., Suite 310 **Carmel, Indiana**	**46032**
(Address of principal executive offices)	(zip code)

(833) 509-4583
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	ASMB	The Nasdaq Global Select Market

As of May 6, 2019, there were 25,600,979 shares of the registrant's common stock outstanding.

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PART I - FINANCIAL INFORMATION
Item 1. Condensed Consolidated Financial Statements (unaudited)

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
($ in thousands except for share and per share amounts)

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 29,107	$ 41,471
Marketable securities	164,429	176,609
Accounts receivable from collaboration	2,987	2,430
Prepaid expenses and other current assets	4,283	1,992
Total current assets	200,806	222,502
Property and equipment, net	2,079	557
Operating lease right-of-use assets	13,063	-
Other assets	1,661	3,348
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 259,247**	**$ 268,045**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,427	$ 3,693
Accrued expenses	10,141	9,679
Deferred revenue - short-term	9,933	5,100
Operating lease liabilities - short-term	2,704	-
Total current liabilities	25,205	18,472
Deferred rent	-	108
Deferred tax liabilities	3,252	3,252
Deferred revenue - long-term	29,868	35,560
Operating lease liabilities - long-term	10,521	-
Total liabilities	**68,846**	**57,392**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 25,549,757 and 25,495,425 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	26	25
Additional paid-in capital	559,453	552,762
Accumulated other comprehensive loss	(239)	(347)
Accumulated deficit	(368,839)	(341,787)
Total stockholders' equity	190,401	210,653
Total liabilities and stockholders' equity	**$ 259,247**	**$ 268,045**

See Accompanying Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
($ in thousands except for share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Collaboration revenue	$ 3,885	$ 3,565
Operating expenses:		
Research and development	22,704	14,541
General and administrative	9,517	5,696
Total operating expenses	32,221	20,237
Loss from operations	**(28,336)**	**(16,672)**
Other income (expenses)		
Interest and other income	1,276	446
Other income (expense), net	1	(23)
Total other income	1,277	423
Loss before income taxes	**(27,059)**	**(16,249)**
Income tax benefit	7	-
Net loss	**$ (27,052)**	**$ (16,249)**
Other comprehensive (loss) income		
Unrealized gain (loss) on marketable securities, net of tax	108	(67)
Comprehensive loss	**$ (26,944)**	**$ (16,316)**
Net loss per share, basic and diluted	$ (1.05)	$ (0.80)
Weighted average common shares outstanding, basic and diluted	25,668,798	20,231,804

See Accompanying Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
($ in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (27,052)	$ (16,249)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	135	168
Stock-based compensation	6,577	4,083
Net accretion and amortization of investments in marketable securities	(592)	-
Non-cash rent expense	1,091	-
Deferred income tax benefit	(7)	-
Loss on disposal of fixed assets	102	-
Other	(1)	23
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	(557)	10
Prepaid expenses and other current assets	(2,558)	(906)
Other assets	1,687	-
Accounts payable	(1,266)	249
Accrued expenses	398	(1,491)
Deferred revenue	(859)	(1,301)
Deferred rent	-	(86)
Operating lease liabilities	(1,037)	-
Net cash used in operating activities	(23,939)	(15,500)
Cash flows from investing activities		
Purchases of property and equipment	(1,488)	(39)
Purchases of marketable securities	(49,030)	(13,032)
Proceeds from maturities of marketable securities	61,453	11,971
Proceeds from sale of marketable securities	500	-
Net cash provided by (used in) investing activities	11,435	(1,100)
Cash flows from financing activities		
Proceeds from the exercise of stock options	140	1,494
Net cash provided by financing activities	140	1,494
Net decrease in cash and cash equivalents	(12,364)	(15,106)
Cash and cash equivalents at the beginning of the period	41,471	82,033
Cash and cash equivalents at the end of the period	**$ 29,107**	**$ 66,927**

See Accompanying Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
($ in thousands except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance as of December 31, 2018	**25,495,425**	**$ 25**	**$ 552,762**	**$ (347)**	**$ (341,787)**	**$ 210,653**
Proceeds from the exercise of stock options	21,000	-	140	-	-	140
Issuance of shares for settlement of restricted stock units	33,332	1	(1)	-	-	-
Reclassification of stock-based awards from equity to accrued expenses	-	-	(4)	-	-	(4)
Unrealized gain on marketable securities	-	-	-	108	-	108
Stock-based compensation	-	-	6,556	-	-	6,556
Net loss	-	-	-	-	(27,052)	(27,052)
Balance as of March 31, 2019	**25,549,757**	**$ 26**	**$ 559,453**	**$ (239)**	**$ (368,839)**	**$ 190,401**

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance as of December 31, 2017	**20,137,974**	**$ 20**	**$ 364,528**	**$ (392)**	**$ (251,036)**	**$ 113,120**
Proceeds from the exercise of stock options	248,762	-	1,494	-	-	1,494
Unrealized loss on marketable securities	-	-	-	(67)	-	(67)
Stock-based compensation	-	-	4,083	-	-	4,083
Net loss	-	-	-	-	(16,249)	(16,249)
Balance as of March 31, 2018	**20,386,736**	**$ 20**	**$ 370,105**	**$ (459)**	**$ (267,285)**	**$ 102,381**

See Accompanying Notes to Condensed Consolidated Financial Statements

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc., together with its subsidiaries (Assembly or the Company), incorporated in Delaware in October 2005, is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The Company operates in one segment and is headquartered in Carmel, Indiana with operations in South San Francisco, California and Groton, Connecticut.

The Company's HBV-cure program is pursuing multiple drug candidates that inhibit the HBV lifecycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of increasing the current low cure rates for patients with HBV. Assembly has discovered multiple novel core inhibitors, which are small molecules that directly target and allosterically modify the HBV core (HBc) protein.

The Company's Microbiome program consists of a fully integrated platform that includes a disease-targeted strain isolation, identification, characterization and selection process, methods for strain purification and growth under current Good Manufacturing Practice (cGMP) conditions, and a licensed patented delivery system that the Company calls GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. Using the Company's microbiome platform capabilities, the Company is exploring product candidates for multiple disease indications, including ulcerative colitis (UC), Crohn's disease, irritable bowel syndrome (IBS), non-alcoholic steatohepatitis (NASH) and immuno-oncology, which indications the Company will pursue with Allergan Pharmaceuticals International Limited (Allergan) described herein to the extent covered by the Research, Development, Collaboration and License Agreement (the Collaboration Agreement) or pursue either internally or in collaboration with other partners to the extent outside the scope of the Collaboration Agreement (Note 8).

Liquidity

The Company has not derived any revenue from product sales to date and currently has no approved products. Once a product has been developed, it will need to be approved for sale by the U.S. Food and Drug Administration (FDA) or an applicable foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options, the issuance of debt and an upfront payment related to the Collaboration Agreement. The Company has incurred losses from operations since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months following the date that these unaudited condensed consolidated interim financial statements are issued. If the Company cannot generate significant cash from its operations, it intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, grants or other arrangements. The Company cannot assure such funding will be available on reasonable terms, if at all.

If the Company is unable to generate enough revenue from the Collaboration Agreement when needed or to secure additional sources of funding and receive related full and timely collections of amounts due, it may be necessary to significantly reduce the current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs, including more costly clinical trials.

Note 2 - Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC) and on the same basis as the Company prepares its annual audited consolidated financial statements.

In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include normal recurring adjustments necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. These statements do not include all disclosures required by GAAP and should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2018, which is contained in the Company's Annual Report on Form 10-K as filed with the SEC on February 28, 2019. The results for the three months ended March 31, 2019 are not necessarily indicative of results to be expected for the entire year ending December 31, 2019 or future operating periods.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying unaudited condensed consolidated financial statements include recoverability and useful lives (indefinite or finite) of intangible assets, assessment of impairment of goodwill, provisions for income taxes, amounts receivable under the Collaboration Agreement, measurement of operating lease liabilities, and the fair value of stock options, stock appreciation rights, and restricted stock units (RSUs) granted to employees, directors and consultants.

The Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates and assumptions.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies from those described in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, other than as set forth below.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and Board members over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award.

Prior to the adoption of ASU 2018-07 on January 1, 2019, the Company remeasures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change. Subsequent to the adoption of ASU 2018-07, the Company recognizes non-employees compensation costs over the requisite service period based on a measurement of fair value for each stock award.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

The fair value of restricted stock units is determined based on the number of shares granted and the quoted market price of the Company's common stock on the date of grant. The fair value of restricted stock units with performance conditions deemed probable of being achieved and vesting are amortized to expense over the requisite service period using the straight-line method of expense recognition.

Leases

All of the Company's leases are operating leases for facilities and equipment. Prior to January 1, 2019, the Company recognized related rent expense on a straight-line basis over the term of the lease. Incentives granted under the Company's facilities lease, including allowances for leasehold improvements and rent holidays, were recognized as reductions to rental expense on a straight-line basis over the term of the lease. Deferred rent consisted of the difference between cash payments and the rent expense recognized.

Subsequent to the adoption of the new leasing standard on January 1, 2019, the Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. The Company determines whether an arrangement is or contains a lease at contract inception. Operating leases are included in operating lease right-of-use assets, operating lease liabilities - short-term, and operating lease liabilities - long-term in our condensed consolidated balance sheet at March 31, 2019. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The incremental borrowing rate represents the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. Variable lease expenses are recorded when incurred. The Company has elected to not separate lease and non-lease components for its leased assets and account for all lease and non-lease components of its agreements as a single lease component.

Net Loss per Share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted net loss per share is the same. Securities that could potentially dilute loss per share in the future that were not included in the computation of diluted loss per share at March 31, 2019 and 2018 are as follows:

	Three Months Ended March 31,	
	2019	**2018**
Warrants to purchase common stock	15,296	15,296
Options to purchase common stock	5,111,590	4,826,361
Unvested restricted stock units	607,656	251,559
Total	5,734,542	5,093,216

A reconciliation of the numerators and the denominators of the basic and diluted net (loss) income per common share computations is as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2019	**2018**
Numerator:		
Net (loss) income (in thousands)	$ (27,052)	$ (16,249)
Denominator:		
Weighted average common shares outstanding for diluted net (loss) income per share	25,668,798	20,231,804
Net (loss) income per share:		
Basic	$ (1.05)	$ (0.80)
Diluted	$ (1.05)	$ (0.80)

Adoption of Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases* (ASU 2016-02). Under this standard, which applies to both lessors and lessees, lessees will be required to recognize all leases (except for short-term leases) as a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and as a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement.

The Company adopted the ASU 2016-02 on January 1, 2019 using the modified retrospective approach and elected the package of practical expedients permitted under transition guidance, which allowed the Company to carry forward its historical assessments of: 1) whether contracts are or contain leases, 2) lease classification and 3) initial direct costs. The Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to the current contract portfolio. The Company elected the post-transition practical expedient to not separate lease components from nonlease components for all existing lease classes. The Company also elected a policy of not recording leases on its condensed consolidated balance sheets when the leases have a term of 12 months or less and the Company is not reasonably certain to elect an option to purchase the leased asset.

The adoption of this standard resulted in the recognition of a ROU assets and lease liabilities of $13.8 million and $14.0 million, respectively, and the derecognition of the deferred rent balance of $0.1 million as of January 1, 2019. The adoption of the standard had no impact on the Company's condensed consolidated statements of operations and comprehensive loss or to its cash flows from or used in operating, financing, or investing activities on its condensed consolidated statements of cash flows. No cumulative-effect adjustment within accumulated deficit was required to be recorded as a result of adopting this standard.

On January 1, 2019, the Company adopted ASU 2018-02, *Income Statement - Reporting Comprehensive Income, (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the federal corporate income tax rate enacted under the Tax Cuts and Jobs Act (the Tax Act). The amount of the reclassification would be the difference between the historical corporate income tax rate and the Tax Act's 21% corporate income tax rate. The Company's adoption of this standard did not have a material impact on its condensed consolidated financial statements.

On January 1, 2019, the Company adopted ASU 2018-15, *Intangibles (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. This new standard can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the effect that the updated standard will have on its condensed consolidated financial statements and related disclosures.

On January 1, 2019, the Company adopted ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-17). ASU 2018-07 simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, *Compensation – Stock Compensation* to include share-based payment transactions for acquiring goods and services from nonemployees. The Company's adoption of this standard did not have a material impact on its condensed consolidated financial statements.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. The amendments became effective on November 5, 2018 and impacts the Company's condensed consolidated financial statements through, among other things, the addition of a requirement to present a statement of stockholders' equity for interim periods. As a result of adopting this guidance, the Company is presenting comparative interim statements of stockholders' equity in this Form 10-Q for the quarter ended March 31, 2019 and 2018. Additionally, the guidance also simplified certain non-material disclosures in its SEC filings.

Recent Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606 and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, including adoption in any interim period for public business entities for periods in which financial statements have not been issued. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in Topic 808 retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The Company is currently assessing the impact of this standard on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its condensed consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective on January 1, 2020. Early adoption is available. The Company is currently evaluating the effect that the updated standard will have on its condensed consolidated financial statements and related disclosures.

Note 3 – Investments in Marketable Securities

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable, accrued expenses, lease liability-short term and deferred revenue-short term.

The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

Level 3: Significant unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Investments in marketable securities consisted of the following at:

	March 31, 2019			
($ in thousands)	**Amortized Cost**	**Gross Unrealized Gain [1]**	**Gross Unrealized Loss [1]**	**Fair Value**
Short-term available-for-sale debt securities				
U.S. and foreign corporate debt securities	$ 60,799	$ 12	$ (10)	$ 60,801
Asset-backed securities	33,002	17	(2)	33,017
U.S. treasury securities	29,866	7	-	29,873
U.S. and foreign commercial paper	40,738	-	-	40,738
Total	$ 164,405	$ 36	$ (12)	$ 164,429

(1) Gross unrealized gain (loss) is pre-tax.

	December 31, 2018			
($ in thousands)	**Amortized Cost**	**Gross Unrealized Gain [1]**	**Gross Unrealized Loss [1]**	**Fair Value**
Short-term available-for-sale debt securities				
Corporate bonds	$ 101,701	$ -	$ (122)	$ 101,579
Treasury securities	19,898	-	(4)	19,894
Commercial paper	55,136	-	-	55,136

Total	$ 176,735	$ -	$ (126)	$ 176,609

(1) Gross unrealized gain (loss) is pre-tax.

The contractual term to maturity of short-term marketable securities held by the Company as of March 31, 2019 is less than one year. There were no long-term marketable securities held by the Company as of March 31, 2019.

Realized gains and losses for the three months ended March 31, 2018 and 2017 were not significant. The unrealized losses for the Company's investments that have been in a continuous unrealized loss position for more than 12 months as of March 31, 2019 and December 31, 2018 were also not significant.

The following tables present the fair value of the Company's financial assets measured at fair value on a recurring basis:

	March 31, 2019			
($ in thousands)	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Cash equivalents				
Money market fund	$ 25,434	$ -	$ -	$ 25,434
Total cash equivalents	25,434	-	-	25,434
Short-term investments				
U.S. and foreign corporate debt securities	-	60,801	-	60,801
Asset-backed securities	-	33,017	-	33,017
U.S. treasury securities	-	29,873	-	29,873
U.S. and foreign commercial paper	-	40,738	-	40,738
Total short-term investments	-	164,429	-	164,429
Total assets measured at fair value	$ 25,434	$ 164,429	$ -	$ 189,863

	December 31, 2018			
($ in thousands)	**Level 1**	**Level 2**	**Level 3**	**Fair Value**
Cash equivalents:				
Money market funds	$ 39,345	$ -	$ -	$ 39,345
U.S. and foreign commercial paper	-	-	-	
Total cash equivalents	39,345			39,345
Short-term investments:				
U.S. and foreign commercial paper	-	55,136	-	55,136
U.S. and foreign corporate debt securities	-	73,159	-	73,159
Asset-backed securities	-	28,419	-	28,419
U.S. treasury securities	-	19,895	-	19,895
Total short-term investments	-	176,609	-	176,609
Total assets measured at fair value	$ 39,345	$ 176,609	$ -	$ 215,954

The Company estimates the fair value of its corporate debt, asset-backed securities, and U.S. treasury securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data, and other observable inputs.

There were no transfers between Level 1, Level 2 or Level 3 during the periods presented.

Note 4 - Property and Equipment, net

Property and equipment consists of the following:

($ in thousands)	Useful life (Years)	March 31, 2019	December 31, 2018
Computer hardware and software	3	$ -	$ 194
Lab equipment	3 to 5	215	407
Office equipment	7	633	70
Leasehold improvement	1 to 3.25	722	790
Total property and equipment		1,570	1,461
Less: Accumulated depreciation and amortization		(838)	(1,057)
Construction in progress	N/A	1,347	153
Property and equipment, net		$ 2,079	$ 557

Depreciation expense for the three months ended March 31, 2019 and 2018 was approximately $0.1 million and $0.2 million, respectively, and was recorded in both research and development expense and general and administrative expense in the unaudited condensed consolidated statements of operations and comprehensive loss.

Note 5 – Accrued Expenses

Accrued expenses consist of the following:

($ in thousands)	March 31, 2019	December 31, 2018
Accrued expenses:		
Accrued compensation	$ 2,276	$ 5,011
Accrued clinical trial expenses	6,638	3,561
Accrued professional fees and other	1,227	1,107
Total accrued expenses	$ 10,141	$ 9,679

Note 6 - Stockholders' Equity

Common Stock

The Company was authorized to issue 5,000,000 shares of preferred stock as of March 31, 2019 and December 31, 2018. The Company was authorized to issue 100,000,000 shares of common stock as of March 31, 2019 and December 31, 2018.

For the three months ended March 31, 2019, the Company issued an aggregate of 21,000 shares of common stock and received gross proceeds of approximately $0.1 million from the exercise of options.

Note 7 - Stock-Based Compensation

Equity Incentive Plans

In May 2018, the Company's stockholders approved the Assembly Biosciences, Inc. 2018 Stock Incentive Plan (the 2018 Plan) pursuant to which the Company reserved 1,900,000 shares of its common stock for issuance in connection with equity incentive awards. In May 2018, the Company's stockholders also approved the Assembly Biosciences, Inc. Employee Stock Purchase Plan (the 2018 ESPP), pursuant to which eligible employees can purchase an aggregate of up to 400,000 shares of the Company's common stock at the end of predetermined offering periods at 85% of the lower of the fair market value at the beginning or end of the offering period.

As of March 31, 2019, the Company had awards outstanding under the following shareholder approved plans: 2010 Equity Incentive Plan (the 2010 Plan), which has been frozen; the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan); and the 2018 Plan. Shares of common stock underlying awards that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. Shares underlying awards that are forfeited under the 2014 Plan on or after May 30, 2018 will also become available for issuance under the 2018 Plan. As of March 31, 2019, the Company also had awards outstanding under the Assembly Biosciences, Inc. 2017 Inducement Award Plan (the 2017 Plan).

The Company issues new shares of common stock to settle options exercised and upon settlement of vested RSUs.

Stock Plan Activity

Stock Options

A summary of the Company's option activity and related information for the three-month period ended March 31, 2019 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	4,637,145	$ 17.21	$ 48,179
Granted	506,750	20.06	-
Exercised	(21,000)	6.68	290
Forfeited	(11,305)	27.28	48
Outstanding as of March 31, 2019	5,111,590	$ 17.52	$ 38,619
Options vested and exercisable	3,340,107	$ 11.37	$ 35,303

Restricted Stock Units (RSU)

A summary of the Company's RSUs and related information is as follows:

	Number of RSUs	Weighted average grant price
Outstanding as of December 31, 2018	568,005	$ 37.18
Granted	215,928	19.69
Vested and settled	(63,920)	46.03
Forfeited	(690)	49.14
Outstanding as of March 31, 2019	719,323(1)	$ 31.13

(1) Includes 111,667 RSUs that have vested but are subject to deferred settlement.

As of March 31, 2019, RSUs outstanding include 145,000 RSUs granted in December 2017 and 2018 with performance-based conditions to executives of the Company. Of these awards, 100,000 RSUs with a grant date fair value of $2.4 million vest over time but will be accelerated upon the achievement of certain performance conditions. The Company is recognizing expense for this award over the vesting period as it does not believe that any of the performance conditions are probable of being met. The remaining 45,000 RSUs with a grant date fair value of $1.9 million vest upon the performance conditions not yet deemed probable and accordingly no compensation expense has been recognized as of March 31, 2019 for these awards.

As of March 31, 2019, the Company had unrecognized stock-based compensation expense related to all unvested RSUs of $13.2 million. The weighted average remaining contractual term of unvested RSUs is approximately 9.6 years at March 31, 2019.

Valuation Assumptions

The fair value of the stock options granted or modified during the periods indicated was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Three Months Ended March 31,	
	2019	**2018**
Exercise price	$ 19.69 - $23.04	$ 45.80 - $57.53
Expected volatility	75.0% - 83.2%	77.0% - 86.1%
Risk-free rate	2.24% - 2.65%	2.57% - 2.79%
Expected term (years)	5.5 – 7.0	5.5 - 7.0
Dividend yield	0%	0%

The fair value of RSUs granted is determined based on the price of the Company's common stock on the date of grant.

Stock-Based Compensation Expense

The following table summarizes the components of total stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended March 31,	
($ in thousands)	**2019**	**2018**
Research and development	$ 2,728	$ 2,524
General and administrative	3,849	1,559
Total stock-based compensation expense	$ 6,577	$ 4,083

Note 8 - Collaboration Agreement

Allergan

In January 2017, the Company entered into the Collaboration Agreement with Allergan to develop and commercialize select microbiome gastrointestinal disease therapies. Pursuant to the Collaboration Agreement, the Company granted Allergan an exclusive worldwide license to certain of its intellectual property, including its intellectual property arising under the Collaboration Agreement, to develop and commercialize licensed compounds for UC, Crohn's disease, and two compounds for IBS. Allergan and the Company also agreed to collaborate on research and development activities with respect to the licensed compounds in accordance with a mutually agreed upon research and development plan. Per the terms of the Collaboration Agreement, Allergan can select backups and additional target indications to add to the licenses granted for additional consideration and also has the ability to enter into a contract manufacturing agreement with the Company for compound supply at cost plus an agreed upon margin. In addition, the Company will participate on a Joint Development Committee (JDC) and Joint Patent Committee (JPC). The Company provided to Allegan standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services.

Allergan paid the Company an upfront non-refundable payment of $50.0 million, which was received in 2017. Additionally, the Company is eligible to receive variable consideration in the form of research and development cost reimbursements, up to approximately $631.0 million related to seven development milestones and up to approximately $2.14 billion related to 12 commercial development and sales milestones in connection with the successful development and commercialization of licensed compounds. In addition, the Company is eligible to receive tiered royalties at rates ranging from the mid-single digits to the mid-teens based on net sales.

Allergan and the Company have agreed to share research and development costs up to an aggregate of $75.0 million through proof-of-concept (POC) studies on a ⅔, ⅓ basis, respectively, and Allergan has agreed to assume all post-POC development costs. In the event any pre-POC development costs exceed $75.0 million in the aggregate, the Company may elect either (a) to fund ⅓ of such costs in excess of $75.0 million or (b) to allow Allergan to deduct from future development milestone payments ⅓ of the development costs funded by Allergan in excess of $75.0 million plus a premium of 25%. The Company has an option to co-promote the licensed programs in the U.S. and China, subject to certain conditions set forth in the Collaboration Agreement.

Allergan may terminate the Collaboration Agreement at any time upon either 90 days' (prior to the initiation of the first POC trial of a licensed product) or 120 days' (after the initiation of the first POC trial of a licensed product), as applicable, advance written notice to the Company. Unless terminated early, the Collaboration Agreement has a term that ends on the earlier of the (i) the period when POC studies have been completed and no further licensed compounds are in development, and (ii) expiration of the last to exist valid claim covering the manufacture, use and sale of the licensed compounds. The Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the Collaboration Agreement, subject to cure. Upon termination for convenience, the licenses granted by the Company and its know how all revert to the Company.

The Company concluded that Allegan is a customer and that the Collaboration Agreement is not subject to accounting literature on collaborative arrangements. This is because the Company granted to Allergan licenses to its intellectual property, and research and development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration. The Company identified the following material promises under the Collaboration Agreement: (1) transfer of a licenses to intellectual property for the four initial indications, inclusive of the related technology know-how (Licenses); and (2) the obligation to perform research development services through POC (Development Services). The Company's participation on the JDC and JPC were considered to be immaterial in the context of the contract. The Company's co-promotion option was not considered to be a performance obligation. Allergan's selection of backups or additional target indications to add to the licenses granted for additional consideration and ability to enter into a contract manufacturing agreement with the Company for compound supply at cost plus an agreed upon margin were not considered to be performance obligations as the Company concluded the options were not offered at a discount that exceeds discounts available to other customers, and therefore were not material rights. The grant of additional licensing rights upon option exercises and contract manufacturing agreements will be accounted for as separate contracts when they occur.

The Company concluded the Licenses each were considered to be functional as they have significant standalone functionality and were capable of being distinct. However, the Company determined that each of the Licenses individually were not distinct from the Development Services within the context of the agreement. This is because Allergan is dependent on the Company to execute the Development Services, that it is only uniquely able to perform, in order for Allergan to benefit from the Licenses. As such, the Company determined that it has four performance obligations under the Collaboration Agreement associated with the transfer of the four compound Licenses combined with the performance of the Development Services for each of the four compound indications. The Company determined that the four performance obligations will be performed over the duration of the contract, which began in February 2017 and ends upon completion of the Development Services which is currently estimated to occur in 2024. The Company is using a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Allegan. In applying the cost-based input method of revenue recognition, the Company measures costs incurred relative to budgeted costs to fulfill the four performance obligations. These costs consist primarily of third-party contract costs and internal labor costs. Revenue will be recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

To allocate transaction price among the four performance obligations, the Company estimated their standalone selling price (SSP) using income-based valuation approach for the estimated value a licensor of the compounds would receive considering the stage of the compounds development. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the four performance obligations would not have a significant effect on the allocation of consideration received to the four performance obligations.

The transaction price at the inception of the agreement and upon adoption of ASC 606, was limited to $50.0 million upfront payment. Of this amount, the Company allocated $12.5 million to each of the four performance obligations. Research and development cost reimbursement payments are included in the transaction price in the reporting period that the Company concludes that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. The variable consideration related to the remaining development and commercialization milestone payments has not been included in the transaction price as these were fully constrained at March 31, 2019. As part of the Company's evaluation of the development and commercialization milestones constraint, the Company determined that the achievement of such milestones are contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Allergan. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company did not incur any significant incremental costs of obtaining the Allergan contract.

For the three months ended March 31, 2019 and 2018, the Company recorded approximately $3.9 million and $3.6 million, respectively, in revenue associated with the Collaboration Agreement. Short-term and long-term deferred revenue contract liabilities related to the Collaboration Agreement were approximately $9.9 million and approximately $29.9 million at March 31, 2019 and approximately $5.1 million and approximately $35.6 million at December 31, 2018.

On the unaudited condensed consolidated balance sheets, contract asset balances of approximately $3.0 million and approximately $2.4 million were recorded as accounts receivable from collaboration as of March 31, 2019 and December 31, 2018, respectively.

The following table presents changes in the Company's contract liabilities ($ in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three Months Ended March 31, 2019				
Contract liabilities:				
Deferred revenue	$ 40,660	$ -	$ (859)	$ 39,801

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three Months Ended March 31, 2018				
Contract liabilities:				
Deferred revenue	$ 45,551	$ -	$ (1,231)	$ 44,320

	Three Months Ended March 31,	
($ in thousands)	**2019**	**2018**
Collaboration revenue recognized in the period from:		
Amounts included in deferred revenue at the beginning of the period	$ 859	$ 1,231
Performance obligations satisfied in previous period	-	-

Note 9 - Milestones and Research Agreements

HBV Research Agreement with Indiana University

Since September 2013, the Company has been party to an exclusive License Agreement dated September 3, 2013 with Indiana University Research and Technology Corporation (IURTC) from whom it has licensed aspects of the Company's HBV program held by IURTC. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, should all milestones through development be met, is approximately $0.8 million, with a portion related to the first performance milestone having been paid. The Company also is obligated to pay IURTC royalty payments based on net sales of the licensed technology. The Company is also obligated to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year. Amounts paid in the three months ended March 31, 2019 and 2018 were insignificant.

Microbiome Targeted Colonic Delivery Platform

In November 2013, the Company entered into a License and Collaboration Agreement with Therabiome, LLC (Therabiome), for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release capsule-in-capsule technology. The Company will be solely responsible for all research and development activities with respect to any product it develops under the license.

The Company must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. The Company also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region. The Company also must pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed certain thresholds, a one-time cash payment upon reaching the thresholds.

Therabiome must pay the Company royalties on annual net sales of any product Therabiome is permitted to develop using the intellectual property in the low double to mid-double-digit percentages, depending on the level of development or involvement the Company had in the product.

A regulatory milestone was determined to have occurred and was paid under this agreement as of and during the three months ended March 31, 2019. No amounts were accrued for this agreement as of and for the three months ended March 31, 2018.

Note 10 - Leases

Operating Leases

The Company leases office space for corporate and administrative functions in Carmel, Indiana under a lease agreement that expires in August 2023. The Company leases office and laboratory space in South San Francisco, California under a sub-sublease that expires in December 2023. Prior to moving into the South San Francisco office and laboratory space in February 2019, the Company leased office and laboratory space in San Francisco, California, under a sublease that expired on February 28, 2019. The Company also leases office and laboratory space in Groton, Connecticut under a lease that expires in March 2020. Our China subsidiary leases office space in Shanghai that expires in June 2019 and rents lab space in Shanghai that expires in December 2019. Additionally, our China subsidiary leases office space in Beijing that expires in December 2019. Certain lease contracts contain renewal clauses which the company assesses on a case by case basis. The Company also leases certain laboratory equipment accounted for as operating leases. These equipment leases began to expire in 2017, with the final lease expiring in 2021.

When the Company cannot determine the implicit rate in its leasing arrangements the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment.

At March 31, 2019, the Company had operating lease liabilities of $13.2 million and right-of-use assets of $13.1 million, which were included in the condensed consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases:

($ in thousands)	**Three Months Ended March 31, 2019**
Lease cost	
Operating lease cost	$ 1,091
Short-term lease cost	321
Variable lease cost	299
Total lease cost	$ 1,711

($ in thousands)	**Three Months Ended March 31, 2019**
Operating cash flows from operating leases	$ 1,037
Right-of-use assets exchanged for new operating lease liabilities	$ -
Weighted-average remaining lease term – operating leases	4.5
Weighted-average discount rate – operating leases	9.6%

As of March 31, 2019, the maturities of the Company's operating lease liabilities were as follows (in thousands):

2019 (from April to December)	$ 2,915
2020	3,735
2021	3,250
2022	3,267
2023	3,303
Total undiscounted future minimum lease payments	16,470
Less: present value adjustment	(3,245)
Operating lease liabilities	$ 13,225

Operating lease cost for three months ended March 31, 2019 and 2018 were approximately $1.1 million and $0.4 million, respectively.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission on February 28, 2019 (2018 Annual Report). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our 2018 Annual Report, "Part II. Item 1A. Risk Factors" in this report, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a clinical-stage biotechnology company developing innovative therapeutics targeting chronic hepatitis B virus (HBV) infection and diseases associated with the microbiome.

HBV-cure Program

Over 250 million people worldwide are chronically infected with HBV. Our HBV-cure program is pursuing multiple drug candidates that inhibit the HBV lifecycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of increasing the current low cure rate for patients with HBV. We have discovered multiple novel core inhibitors, which are small molecules that directly target and allosterically modulate the HBV core (HBc) protein.

ABI-H0731

The lead product candidate from this program, ABI-H0731, has completed a Phase 1a/1b human clinical study in countries outside the United States. We have also completed an additional Phase 1a (ABI-H0731-102) pharmacokinetic (PK), safety and tolerability study of ABI-H0731 in healthy volunteers in the United States. In 2018, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to ABI-H0731 for the treatment of patients with chronic HBV infection.

Final data from our completed Phase 1a (ABI-H0731-102) PK, safety and tolerability study and Phase 1b (ABI-H0731-101b) study showed antiviral activity across all patient cohorts. In the 300 mg dose cohort, the mean maximal declines from baseline were reported as $\geq 2.8^{*}$ $\log_{10}$ IU/mL after 28 days, with ≥ 2.9 and 2.5^{*} $\log_{10}$ IU/mL mean declines in HBeAg positive and negative patients, respectively. Maximal viral load declines of 3.6 to 4.0 $\log_{10}$ IU/mL were observed in HBeAg negative patients treated at all dose levels (100 mg to 400 mg). Mean RNA reductions observed in the 300 mg dose cohort were 2.3 $\log_{10}$ IU/mL over 28 days. The observed reductions in viral RNA levels are a distinguishing feature of this class of inhibitors compared to standard of care Nuc therapy.

Across all cohorts in the Phase 1a and Phase 1b studies, ABI-H0731 was generally well-tolerated. No serious adverse effects or dose-limiting toxicities were identified, and there was no pattern of treatment emergent clinical or laboratory abnormalities observed. With the exception of an isolated Grade 3 rash at the 400 mg dose that resolved with no intervention required other than treatment discontinuation, there were no other Grade 3 or Grade 4 adverse events, and no other drug discontinuations have occurred in these studies.

In July 2018, we commenced two Phase 2a combination studies for ABI-H0731 at sites in the United States, Canada, Hong Kong, New Zealand and the United Kingdom. The first Phase 2a trial, ABI-H0731-201 (Study 201), enrolled HBV patients whose viral load had already been suppressed on a standard of care Nuc therapy. Seventy-three patients were randomized 3:2 to receive either 300 mg of ABI-H0731 daily or placebo in addition to their continued Nuc therapy for six months. Study 201 compares the safety and tolerability of combination therapy with ABI-H0731, as well as evaluates declines in HBV S antigen (HBsAg), HBV E antigen (HBeAg) and HBV and RNA levels, to those seen in patients on Nuc monotherapy.

The second Phase 2a trial, ABI-H0731-202 (Study 202), enrolled 25 HBeAg positive HBV patients who are naïve to Nuc treatment and randomized 1:1 to receive either 300 mg of ABI-H0731 daily or placebo in combination with standard of care entecavir (0.5 mg) for six months. Study 202 assesses the relative antiviral potency of combination therapy compared with entecavir alone. Endpoints include the speed and depth of viral suppression, as well as changes in biomarkers (HBsAg and HBeAg) and HBV RNA levels, and the safety and tolerability of ABI-H0731.

We presented interim safety and efficacy data from Studies 201 and 202 during a late-breaker oral session at The International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL) in April 2019. The late-breaker abstract was also selected for inclusion in the "Best of ILC" presentation. The initial safety data suggests that ABI-H0731 in combination with Nuc therapy was well tolerated. Adverse events (AEs) were mild, infrequent, and evaluated as generally unrelated to treatment. There were no treatment related discontinuations, no serious adverse events and no clinical AEs greater than Grade 2 observed. Lab abnormalities were mostly Grade 1, transient, and not thought to be related to drug. Final six-month data from both studies is expected in the fourth quarter of 2019. The initial efficacy data suggests that combination therapy exhibits rapid and enhanced antiviral benefit in suppressing HBV DNA and RNA levels, with the latter not observed with Nuc treatment alone. In treatment naïve patients enrolled in Study 202, accelerated and significant declines in HBV DNA were observed starting as early as Week 2 of treatment. Reduction in residual viral DNA levels that persist on extended Nuc therapy, were only observed with combination therapy. We believe that complete suppression of viral replication will likely be required to cure HBV and that the initial efficacy data supports the use of core inhibitors in HBV treatment regimens. If complete suppression of viral replication can be sustainably achieved, it is anticipated that this may lead to higher rates of "cure" defined as a sustained antiviral suppression of treatment (potentially with loss or diminution of viral antigens).

* Excludes one subject found to have resistance at baseline.

All subjects who complete treatment in Studies 201 or 202 have the option to roll over into a long-term open label study of ABI-H0731 (Study 211) and receive the combination of ABI-H0731 with ongoing standard of care Nuc therapy. Subjects on the 211 Study will be treated for up to an additional year from the time of completion of their participation in Studies 201 or 202, as applicable. Subjects in Study 211 who achieve a complete response, defined as HBsAg <100 IU, loss of HBeAg and viral load below limits of detection, will have the opportunity to stop all treatment (ABI-H0731 and standard of care Nuc therapy) and be monitored for six months off therapy to assess whether combination therapy improves the rate of sustained viral responses.

ABI-H2158

ABI-H2158, our second product candidate in the HBV-cure program, is an internally discovered and developed drug product candidate that is chemically distinct from ABI-H0731. In November 2018, we initiated a Phase 1a/1b dose-ranging clinical study of ABI-H2158 in New Zealand, to assess the safety, tolerability and PK of ABI-H2158 in healthy volunteers and then subsequently assess the safety, tolerability, PK and initial antiviral potency in non-cirrhotic patients with chronic HBV infection.

We presented final data from the Phase 1a portion of the Phase 1a/1b dose-ranging clinical study at EASL in April 2019. The Phase 1a study assessed safety, tolerability and PK in 48 healthy volunteers. ABI-H2158 was well tolerated following single and multiple ascending doses. There were no dose dependent treatment-emergent adverse events, and no pattern of clinical safety or laboratory abnormalities observed within or across any cohorts. Once daily administration is projected to result in trough liver concentrations in excess of the *in vitro* EC_{50} of 334 nM at which cccDNA establishment is inhibited. We initiated the Phase 1b dose-ranging portion of this study in April 2019 to assess the safety, PK and antiviral activity of ABI-H2158 in patients with chronic HBV infection. Data from this study is expected by the first quarter of 2020.

ABI-H3733

ABI-H3733 is our third clinical product candidate for the treatment of HBV and is currently undergoing IND-enabling studies. ABI-H3733 exhibits a novel chemical scaffold separate from ABI-H0731 and ABI-H2158. We presented a preclinical profile of this candidate at EASL in April 2019. In preclinical studies, ABI-H3733 demonstrated potent inhibitory activity against multiple steps in the HBV infection cycle, particularly those relating to cccDNA generation. ABI-H3733 possesses promising physical properties, low drug-drug interaction potential and a favorable PK profile in multiple species. Mechanism of action studies suggest enhanced potency in blocking encapsidation of pgRNA and disruption of pre-formed capsids, leading to premature disassembly during trafficking of rcDNA containing capsids to the nucleus during infection. ABI-H3733 inhibited cccDNA formation with an EC_{50} of 125 nM. ABI-H3733's enhanced potency and favorable preclinical profile support advancement into Phase 1a studies, which we expect to initiate in the first quarter of 2020.

Other Product Candidates

We plan to conduct additional research and development to identify additional product candidates for our HBV-cure program.

Microbiome Program

Our Microbiome program consists of a fully integrated platform that includes a disease-targeted strain isolation, identification, characterization and selection process, methods for strain purification and growth under current Good Manufacturing Practice (cGMP) conditions, and a licensed patented delivery system that we call GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. In connection with our Microbiome program, we filed an Investigational New Drug (IND) application in December 2018 for ABI-M201 (Ulcerative Colitis). In February 2019, we initiated a Phase 1b human clinical study for ABI-M201 in patients with mildly to moderately active ulcerative colitis to evaluate safety, efficacy and exploratory endpoints. Using our microbiome platform capabilities, we are exploring additional product candidates for other disease indications, including Crohn's disease, irritable bowel syndrome, non-alcoholic steatohepatitis (NASH) and immuno-oncology, which indications we will pursue with Allergan Pharmaceuticals International Limited (Allergan) to the extent covered by the Collaboration Agreement discussed below or pursue either internally or in collaboration with other partners to the extent outside the scope of the Collaboration Agreement.

On January 6, 2017, we entered into the Research, Development, Collaboration and License Agreement (the Collaboration Agreement) with Allergan to develop and commercialize select microbiome gastrointestinal programs. Pursuant to the terms of the Collaboration Agreement, in connection with the closing of the transaction in February 2017, Allergan paid us an upfront payment of $50.0 million. Additionally, we are eligible to receive up to approximately $631.0 million in payments related to seven development milestones and up to approximately $2.14 billion in payments related to 12 commercial development and sales milestones in connection with the successful development and commercialization of licensed compounds for up to six different indications. We have agreed with Allergan to share development costs up to an aggregate of $75.0 million through proof-of-concept (POC) studies on a ⅔, ⅓ basis, respectively, and Allergan has agreed to assume all post-POC development costs. Additionally, we have an option to co-promote the licensed programs in the United States and China, subject to certain conditions set forth in the Collaboration Agreement.

Operations

We currently have corporate and administrative offices in Carmel, Indiana, administrative offices and research laboratory space in South San Francisco, California and research, development and small-scale manufacturing activities in Groton, Connecticut. We also currently have an administrative office and research laboratory space in Shanghai, China and a regulatory office in Beijing, China.

Since our inception, we have had no revenue from product sales and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings and collaborations. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, discovering and developing our product candidates, establishing initial manufacturing capabilities for certain of our product candidates, maintaining and improving our patent portfolio and raising capital. We have generated significant losses to date, and we expect to continue to generate losses as we continue to develop our product candidates. As of March 31, 2019, we had an accumulated deficit of approximately $367.3 million. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses.

We evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation, on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and significant estimates are detailed in our 2018 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2018 Annual Report, except for those accounting subjects discussed in the section of Note 2 to the unaudited condensed consolidated financial statements titled Adoption of Recent Accounting Pronouncements included in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

Collaboration Revenue

For the three months ended March 31, 2019 and 2018, collaboration revenue was approximately $3.9 million and $3.6 million, respectively, which included the amortization of deferred revenue and reimbursement revenue in each case incurred under the Collaboration Agreement. This decrease is the result of decreased activities under the Collaboration Agreement and related reimbursements received from Allergan.

Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was approximately $20.0 million for the three months ended March 31, 2019, an increase of approximately $8.0 million from approximately $12.0 million for the same period in 2018. The increase was primarily due to an increase of approximately $1.6 million in research expenses for our Microbiome program and an increase of approximately $6.4 million in research expenses for our HBV-cure program.

Stock-based compensation expense was approximately $2.7 million for the three months ended March 31, 2019, an increase of approximately $0.2 million from approximately $2.5 million for the same period in 2018.

General and Administrative Expense

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the stock-based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expense, excluding stock-based compensation expense, was approximately $5.7 million for the three months ended March 31, 2019, an increase of approximately $1.6 million from approximately $4.1 million for the same period in 2018. The increase was primarily due to an increase of approximately $0.8 million of professional fees, $0.4 million of employee related expenses, and $0.4 of rent expenses

Stock-based compensation expense was approximately $3.8 million for the three months ended March 31, 2019, an increase of approximately $2.2 million from approximately $1.6 million for the same period in 2018.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through March 31, 2019 principally through equity financing, raising an aggregate of approximately $412.8 million in net proceeds, and a strategic collaboration raising an aggregate of $50 million through an upfront payment.

Cash Flows for the Three Months Ended March 31, 2019 and 2018

Net Cash from Operating Activities

Net cash used in operating activities was approximately $23.9 million for the three months ended March 31, 2019. This was primarily due to a $27.1 million net loss, $0.6 million of accretion of discount of marketable securities and a decrease of $3.9 million of operating assets and liabilities and offset by a $6.6 million non-cash expense recorded for the stock-based compensation, $0.8 million of amortization of operating lease right-of-use assets and $0.1 million of depreciation and amortization expense.

Net cash used in operating activities was approximately $15.5 million for the three months ended March 31, 2018. This was primarily due to a $16.2 million net loss and a decrease of $3.5 million of operating assets and liabilities and offset by a $4.1 million non-cash expense recorded for the stock-based compensation and $0.2 million of depreciation and amortization expense.

Net Cash from Investing Activities

Net cash provided by investing activities from continuing operations for the three months ended March 31, 2019 was $11.4 million due to the purchase of approximately $49.0 million of marketable securities and $1.5 million of fixed assets, which were offset by a $61.5 million redemption of marketable securities and $0.5 million of sale of marketable securities.

Net cash used in investing activities from continuing operations for the three months ended March 31, 2018 was $1.1 million due to the purchase of approximately $13.0 million of marketable securities and $40,000 of fixed assets and offset by a $12.0 million redemption of marketable securities.

Net Cash from Financing Activities

Net cash provided by financing activities from continuing operations for the three months ended March 31, 2019 was $0.1 million resulting from the exercise of stock options to purchase 21,000 shares of common stock.

Net cash provided by financing activities from continuing operations for the three months ended March 31, 2018 was $1.5 million resulting from the exercise of stock options to purchase 248,762 shares of common stock.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical studies of our product candidates and pursue our intellectual property strategy. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We monitor our cash needs and the status of the capital markets on a continuous basis. From time to time, we opportunistically raise capital and have done so numerous times since our initial public offering by issuing equity securities, most recently in July 2018. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

- the initiation, scope, progress, timing, results and costs of our ongoing drug discovery, nonclinical development, laboratory testing and clinical studies of our product candidates and any additional clinical studies we may conduct in the future;
- the extent to which we further acquire or in-license other product candidates and technologies;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical studies and any eventual commercialization;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications in the United States and abroad, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting nonclinical testing and clinical studies is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financings to achieve our business objectives. Adequate additional financings may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances 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 to 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, limit, reduce or terminate 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.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

There were no material changes in our commitments under contractual obligations as disclosed in our 2018 Annual Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our 2018 Annual Report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that is designed to provide reasonable assurance that information that is required to be disclosed in our reports filed pursuant to the Exchange Act, is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, who serves as our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in the quarter ended March 31, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are not a party to any material legal proceedings. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors.

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.

You should carefully consider the following risk factors, together with all other information in this report, including our financial statements and notes thereto, and in our other filings with the Securities and Exchange Commission. If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We have no approved products and currently are dependent on the future success of our HBV-cure and Microbiome programs.

To date, we have no approved products on the market and have generated no product revenues. Our prospects are substantially dependent on our ability to develop and commercialize our HBV and microbiome product candidates. Unless and until we receive approval from the FDA or other regulatory authorities for our product candidates, we cannot sell our product candidates and will not have product revenues. We will have to fund all of our operations and capital expenditures from cash on hand, any future securities offerings or debt financings and any fees we may generate from out-licensing, collaborations or other strategic arrangements. If we are unable to develop and commercialize any product candidates from our HBV-cure and Microbiome programs, we will be unable to generate revenues from the sale of products or build a sustainable or profitable business.

In addition, all of our product candidates are currently in early clinical development or in varying stages of nonclinical development and their risk of failure is high. The data supporting our drug discovery and nonclinical and clinical development programs are derived from either laboratory, nonclinical studies, Phase 1a/1b and initial Phase 2a clinical data. We cannot predict when or if any one of our product candidates will prove safe and effective in humans or will receive regulatory approval. The scientific evidence to support the feasibility of our product candidates and therapeutic approaches is limited, and many companies, some with more resources than we have, are and may be developing competitive product candidates. For these and other reasons, our drug discovery and development may not be successful, and we may not generate viable products or revenue.

We depend entirely on the success of product candidates from our HBV-cure program and our Microbiome program. We cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, product candidates from either of our current programs or any other product candidates we may subsequently identify.

We and our collaborators are not permitted to market or promote any product candidates in the United States, Europe or other countries before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for our current product candidates. We have not submitted a biologics license application (BLA) or new drug application (NDA) to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so in the foreseeable future.

All of our product candidates are currently in early clinical development or in varying stages of nonclinical development. It may be years before the larger, pivotal trials necessary to support regulatory approval of our product candidates are initiated, if ever. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must successfully meet a number of critical developmental milestones, including:

- developing dosages that will be tolerated, safe and effective;
- reaching agreement with the FDA or comparable foreign regulatory authorities regarding the scope, design and data necessary to support regulatory approval for the product candidate;
- demonstrating through clinical studies that the product candidate is safe and effective in patients for the intended indication;
- determining the appropriate delivery mechanism;
- demonstrating that the product candidate formulation will be stable for commercially reasonable time periods; and
- completing the development and scale-up to permit manufacture of our product candidates in quantities sufficient to execute on our clinical development plans and, eventually, in commercial quantities and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for our HBV and microbiome therapies or any other product candidates that we may develop. We have not yet completed and may never complete the development of any products. If we are unable to complete clinical development of our HBV or microbiome therapies, or any other product candidates that we may identify, we will be unable to generate revenue from the sale of products or build a sustainable or profitable business.

Nonclinical studies may not be representative of disease behavior in clinical studies. The outcomes of nonclinical testing and clinical studies are uncertain, and results of earlier nonclinical studies and clinical studies may not be predictive of future clinical study results.

The results of nonclinical studies may not be representative of disease behavior in a clinical setting and thus may not be predictive of the outcomes of our clinical studies. In addition, the results of nonclinical studies and early clinical studies of product candidates may not be predictive of the results of later-stage clinical studies, and the results of any study or trial for any of our product candidates may not be as positive as the results for any prior studies or trials, if at all.

Nonclinical studies and clinical testing are expensive, can take many years to complete and their outcomes are highly uncertain. Failure can occur at any time during the nonclinical study and clinical study processes due to inadequate performance of a drug candidate or inadequate adherence by patients or investigators to clinical study protocols. Further, clinical studies might not provide statistically significant data supporting a product candidate's safety and effectiveness to obtain the requisite regulatory approvals. In addition, there is a high failure rate for drugs and biologics proceeding through clinical studies. Our failure to replicate earlier positive results in later-stage clinical studies or otherwise demonstrate the required characteristics to support marketing approval for any of our product candidates would substantially harm our business, prospects, financial condition and results of operations.

Top-line or initial data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose top-line or initial data from time to time, which is based on a preliminary analysis of then-available efficacy, tolerability, PK and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate fully and carefully all data. As a result, the top-line or initial results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the initial or preliminary data we previously published. As a result, top-line and initial data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or biotherapeutic and our company in general. In addition, the information we may publicly disclose regarding a particular nonclinical or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line or initial data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

Nonclinical and clinical testing required for our product candidates is expensive and time-consuming and may result in delays or may fail to demonstrate safety and efficacy for desired indications. Such delays or failures could delay or prevent our receipt of licensing, sales and/or milestone revenue.

Before we or any commercial partners can obtain FDA approval (or other foreign approvals) necessary to sell any of our product candidates, we must show through nonclinical studies and human testing in clinical studies that each potential product is safe and effective in humans. To meet these requirements, we must conduct extensive nonclinical testing and sufficient adequate and well-controlled clinical studies. Conducting clinical studies is a lengthy, time consuming, and expensive process. The length of time might vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with product candidates for which we are directly conducting nonclinical studies or clinical studies might cause us to incur additional operating expenses. The commencement and rate of completion of clinical studies might be delayed by many factors, including, for example:

- delays in reaching agreement with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites;
- failure to demonstrate efficacy during clinical studies;
- the emergence of unforeseen safety issues;
- inability to manufacture sufficient quantities of qualified materials under cGMP for use in clinical studies;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of eligible patients, which may be due to a number of reasons, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, and other potential drug candidates being studied;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects, disease progression or other reasons;
- clinical sites dropping out of a trial to the detriment of enrollment;
- modification of clinical study protocols;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical study materials;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements for clinical studies;
- delays, suspension, or termination of clinical studies by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government, institutional review board, ethics committee, or other regulatory delays or clinical holds requiring suspension or termination of the trials.

We have used and intend to continue to rely on one or more CROs to conduct our nonclinical studies and clinical studies. We are highly dependent on these CROs to conduct our studies and trials in accordance with the requirements of the FDA, applicable local laws and good clinical and scientific practice. In the event the CROs fail to perform their duties in such a fashion, we may not be able to complete our clinical studies and may fail to obtain regulatory approval for any of our product candidates.

The failure of nonclinical studies and clinical studies to demonstrate safety and effectiveness of a product candidate for the desired indications could harm the development of that product candidate or other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our nonclinical studies or clinical studies would delay the filing of our NDAs or BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical studies could materially harm our business, financial condition, and results of operation.

Any product candidates that we may discover and develop may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development. Undesirable side effects caused by any product candidates that we may discover or develop, or safety, tolerability or toxicity issues that may occur in our nonclinical studies, clinical studies or in the future, could cause us or regulatory authorities to interrupt, restrict, delay, or halt clinical studies. Such results could also cause us to, or regulatory authorities to require us to, cease further development of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, prospects, financial condition and results of operations.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by these product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and require us to take them off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a Risk Evaluation Mitigation Strategies (REMS) plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is administered, conduct additional clinical studies or change the labeling of a product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

We have a limited operating history and a history of operating losses and expect to incur significant additional operating losses.

We merged with Assembly Pharmaceuticals, Inc. (Assembly Pharmaceuticals), a private company, in July 2014. We have only a limited operating history since the merger. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We, and Assembly Pharmaceuticals prior to our merger, have generated losses since we began operations and as of March 31, 2019 and December 31, 2018, the combined company had an accumulated deficit of approximately $367.3 million and $341.8 million, respectively, and net losses of approximately $90.8 million, $42.8 million, and $44.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to incur substantial additional losses over the next several years as we continue to pursue our research, development, nonclinical studies and clinical study activities. Further, since our initial public offering, we have incurred and will continue to incur as a public company significant additional legal, accounting and other expenses to which we were not subject to as a private company, including expenses related to our efforts in complying with the requirements of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and other public company disclosure and corporate governance requirements and responding to requests of government regulators. The amount of future losses and when, if ever, we will achieve profitability are uncertain and will depend, in part, on the rate of increase in our expenses, our ability to generate revenues from the sale of products and our ability to raise additional capital. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products unless and until our HBV or microbiome therapies or any other product candidate is approved by the FDA for sale, and we might never generate revenues from the sale of products.

We are not currently profitable and might never become profitable.

We have a history of losses and expect to incur significant operating and capital expenditures and resultant substantial losses and negative operating cash flow for the next several years and beyond if we do not successfully launch and commercialize any product candidates from our HBV or Microbiome programs. We might never achieve or maintain profitability. We anticipate that our expenses will continue to be substantial in the foreseeable future as we:

- advance ABI-H0731, our first HBV-cure candidate, through clinical development and conduct nonclinical studies and clinical studies with ABI-H2158 and ABI-H3733, our second and third HBV-cure product candidates, respectively;
- advance ABI-M201 (Ulcerative Colitis), our first candidate from our Microbiome program, through clinical development;
- continue to undertake research and development to identify potential additional product candidates in both our HBV-cure and Microbiome programs;
- seek regulatory approvals for our product candidates; and
- pursue our intellectual property strategy.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical studies or the development of any of our product candidates.

As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Our ability to generate revenue from the sale of products and achieve profitability will depend on, among other things:

- successful completion of research, nonclinical studies and clinical studies for our product candidates;
- obtaining necessary regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates;
- maintaining patent protection for our products, methods, processes and technologies and/or obtaining regulatory exclusivity;
- establishing manufacturing, sales, and marketing arrangements internally and/or with third parties for any approved products; and
- raising sufficient funds to finance our activities, if and when needed.

We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations might be materially adversely affected.

We are an early stage company and might not be able to commercialize any product candidates.

We are an early stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- continuing to undertake research and development and nonclinical studies and clinical studies;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales, marketing and distribution activities.

We currently do not have the infrastructure to manufacture, market and sell our product candidates. If we partner with one or more third-party entities, those commercial partners may demand and receive rights to control product development and commercialization. As a result, these commercial partners may conduct these programs and activities more slowly or in a different manner than expected. If any of these events were to occur, the development of any product candidate could be significantly delayed, more expensive or less lucrative to us than anticipated, any of which would have a significant adverse effect on our business.

Our failure to commercialize successfully our product candidates would negatively impact the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, or continue our operations.

Our development of product candidates is subject to risks and delays.

Our development of our product candidates is subject to the risks of failure and delay inherent in the development of new pharmaceutical products and products based on new technologies, including:

- delays in product development, nonclinical and clinical testing;
- unplanned expenditures in product development, nonclinical and clinical testing;
- failure of a product candidate to demonstrate acceptable safety and efficacy;
- failure to receive regulatory approvals;
- emergence of superior or equivalent products;
- inability to manufacture and sell on our own, or through others, product candidates on a commercial scale or at a financially viable cost; and
- failure to achieve market acceptance.

Because of these risks, our research and development efforts might not result in any commercially viable products. If we do not successfully complete a significant portion of these development efforts, obtain required regulatory approvals, and have commercial success with any approved products, our business, financial condition and results of operations will be materially harmed.

There are substantial risks inherent in attempting to commercialize new drugs and biologics, and, as a result, we may not be able to develop successfully products for commercial use.

Scientific research and development require significant amounts of capital and takes a long time to reach commercial viability, if it can be achieved at all. To date, our research and development projects have not produced commercially viable drugs or biologics and may never do so. During the research and development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs are not fully proven.

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins with core inhibitors. The development of our core inhibitor technology is in early stages, and the commercial feasibility and acceptance of our core inhibitor technology is unknown. More specifically, the theory that treatment with core inhibitors may result in more rapid loss of covalently closed circular DNA (cccDNA) compared to conventional (standard of care) therapies is unproven. It is also unknown if the biomarkers assumed to be indicators of active cccDNA (serum viral antigen levels in HBV patients) will be meaningfully altered in patients on treatment with core inhibitors. Additionally, even if core inhibitor technology is successful at targeting the HBV core protein and treatment is successful at reducing cccDNA levels in HBV patients, it may not result in a commercially viable drug if there is not a corresponding medical benefit related to the underlying HBV infection.

Similarly, our Microbiome program is based on a novel therapeutic approach designed to treat disorders associated with the microbiome. To our knowledge, no companies have received regulatory approval for, or manufactured on a commercial scale, any microbiome-based therapeutics. Our microbiome therapy candidates are in nonclinical and early clinical development, and our GEMICEL® dual-targeted release capsule formulation is novel and has not yet shown to deliver successfully live bacteria in patients. The ability to deliver bacteria effectively and reliably to the GI tract is unproven, and, even if it can be proven, it may be difficult or impossible to provide the treatment economically. Because of these uncertainties, it is possible that no commercial products will be successfully developed. If we are unable to develop successfully commercial products, we will be unable to generate revenue from the sale of products or build a sustainable or profitable business.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track designation for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for FDA fast track designation. Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. In 2018, the FDA granted Fast Track designation to ABI-H0731 for the treatment of patients with chronic HBV infection. Even though we received fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast track designation does not assure ultimate approval by the FDA. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our product development program.

A breakthrough therapy designation by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the designation.

We will need additional financing to complete the development of any product candidate and fund our activities in the future.

We anticipate that we will incur operating losses for the next several years as we continue to develop our HBV product candidates and our microbiome platform as well as initiate development of any other product candidates and will require substantial funds during that time to support our operations. We expect that our current resources will provide us with sufficient capital to fund our operations for at least the next twelve months. However, we might consume our available capital before that time if, for example, we are not efficient in managing our resources or if we encounter unforeseen costs, delays or other issues or if regulatory requirements change or if clinical study timelines are accelerated. If that happens, we may need additional financing to continue the development of our HBV and Microbiome product candidates, which we might seek and receive from the public financial markets, third-party commercial partners, private placements, debt financings and/or other sources. There is no assurance that we will be able to generate sufficient revenue from our Collaboration Agreement with Allergan or that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If such events or other unforeseen circumstances occurred and we were unable to generate sufficient revenue or raise capital, we could be forced to delay, scale back or discontinue product development, sacrifice attractive business opportunities, cease operations entirely and sell or otherwise transfer all or substantially all of our remaining assets.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

In addition, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If another prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or our ability to raise capital through the public financial markets, either of which could have a material adverse effect on our business.

We are substantially dependent on our Collaboration Agreement with Allergan, which may be terminated or may not be successful due to a number of factors, which could have a material adverse effect on our business and operating results.

In January 2017, we entered into the Collaboration Agreement for the development and commercialization of select microbiome gastrointestinal programs in ulcerative colitis, Crohn's disease and irritable bowel syndromes. Our collaboration with Allergan may be terminated, or may not be successful, due to a number of factors. In particular, Allergan may terminate the Collaboration Agreement for convenience at any time upon either 90 days' (prior to the initiation of the first proof of concept (POC) trial of a licensed product) or 120 days' (after the initiation of the first POC trial of a licensed product), as applicable, advance written notice to us. The Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the Collaboration Agreement, subject to cure. In addition, if we are unable to identify product candidates for the licensed indications or we are unable to protect our products by obtaining and defending patents, the collaboration could fail. If the collaboration is unsuccessful for these or other reasons, or is otherwise terminated for any reason, we may not receive all or any of the research program funding, milestone payments or royalties under the agreement. Any of the foregoing could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

We are dependent on a license relationship for each of our HBV-cure program and our Microbiome program.

Our license agreement with Indiana University Research and Technology Corporation (IURTC) from whom we have licensed ABI-H0731 and certain other HBV therapies, requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to ABI-H0731 and certain other HBV therapies. The aggregate amount of all performance milestone payments under the IURTC License Agreement, should all performance milestones through development be met, is $825,000, with a portion related to the first performance milestone having been paid. We also are obligated to pay IURTC royalty payments based on net sales of the licensed technology. We are also obligated to pay diligence maintenance fees ($75,000 to $100,000) each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year. Our license with Therabiome, LLC (Therabiome), from whom we have licensed our delivery platform of our Microbiome program, also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to the targeted delivery mechanism of our Microbiome program. If we fail to comply with similar obligations to any other licensor, then that licensor would have the right to terminate the license, in which event we would not be able to commercialize drug candidates or technologies that were covered by the license. In addition, the milestone and other payments associated with licenses will make it less profitable for us to develop our drug candidates than if we owned the technology ourselves.

Corporate and academic collaborators might take actions to delay, prevent, or undermine the success of our product candidates.

Our operating and financial strategy for the development, nonclinical and clinical testing, manufacture, and commercialization of drug candidates heavily depends on collaborating with corporations, academic institutions, licensors, licensees, and other parties. However, there can be no assurance that we will successfully establish or maintain these collaborations. In addition, should a collaboration be terminated, replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration is not successful, we might require substantially greater capital to undertake development and marketing of our proposed products and might not be able to develop and market these products effectively, if at all. In addition, a lack of development and marketing collaborations might lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

We rely on data provided by our collaborators and others that has not been independently verified and could prove to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, investigators and collaborators to provide us with significant data and other information related to our projects, nonclinical studies and clinical studies, and our business. If these third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

Research, development and commercialization goals may not be achieved in the timeframes that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expectations, regarding the timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, without limitation, the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the clinical development and regulatory approval process. As a result, there can be no assurance that we or any collaborators will initiate or complete clinical development activities, make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones as planned, our business could be materially adversely affected, and the price of our common stock could decline.

We lack suitable facilities for certain nonclinical and clinical testing and expect to rely on third parties to conduct some of our research and nonclinical testing and our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such research, testing or trials.

We do not have sufficient facilities to conduct all of our anticipated nonclinical and clinical testing. As a result, we expect to contract with third parties to conduct a significant portion of our nonclinical and clinical testing required for regulatory approval for our product candidates. We will be reliant on the services of third parties to conduct studies on our behalf. If we are unable to retain or continue with third parties for these purposes on acceptable terms, we may be unable to develop successfully our product candidates. In addition, any failures by third parties to perform adequately their responsibilities may delay the submission of our product candidates for regulatory approval, which would impair our financial condition and business prospects.

Our reliance on these third parties for research and development activities also reduces 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, including, in the case of clinical studies, good clinical practices, and our reliance on third parties does not relieve us of our regulatory responsibilities. Furthermore, these third parties 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 and nonclinical 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 research, nonclinical studies or clinical studies may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. As a result, our results of operations and business prospects would be harmed, our costs could increase and our ability to generate revenues from the sale of products could be delayed.

We will need to either establish our own clinical and commercial manufacturing capabilities or rely on third parties to formulate and manufacture our product candidates, and we rely on third parties to manufacture products that we study in combination with our product candidates. Our use of third parties to manufacture these materials may increase the risk that we will not have sufficient quantities of our product candidates or other products, or necessary quantities of such materials on time or at an acceptable cost.

We currently rely on third-party manufacturers to supply the quantities of ABI-H0731, ABI-H2158 and ABI-H3733 used in our clinical and nonclinical studies and the drug substance for our Microbiome program. We currently manufacture our microbiome drug product for use in our planned nonclinical studies and early-stage clinical studies; however, we may require third-party manufacturers for subsequent clinical studies or other microbiome drug products. In addition, if any product candidate we might develop or acquire in the future receives FDA or other regulatory approval, we will need to either manufacture commercial quantities of the product on our own or rely on one or more third-party contractors to manufacture our products. The establishment of internal manufacturing capabilities is difficult and costly, and we may not be successful in doing so. If, for any reason, we are unable to establish our own manufacturing capabilities and we are unable to rely on any third-party sources we have identified to manufacture our product candidates, either for clinical studies or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds, drug substance and drug products for nonclinical, clinical and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity either on our own or through third parties, the development and sales of our products and our financial performance will be materially and adversely affected.

In addition, before we or any of our collaborators can begin to commercially manufacture our product candidates, each manufacturing facility and process is subject to regulatory review. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's cGMPs and applicable non-U.S. regulatory requirements. The cGMP requirements govern compliance and documentation policies and procedures. Complying with cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and compliance to assure that the product meets applicable specifications and other requirements. Any manufacturing facility must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection might significantly delay FDA approval of our product candidates. If we or any of our future collaborators fails to comply with these requirements with respect to the manufacture of any of our product candidates, regulatory action could limit the jurisdictions in which we are permitted to sell our products, if approved. As a result, our business, financial condition, and results of operations might be materially harmed.

We are exposed to the following risks with respect to the manufacture of our product candidates:

- If we are unable to establish our own manufacturing capabilities, we will need to identify manufacturers for commercial supply on acceptable terms, which we may not be able to do because the number of potential manufacturers is limited, and the FDA must approve any new or replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- We or any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and, if approved, commercial needs in a timely manner.

- Any third-party manufacturers with whom we contract might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical studies or to produce, store and successfully distribute our products.

- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. Any internal manufacturing facilities we establish may fail to comply, and we would not have complete control over any third-party manufacturers' compliance, with these regulations and requirements.

- We may be required to obtain additional intellectual property rights from third parties in order to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors.

- We may be required to share our trade secrets and know-how with third parties, thereby risking the misappropriation or disclosure of our intellectual property by or to third parties.

- If we contract with third-party manufacturers, we might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

Each of these risks could delay our development efforts, nonclinical studies and clinical studies or the approval, if any, of our product candidates by the FDA or applicable non-U.S. regulatory authorities or the commercialization of our product candidates and could result in higher costs or deprive us of potential product revenues. As a result, our business, financial condition, and results of operations might be materially harmed.

If we or our collaborators cannot compete successfully for market share against other companies, we might not achieve sufficient product revenues and our business will suffer.

If our product candidates receive approval from the FDA or applicable non-U.S. regulatory authorities, they will compete with a number of existing and future drugs and biologics developed, manufactured and marketed by others. Existing or future competing drugs might provide greater therapeutic convenience or clinical or other benefits for a specific indication than our product candidates or might offer comparable performance at a lower cost. If our product candidates fail to capture and maintain market share, we might not achieve sufficient product revenues and our business will suffer.

We might compete against fully integrated pharmaceutical or biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking nonclinical testing and human clinical studies;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

We may not have or be able to obtain the same resources and experience as our competitors. If we are unable to perform these tasks effectively and efficiently, our results of operations might be materially adversely affected.

Developments by competitors might render our product candidates or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. In addition, the clinical and commercial landscape for HBV, ulcerative colitis (UC), inflammatory bowel disease (IBD), including Crohn's disease, irritable bowel syndrome (IBS), nonalcoholic steatohepatitis disease (NASH) and immuno-oncology is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We will compete with organizations that have existing treatments and that are or will be developing treatments for the indications that our product candidates target. If our competitors develop effective treatments for HBV, UC, IBD, IBS, NASH and immuno-oncology or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects might be materially harmed, due to intense competition in these markets.

Companies with microbiome products or core inhibitor products may produce negative clinical data which will adversely affect public perception of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Negative data from clinical trials using microbiome-based therapies (e.g., fecal transplant) or core inhibitors could negatively impact the perception of the therapeutic use of our microbiome or HBV-cure product candidates. This could negatively impact our ability to enroll patients in clinical trials. The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of the use of oral live microbial biotherapeutic products (LBPs) and core inhibitor product candidates. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of LBPs or core inhibitor product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing microbiome therapies or core inhibitor therapies, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products.

Our product candidates under development in our Microbiome program will be subject to regulation as biologics. These candidates, and any other future product candidates for which we or our collaborators intend to seek approval as biologic products, may face competition sooner than anticipated.

The Affordable Care Act (ACA) includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if product candidates from our Microbiome program are approved as biological products under a BLA, they should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If we or our collaborators are not able to develop collaborative marketing relationships with licensees or partners, or create effective internal sales, marketing, and distribution capability, we might be unable to market our products successfully.

To market our product candidates, if approved, we will have to establish our own marketing and sales force or out-license our product candidates to, or collaborate with, larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will be able to successfully establish our own marketing capabilities or establish marketing, sales, or distribution relationships with third parties; that such relationships, if established, will be successful; or that we will be successful in gaining market acceptance for our product candidates. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold our products directly, and any revenues we receive will depend upon the efforts of such third parties. If we are unable to establish such third-party sales and marketing relationships, or choose not to do so, we will have to establish our own in-house capabilities. We, as a company, have no experience in marketing or selling pharmaceutical products and currently have no sales, marketing, or distribution infrastructure. To market any of our products directly, we would need to develop a marketing, sales, and distribution force that both has technical expertise and the ability to support a distribution capability. To establish our own marketing, sales, and distribution capacity would significantly increase our costs, and require substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we might not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. There can be no assurance that we will be able to establish internal marketing, sales, or distribution capabilities.

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

The commercial success of our products, if approved for marketing, will depend in part on the medical community, patients and third-party payors accepting our product candidates as effective and safe. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our products, if approved for marketing, will depend on a number of factors, including:

- the actual or perceived safety and efficacy of the products, and advantages over alternative treatments;
- the pricing and cost-effectiveness of our products relative to competing products or therapies, including generic drugs or biosimilars, if available;
- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the emergence, and timing of market introduction, of competitive products;
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- the availability of third-party insurance coverage or governmental reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in nonclinical studies and clinical studies, market acceptance of the product will not be known until after it is launched. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other significant personnel or experience increases in our compensation costs, our business might materially suffer.

We are highly dependent on the services of our executive officers and senior management team. Our employment agreements with our executive officers and senior management team members do not ensure their retention.

Furthermore, our future success also depends, in part, on our ability to identify, hire, and retain additional management team members as our operations grow and our ability to replace our management team members in the event any leave us for any reason. We expect to experience intense competition for qualified personnel and might be unable to attract and retain the personnel necessary for the development of our business. Finally, we do not currently maintain, nor do we intend to obtain in the future, “key man” life insurance that would compensate us in the event of the death or disability of any of the members of our management team.

The failure by us to retain, attract and motivate executives and other key employees could have a material adverse impact on our business, financial condition and results of operations.

If we are unable to hire additional qualified personnel, our ability to grow our business might be harmed.

As of March 31, 2019, we had 103 employees and contracts with a number of temporary contractors, consultants and contract research organizations. We will need to hire or contract with additional qualified personnel with expertise in clinical research and testing, formulation and manufacturing and sales and marketing to commercialize our HBV drug candidates and our microbiome biotherapeutic candidates or any other product candidate we may seek to develop. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent this data from being compromised, and we rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyberterrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state and non-U.S. privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Clinical Health Act of 2009 (HITECH), and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission, state breach notification law and the European Union's General Data Protection Regulation (GDPR). We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

We might not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our current and future management and other administrative and operational resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We might seek to develop our business through acquisitions of or investment in new or complementary businesses, products or technologies, and the failure to manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

- assimilating the purchased technologies, products or business operations;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;

- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory requirements; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business or retain key personnel, suppliers or collaborators.

Our ability to develop successfully our business through acquisitions would depend on our ability to identify, negotiate, complete and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to integrate efficiently any acquired business, technology or product into our business, our business and financial condition might be adversely affected.

Risks Related to Our Regulatory and Legal Environment

We are and will be subject to extensive and costly government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. Both before and after approval of any product, we and our collaborators, suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning or untitled letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; voluntary product recall; product seizure; interruption of manufacturing or clinical studies; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; exclusion from federal health care programs such as Medicare and Medicaid; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation might be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our product candidates. The regulatory review and approval process, which includes nonclinical testing and clinical studies of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical studies and approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive nonclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy for each intended use. The development and approval process might take many years, requires substantial resources, and might never lead to the approval of a product.

Even if we or our collaborators are able to obtain regulatory approval for a particular product, the approval might limit the intended medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, might require further regulatory review and approval. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal by a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; untitled letters or warning letters; fines; import and export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

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

We, or any current or future collaborators, cannot assure you that we will receive the approvals necessary to commercialize for sale any of our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the applicable regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA, in the case of our HBV-cure program, or a BLA, in the case of our product candidates in our Microbiome program, demonstrating that the product candidate is safe for humans and effective for its intended use (for biological products, this standard is referred to as safe, pure and potent). This demonstration requires significant research, nonclinical studies, and clinical studies. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs or biological products that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the approval process and might require us to conduct additional nonclinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any approval we obtain.

The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs or BLAs. We cannot be sure that we will ever obtain regulatory approval for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate could be developed or obtained. There is no guarantee that we will ever be able to develop an existing, or acquire another, product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any product candidates. The risks associated with foreign regulatory approval processes are similar to the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

Even if our product candidates are approved, we and our collaborators will be subject to extensive post-approval regulation, including ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, our product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any 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.

Once a product candidate is approved, numerous post-approval requirements apply. Among other things, we and our collaborators will be subject to requirements regarding testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. The holder of an approved NDA or BLA is subject to ongoing FDA oversight, monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA or BLA. Application holders must submit new or supplemental applications and obtain FDA approval for changes to the approved product, product labeling, or manufacturing process, depending on the nature of the change. Application holders also must submit advertising and other promotional material to the FDA and report on ongoing clinical studies. The FDA also has the authority to require changes in the labeling of approved drug products and to require post-marketing studies. The FDA can also impose distribution and use restrictions under a REMS.

Advertising and promotional materials must comply with FDA rules in addition to other applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's cGMP requirements. Sales, marketing, and scientific/educational grant programs, among other activities, must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We 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 current administration may impact our business and industry. Namely, the current 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, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, an Executive Order was issued directing all executive agencies, including the FDA, that, for each notice of proposed rulemaking or final regulation to be issued in fiscal years 2018 and beyond, the agencies must identify regulations to offset any incremental cost of a new regulation. On September 8, 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified in compliance with these Executive Orders. 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 restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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.

Even if we or our collaborators are able to commercialize any product candidates, those products may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize successfully any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to obtain promptly coverage and profitable payment rates from both government-funded and private payors for any approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

In the United States and in other countries, there have been, and we expect there will continue to be, a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the Affordable Care Act and its amendment, the Health Care and Education Reconciliation Act (the ACA).

Among the provisions of the ACA of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologics;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of 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 (which was increased to 70% as of January 1, 2019 under the Bipartisan Budget Act of 2018 (BBA));
- 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 Act 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.

Since its enactment, there have been many judicial, Presidential, and Congressional challenges to numerous aspects of the ACA. In 2012, the U.S. Supreme Court heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, as a result of tax reform legislation passed in late December 2017, the individual mandate has been eliminated. The long ranging effects of the elimination of the individual mandate on the viability of the ACA are unknown at this time.

On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, Centers for Medicare & Medicaid Services has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. The Tax Cuts and Jobs Act of 2017 (the Tax Act) includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. The Texas District Court Judge, as well as the Trump Administration and the Centers for Medicare & Medicaid Services (CMS), have stated that the ruling will have no immediate effect, and on December 30, 2018, the Texas District Court Judge issued an order staying the judgment pending appeal. It is unclear what effects this decision, subsequent appeals of this decision, and other efforts to repeal and replace the ACA will have. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device exercise tax on nonexempt medical devices. Further, the BBA, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS announced that it is suspending further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. The full impact of the ACA, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, 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 laws may result in additional reductions in Medicare and other healthcare funding. Further, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues from the sale of products, and to achieve and maintain profitability.

We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, and health information privacy and security laws, which could expose us or them to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the U.S. federal Food, Drug and Cosmetic Act (FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices, and the Public Health Service Act (PHSA), which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

In addition, regulators globally are also imposing greater monetary fines for privacy violations. The GDPR, which went into effect on May 25, 2018, applies to any company established in the European Union (EU) as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Noncompliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. Compliance with the GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of developing our products and services or even prevent us from offering certain products in jurisdictions that we may operate in.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. 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 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, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business with are 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, which may also adversely affect our business.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to refine our disclosure controls and other procedures that are designed to ensure that the information that we are required to disclose in the reports that we will file with the SEC is properly recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are also continuing to improve our internal control over financial reporting. We have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting.

Our current controls and any new controls that we develop in the future may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will be required to include in our periodic reports that will be filed with the SEC. If we were to have ineffective disclosure controls and procedures or internal control over financial reporting, our investors could lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

We face the risk of product liability claims and might not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs and biotherapeutics. If the use of one or more of our product candidates or approved drugs, if any, harms people, we might be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability/clinical study insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we maintain might not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include product liability insurance covering the sale of commercial products if we obtain marketing approval for our drug candidates in development, but we might be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products, our liability could exceed our total assets and our ability to pay the liability. Any successful product liability claims or series of claims brought against us would decrease our cash and could cause the value of our common stock to decrease.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures, and those of our contractors, for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations. We currently do not carry hazardous materials liability insurance. We intend to obtain such insurance in the future, if necessary, but cannot give assurance that we could obtain such coverage.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct, including intentional failure to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;

- comply with the United States Foreign Corrupt Practices Act (the FCPA), the U.K. Bribery Act 2010, the PRC Criminal Law, the PRC Anti-unfair Competition Law and other anti-bribery laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical studies, creating fraudulent data in our nonclinical studies or clinical studies or illegal misappropriation of product materials, which could result in regulatory sanctions, delays in clinical studies, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees (the Code of Conduct), but it is not always possible to identify and deter employee misconduct. 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws). We can face serious consequences for violations.

Among other matters, Trade Laws prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities, particularly in China, to increase in time. We engage third parties for clinical studies and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We have international operations, including in China, and conduct clinical studies outside of the United States. A number of risks associated with international operations could materially and adversely affect our business.

We expect to be subject to a number of risks related with our international operations, many of which may be beyond our control. These risks include:

- different regulatory requirements for drug approvals in foreign countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- different reimbursement systems and different competitive drugs indicated to treat the indication for which our product candidates are being developed;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- compliance with the FCPA and other anti-corruption and anti-bribery laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations and compliance with foreign currency exchange rules, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including tariffs, war and terrorism, or natural disasters.

The results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." This referendum has created political and economic uncertainty, particularly in the UK and the EU, and this uncertainty may persist for years. A withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the UK and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. The UK's vote to exit the EU could also result in similar referendums or votes in other European countries in which we do business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us.

For example, Brexit could result in the UK or the EU significantly altering its regulations affecting the clearance or approval of our product candidates that are developed in the UK. Any new regulations could add time and expense to the conduct of our business, as well as the process by which our products receive regulatory approval in the UK, the EU and elsewhere. In addition, the announcement of Brexit and the withdrawal of the UK from the EU have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity and financial condition.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

If we and our licensors, IURTC and Therabiome, do not obtain protection for our respective intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and chemical and biological compositions that are important to our business. To date, we and our licensors have filed patent applications intended to cover our products candidates and their methods of use. Although we have an issued patent in the U.S. directed to compositions of matter that includes ABI-H0731, which is expected to expire in 2035, and we have an in-licensed issued U.S. patent related to delivery technology for our Microbiome program, which is expected to expire in 2034, we do not own or have any rights to any issued patents that cover any of our other product candidates, and we cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary product candidates and technologies. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute 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.

The patent process also is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- Any patent rights, if obtained, might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful; and
- Countries other than the United States might have patent laws that provide less protection than those governing U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the U.S. Patent and Trademark Office (the USPTO) and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections, if obtained, will prove inadequate. Our business and prospects will be harmed if we fail to obtain these protections or they prove insufficient.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates and technologies through intellectual property license agreements with third parties, including IURTC and Therabiome. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under our license agreements, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. There is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

We rely on trade secret protections through confidentiality agreements with our employees, collaborators and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality, invention, and nondisclosure agreements with our employees, scientific advisors, consultants, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

If our employees or consultants breach their confidentiality obligations, to be able to enforce these confidentiality provisions, we would need to know of the breach and have sufficient funds to enforce the provisions. We cannot assure you that we would know of or be able to afford enforcement of any breach. In addition, such provisions are subject to state law and interpretation by courts, which could limit the scope and duration of these provisions. Any limitation on or non-enforcement of these confidentiality provisions could have an adverse effect on our business.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of any product candidates that we develop will not infringe third-party patents.

A third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. Patent litigation is costly and time consuming. We may not have sufficient resources to address these actions, and such actions could affect our results of operations and divert the attention of managerial and scientific personnel.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property, unless that third party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue development, manufacture or sale of our products. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual position allow us to do so. Any disclosure to or misappropriation by third parties of our trade secrets or confidential information could compromise our competitive position. Moreover, we may in the future be involved in legal or administrative proceedings involving our intellectual property initiated by third parties, and which proceedings can result in significant costs and commitment of management time and attention. As our product candidates continue in development, third parties may attempt to challenge the validity and enforceability of our patents and proprietary information and technologies.

We may in the future be involved in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. These proceedings can result in significant costs and commitment of management time and attention, and there can be no assurance that our efforts would be successful in preventing or limiting the ability of our competitors to market competing products.

Composition-of-matter patents relating to the active pharmaceutical ingredient (API) are generally considered to be the strongest form of intellectual property protection for pharmaceutical products. Such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s), and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions and can be uncertain. Any patent applications that we own or license may fail to result in issued patents. Even if patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, competitors with significantly greater resources could threaten our ability to commercialize our product candidates. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the United States and other countries are typically not published until 18 months after filing, and in some cases are never published. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that we or our licensors were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the United States, the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The United States moved to a “first to file” system under the Leahy-Smith America Invents Act (AIA), effective March 16, 2013. The effects of this change and other elements of the AIA are currently unclear, as the USPTO is still implementing associated regulations, and the applicability of the AIA and associated regulations to our patents and patent applications have not been fully determined. This new system also includes new procedures for challenging issued patents and pending patent applications, which creates additional uncertainty. We may become involved in any variety of proceedings challenging our patents and patent applications or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of, invalidate, and/or find our patent rights unenforceable, allowing third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others. In addition to ongoing changes with the AIA and USPTO regulations, recent decisions of the Supreme Court of the United States, and the possibility of statutory change to patent subject matter eligibility law advocated by such groups as the Intellectual Property Owners Association and the American Intellectual Property Law Association, provide additional uncertainty.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries, in particular China, where we anticipate increasing our activity and commercializing our product candidates, do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third-party contractors to develop and manufacture our product candidates is based upon agreements that limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information are disclosed or used, even if unintentionally, in violation of these agreements. In the highly competitive markets in which our product candidates are expected to compete, protecting our trade secrets, including our strategies for addressing competing products, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations.

In addition, some of our collaboration partners are larger, more complex organizations than ours, and the risk of inadvertent disclosure of our proprietary information may be increased despite their internal procedures and contractual obligations in place with our collaboration partners. Despite our efforts to protect our trade secrets and other confidential information, a competitor's discovery of such trade secrets and information could impair our competitive position and have an adverse impact on our business.

We are developing an extensive worldwide patent portfolio. The cost of maintaining our patent protection is high and maintaining our patent protection requires continuous review and compliance in order to maintain worldwide patent protection. We may not be able to maintain effectively our intellectual property position throughout the major markets of the world.

The USPTO and foreign patent authorities require maintenance fees and payments as well as continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing costs and the potential protection afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries throughout the world, or from selling or importing products made using our inventions in and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the United States, and we may encounter significant problems in securing and defending our intellectual property rights outside the United States

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly countries such as China, do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights. In China, our intended establishment of significant operations will depend in substantial part on our ability to enforce effectively our intellectual property rights in that country. Proceedings to enforce our intellectual property rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business and could put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted and could provoke third parties to assert claims against us. We may not prevail in all legal or other proceedings that we may initiate and, if we were to prevail, 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 develop or license.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

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

- Others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.

- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.

- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.

- The prosecution of our pending patent applications may not result in granted patents.

- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.

- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

The existence of counterfeit pharmaceutical products in pharmaceutical markets may damage our brand and reputation and have a material adverse effect on our business, operations and prospects.

Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, counterfeit products could be used in nonclinical studies or clinical studies or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Our Common Stock

We might not be able to maintain the listing of our common stock on the Nasdaq Global Select Market.

Our common stock is listed on the Nasdaq Global Select Market under the symbol “ASMB.” We might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the “pink sheets” maintained by OTC Markets Group Inc. These alternative markets are generally considered to be markets that are less efficient and less broad than the Nasdaq Global Select Market. A delisting of our common stock from the Nasdaq Global Select Market and our inability to list the stock on another national securities exchange could negatively impact us by: (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets and (iv) impairing our ability to provide equity incentives to our employees.

The price of our common stock might fluctuate significantly, and you could lose all or part of your investment.

Since our merger with Assembly Pharmaceuticals on July 11, 2014 through March 31, 2019, the closing price of our common stock has fluctuated between $4.54 and $64.16. Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock might be volatile and subject to wide price fluctuations in response to various factors, including:

- the progress, results and timing of our clinical studies and nonclinical studies and other studies involving our product candidates;
- success or failure of our product candidates;
- the receipt or loss of required regulatory approvals for our product candidates;
- availability of capital;
- future issuances by us of our common stock or securities exercisable for or convertible into common stock;
- sale of shares of our common stock by our significant stockholders or members of our management;
- additions or departures of key personnel;
- investor perceptions of us and the pharmaceutical industry;
- issuance of new or changed securities analysts' reports or recommendations, or the announcement of any changes to our credit rating;
- introduction of new products or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- threatened or actual litigation and government investigations;
- legislative, political or regulatory developments;
- the overall performance of the equity markets;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- general economic conditions;
- changes in interest rates; and
- changes in accounting standards, policies, guidance, interpretations or principles.

These and other factors might cause the market price of our common stock to fluctuate substantially, which might limit or prevent investors from readily selling their shares of our common stock and might otherwise negatively affect the liquidity of our common stock. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce our share price.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2019, our executive officers and directors owned approximately 6.3% of our outstanding voting common stock, and this group together with other stockholders holding beneficially 5% of more of our outstanding voting common stock, owned approximately 41.9% of our outstanding voting common stock. Therefore, these stockholders, if acting together, have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of certain significant matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Our ability to use our net operating loss and credit carryforwards to offset future taxable income may be subject to certain limitations.

At December 31, 2018, we had potentially utilizable gross Federal net operating loss carryforwards of approximately $209.2 million, State net operating loss carryforwards of approximately $209.0 million, Federal and California research and development credit carryforwards of approximately $3.6 million and $2.4 million, respectively, all of which expire between 2027 and 2038. Our ability to utilize our net operating loss and credit carryforwards is dependent upon our ability to generate taxable income in future periods and may be limited due to restrictions imposed on utilization of net operating loss and credit carryforwards under federal and state laws upon a change in ownership.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ownership change,” is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year period (calculated on a rolling basis). We have determined that an ownership change occurred in each of December 2010, January 2013 and October 2014. The result of these ownership changes is that approximately $40.0 million of our approximately $153.2 million of net operating losses will not be available to us to offset future taxable income. In addition, we may experience ownership changes in the future, some of which are outside our control. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits. Limitations on our ability to utilize our net operating losses to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Because U.S. federal net operating losses incurred in taxable periods beginning before January 1, 2018 generally may be carried forward for up to 20 years, the annual limitation may effectively provide a cap on the cumulative amount of pre-ownership change losses, including certain recognized built-in losses that may be utilized. Such pre-ownership change losses in excess of the cap may be lost. In addition, if an ownership change were to occur, it is possible that the limitations imposed on our ability to use pre-ownership change losses and certain recognized built-in losses could cause a net increase in our U.S. federal income tax liability and require U.S. federal income taxes to be paid earlier than otherwise would be paid if such limitations were not in effect. Further, if for financial reporting purposes the amount or value of these deferred tax assets is reduced, such reduction would have a negative impact on the book value of our common stock.

In addition, under the Tax Act, the amount of U.S. federal net operating losses generated in taxable periods beginning after December 31, 2017 that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The Tax Act generally eliminates the ability to carry back any post-2017 NOL to prior taxable years, while allowing unused post-2017 NOLs to be carried forward indefinitely. There is a risk that due to ownership changes, changes in law or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

We do not intend to pay dividends for the foreseeable future and our stock may not appreciate in value.

We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in shares of our common stock will depend upon any future appreciation in its value. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

The requirements of being a public company add to our operating costs and might strain our resources and distract our management.

As a public company, we face increased legal, accounting, administrative and other costs and expenses not faced by private companies. We are subject to the reporting requirements of the Exchange Act, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act, and the listing standards of the Nasdaq Global Select Market, each of which imposes additional reporting and other obligations on public companies. Although we are currently unable to estimate these costs with any degree of certainty, we expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly and place significant strain on our personnel, systems and resources. These increased costs will require us to divert a significant amount of money that we could otherwise use to develop our product candidates or otherwise expand our business. Complying with these requirements might divert management’s attention from other business concerns, which could have a material adverse effect on our prospects, business, and financial condition. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Several provisions of the Delaware General Corporation Law and our charter documents could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our securities.

Several provisions of the Delaware General Corporation Law and our charter documents could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our securities could be reduced as a result. These provisions may include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholders' approval;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;
- prohibiting shareholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

If securities analysts downgrade our stock or cease coverage of us, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. Currently, a limited number of financial analysts publish reports about us and our business. We do not control these analysts or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If any analyst who covers us downgrades our stock, our stock price would likely decline rapidly. If one or more analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On April 22, 2019, the Company reported that Uri A. Lopatin, Chief Medical Officer, will transition to a clinical and scientific advisor role effective as of the close of business on May 6, 2019 (the "Separation Date"). On May 6, 2019, Dr. Lopatin and the Company entered into (1) a Separation Agreement and General Release of Claims (the "Separation Agreement"), and (2) a Consulting Agreement (the "Consulting Agreement"). The Separation Agreement will be effective on the eighth day following execution if not revoked and the Consulting Agreement will be effective as of May 7, 2019.

Under the terms of the Separation Agreement and consistent with the terms of Dr. Lopatin's employment agreement, except to the extent modified by the Separation Agreement, upon the Separation Agreement becoming effective, Dr. Lopatin is entitled to receive the following benefits: (1) a lump sum payment equal to twelve months of his final base salary for an aggregate amount of $410,000; (2) immediate vesting of all equity awards that would have vested within six months following the Separation Date; (3) with respect to those stock options granted prior to 2018 that were vested on the Separation Date, the extension of the post-termination exercise period for all such vested stock options until term; (4) with respect to those stock options granted in 2018 that are vested on the Separation Date or vest during the term of the Consulting Agreement, the extension of the post-termination exercise period for all such vested stock options until the later of the first anniversary of the termination date and 90 days following the termination of Dr. Lopatin's continuous service to the Company, but not later than the expiration date of the options; (5) to the extent unvested as of the effective date of the Consulting Agreement, each of Dr. Lopatin's outstanding equity awards shall be modified to provide that upon the termination of his continuous service to the Company for any reason other than for Cause within 6 months following the occurrence of a Corporate Transaction (as defined in the applicable stock incentive plan), all unvested equity awards shall immediately vest; and (6) if Dr. Lopatin properly elects COBRA, the Company's payment of Dr. Lopatin's COBRA premiums for 18 months following the Separation Date or until Dr. Lopatin becomes eligible to receive benefits under another employer's health insurance. For purposes of vesting and post-termination exercise period for options, Dr. Lopatin will be deemed to be in "continuous service" while he is performing services under the Consulting Agreement.

Under the Consulting Agreement, Dr. Lopatin will provide consulting services as a clinical and scientific advisor until December 31, 2020 and will serve as interim chief medical officer through July 31, 2019, unless earlier terminated by either party upon 90 days' written notice or without notice for cause or refusal or inability to perform the services, including by reason of death or disability. As a consultant to the Company, Dr. Lopatin will receive $26,000 per month (prorated for any partial month) through July 31, 2019 and $8,600 per month (prorated for any partial month) for the remainder of the Consulting Agreement's term. If Dr. Lopatin's consultant service hours in any month exceed that month's anticipated number of consultant service hours by more than 10%, then Dr. Lopatin is entitled to assess additional fees of $220 per service hour or $110 per hour of travel outside of the San Francisco Bay Area.

The descriptions of the Separation Agreement and Consulting Agreement contained herein do not purport to be complete and are qualified in their entirety by reference to the complete text of the Separation Agreement and Consulting Agreement, which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019.

Item 6. Exhibits

(a) *Exhibits.* The following exhibits are filed as part of this quarterly report on Form 10-Q:

Exhibit Number	Description of Document	Filed Herewith	Incorporated by Reference from	Date	Number
31.1	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	Financials in XBRL format.	X			

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Assembly Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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

Assembly Biosciences, Inc.

Date: May 9, 2019

By: /s/ Derek A. Small
Derek A. Small
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Date: May 9, 2019

By: /s/ Michael P. Samar
Michael P. Samar
Vice President, Finance and Business Operations
(Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Derek A. Small, certify that:

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

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

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

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

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

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

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

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

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

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

Date: May 9, 2019

By: /s/ Derek A. Small
Derek A. Small
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial 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 on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended March 31, 2019 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Derek A. Small, Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to 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 results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Derek A. Small
Derek A. Small
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Date: May 9, 2019