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, 2018

OR

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

For the transition period from _____to_____.

Commission file number: 001-35005

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)

(317) 210-9311
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐ (Do not check if smaller reporting company)	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 ☒

As of May 2, 2018, there were 20,550,718 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

	March 31, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 66,926,630	$ 82,033,209
Marketable securities, at fair value	42,232,348	37,914,482
Accounts receivable from collaboration	2,263,556	2,273,421
Prepaid expenses and other current assets	1,803,066	897,400
Total current assets	113,225,600	123,118,512
Long-term assets		
Marketable securities, at fair value	-	3,347,213
Property, plant and equipment, net	731,500	860,026
Security deposits	425,592	339,558
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	42,795,228	46,184,933
Total assets	**$ 156,020,828**	**$ 169,303,445**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,372,874	$ 2,123,939
Accrued expenses	4,647,472	6,139,000
Deferred revenue - short-term	5,159,587	5,229,227
Total current liabilities	12,179,933	13,492,166
Long-term liabilities		
Deferred tax liabilities	2,135,802	2,135,802
Deferred revenue - long-term	39,323,844	40,555,708
Total long-term liabilities	41,459,646	42,691,510
Total liabilities	**53,639,579**	**56,183,676**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 50,000,000 shares authorized; 20,386,736 and 20,137,974 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	20,387	20,138
Additional paid-in capital	370,104,986	364,528,037
Accumulated other comprehensive loss	(459,350)	(392,391)
Accumulated deficit	(267,284,774)	(251,036,015)
Total stockholders' equity	102,381,249	113,119,769
Total liabilities and stockholders' equity	**$ 156,020,828**	**$ 169,303,445**

See Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended March 31,	
	2018	**2017**
Collaboration revenue	$ 3,565,060	$ 684,369
Operating expenses:		
Research and development	14,541,174	10,573,739
General and administrative	5,696,035	4,040,459
Total operating expenses	20,237,209	14,614,198
Loss from operations	**(16,672,149)**	**(13,929,829)**
Other income (expenses)		
Interest and other income	446,406	136,484
Realized loss from marketable securities	(23,016)	(137,248)
Total other income (expense)	423,390	(764)
Net loss	**$ (16,248,759)**	**$ (13,930,593)**
Other comprehensive (loss) income		
Unrealized loss recognized in accumulated other comprehensive loss before reclassification	(89,975)	(61,156)
Reclassification adjustment of unrealized loss included in net loss	23,016	137,248
Comprehensive loss	**$ (16,315,718)**	**$ (13,854,501)**
Net loss per share, basic and diluted	$ (0.80)	$ (0.81)
Weighted average common shares outstanding, basic and diluted	20,231,804	17,268,280

See Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Three Months Ended March 31,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (16,248,759)	$ (13,930,593)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	168,086	31,916
Stock-based compensation	4,082,767	1,224,647
Realized loss from marketable securities	23,016	137,248
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	9,865	-
Prepaid expenses and other current assets	(905,666)	(687,497)
Accounts payable	248,935	(420,948)
Accrued expenses	(1,491,528)	(739,261)
Deferred revenue	(1,301,504)	49,315,631
Security deposits	(86,034)	13,766
Net cash (used in) provided by operating activities	(15,500,822)	34,944,909
Cash flows from investing activities		
Purchases of fixed assets	(39,560)	-
Purchases of marketable securities	(13,031,628)	-
Redemptions of marketable securities	11,971,000	6,658,000
Net cash (used in) provided by investing activities	(1,100,188)	6,658,000
Cash flows from financing activities		
Proceeds from the exercise of stock options	1,494,431	640,017
Net cash provided by financing activities	1,494,431	640,017
Net (decrease) increase in cash and cash equivalents	(15,106,579)	42,242,926
Cash and cash equivalents at the beginning of the period	82,033,209	28,575,085
Cash and cash equivalents at the end of the period	**$ 66,926,630**	**$ 70,818,011**
Supplemental disclosure of cash flow information:		
Change in unrealized (loss) gain on marketable securities available-for-sale	$ (66,959)	$ 76,092

See Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(UNAUDITED)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2017	**20,137,974**	**$ 20,138**	**$ 364,528,037**	**$ (392,391)**	**$ (251,036,015)**	**$ 113,119,769**
Proceeds from the exercise of stock options	248,762	249	1,494,182	-	-	1,494,431
Change in unrealized loss on marketable securities	-	-	-	(66,959)	-	(66,959)
Stock-based compensation	-	-	4,082,767	-	-	4,082,767
Net loss	-	-	-	-	(16,248,759)	(16,248,759)
Balance as of March 31, 2018	**20,386,736**	**$ 20,387**	**$ 370,104,986**	**$ (459,350)**	**$ (267,284,774)**	**$ 102,381,249**

See Notes to Condensed Consolidated Financial Statements.

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc., together with its subsidiaries (Assembly or the Company), is a clinical stage biotechnology company advancing two innovative platform programs: a new class of oral therapeutic candidates for the treatment of hepatitis B virus (HBV) infection and a novel class of oral synthetic live biotherapeutic candidates, which are designed to treat disorders associated with the microbiome.

Over 250 million people worldwide are chronically infected with HBV. 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 protein Allosteric Modifiers (CpAMs), 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 identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices (cGMP) conditions, and a 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. Using its microbiome platform, the Company is developing product candidates for various disease indications, including ulcerative colitis, Crohn's disease, irritable bowel syndrome, non-alcoholic steatohepatitis (NASH), immuno-oncology and Clostridium difficile infections (CDI), which the Company intends to develop either internally or in collaboration with partners.

On January 6, 2017, the Company entered into a Research, Development, Collaboration and License Agreement (the Collaboration Agreement) with Allergan Pharmaceuticals International Limited (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 on February 10, 2017, Allergan paid the Company an upfront payment of $50 million. Additionally, the Company is eligible to receive up to approximately $630 million in payments related to seven development milestones and up to approximately $2.15 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 (see Note 7). Allergan and the Company have agreed to share development costs up to an aggregate of $75 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, the Company has an option to co-promote the licensed programs in the United States and China, subject to certain conditions set forth in the Collaboration Agreement.

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 up-front payment related to the Collaboration Agreement. The Company has incurred losses from operations and negative cash flows from operating activities 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. 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 condensed consolidated interim financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying 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. The condensed consolidated balance sheet at March 31, 2018, condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2018 and 2017, condensed consolidated statements of cash flows for the three months ended March 31, 2018 and 2017, and condensed consolidated statement of changes in stockholders' equity for the three months ended March 31, 2018 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, that the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The results for the three months ended March 31, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018 or for any future interim period. The consolidated balance sheet at December 31, 2017 has been derived from audited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2017 and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on March 8, 2018 (the 2017 Annual Report).

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with the 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 condensed consolidated financial statements include recoverability and useful lives (indefinite or finite) of intangible assets, assessment of impairment of goodwill, provisions for income taxes, timing of revenue recognition and allocation of the transaction price to performance obligations, and the fair value of stock options and warrants granted to employees, consultants, directors, investors, licensors, placement agents and underwriters.

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 in the Company's significant accounting policies to those previously disclosed in the 2017 Annual Report other than the adoption of the Financial Accounting Standards Board (FASB) Accounting Standard Updates (ASU) 606, *Revenue from Contracts with Customers* (see Note 7).

Loss per Share of Common Stock

Basic net loss per share of common stock excludes dilution and is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock 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 result in diluted loss per share in the future that were not included in the computation of diluted loss per share at March 31, 2018 and 2017 are as follows:

	March 31,	
	2018	**2017**
Warrants to purchase common stock	15,296	16,909
Options to purchase common stock	4,826,361	4,816,126
Restricted stock units	251,559	-
Total	**5,093,216**	**4,833,035**

Revenue Recognition

The Company recognizes revenue under ASC 606, *Revenue from Contracts with Customers*. The core principle of the new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606's definition of a "distinct" good or service (or bundle of goods or services) if both of the following criteria are met:

- the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct); and
- the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts or both. When determining the transaction price, an entity must consider the effects of all of the following:

- variable consideration;
- constraining estimates of variable consideration;
- existence of a significant financing component in the contract;
- noncash consideration; and
- consideration payable to a customer.

Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis.

The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

Revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property is recognized only when (or as) the later of the following events occurs:

- the subsequent sale or usage occurs; or
- the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Adoption of Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606),* as modified by ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net),* ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, and ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*. The revenue recognition principle in ASU 2014-09 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, new and enhanced disclosures will be required. Companies may adopt the new standard either using the full retrospective approach, a modified retrospective approach with practical expedients, or a cumulative effect upon adoption approach. The Company adopted the new standard on January 1, 2018 using the modified retrospective approach. The Collaboration Agreement is the Company's only revenue contract, and adoption of ASU 2014-09 did not have any impact on the Company's accounting for this agreement in the accompanying condensed consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. On January 1, 2018, the Company implemented ASU 2016-01 without any impact on the Company's condensed consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments,* which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. On January 1, 2018, the Company implemented ASU 2016-15 without any material impact on the Company's condensed consolidated statement of cash flows and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. On January 1, 2018, the Company implemented ASU 2017-09 without any material impact on the Company's condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* which supersedes FASB Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. In January 2018, the FASB issued ASU 2018-01, *Leases (Topic 842) Land Easement Practical Expedient for Transition to Topic 842* , which amends ASU 2016-02 to provide entities an optional transition practical expedient to not evaluate under Topic 842 existing or expired land easements that were not previously accounted for as leases under the current leases guidance in Topic 842. An entity that elects this practical expedient should evaluate new or modified land easements under Topic 842 beginning at the date that the entity adopts Topic 842. The standard will be effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the effect that the updated standard will have 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*. ASU 2016-13 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 will be available on January 1, 2019. The Company is currently evaluating the effect that the updated standard will have on its condensed consolidated financial statements and related disclosures.

In February 2018, the FASB issued 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 newly enacted federal corporate income tax rate under the Tax Cuts and Jobs Act. The amount of the reclassification would be the difference between the historical corporate income tax rate and the newly enacted 21% corporate income tax rate. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2018 with early adoption in any interim period permitted. The Company is currently evaluating the effect that the updated standard will have on its condensed consolidated financial statements and related disclosures.

Note 3 - Marketable Securities

Marketable securities consist of the following as of March 31, 2018 and December 31, 2017:

	March 31, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Short-term available-for-sale securities				
Corporate bonds	$ 39,411,091	$ 3,335	$ (260,507)	$ 39,153,919
Commercial paper	2,078,212	1,657	-	2,079,869
U.S. Treasury Securities	998,672	-	(112)	998,560
Total short-term available-for-sale securities	$ 42,487,975	$ 4,992	$ (260,619)	$ 42,232,348
Total	$ 42,487,975	$ 4,992	$ (260,619)	$ 42,232,348

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gain [1]	Gross Unrealized Loss [1]	Fair Value
Short-term available-for-sale securities				
Corporate bonds	$ 38,092,585	$ 5,635	$ (183,738)	$ 37,914,482
Long-term available-for-sale securities				
Corporate bonds	3,357,778	-	(10,565)	3,347,213
Total	$ 41,450,363	$ 5,635	$ (194,303)	$ 41,261,695

(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, 2018 is less than one year.

The fair value of marketable securities was classified into fair value measurement categories as of March 31, 2018 and December 31, 2017 as follows:

	March 31, 2018	December 31, 2017
Quoted prices in active markets for identical assets (Level 1)	$ -	$ -
Quoted prices for similar assets observable in the marketplace (Level 2)	42,232,348	41,261,695
Significant unobservable inputs (Level 3)	-	-
Total	$ 42,232,348	$ 41,261,695

The fair values of marketable securities are determined using quoted market prices from daily exchange traded markets based on the closing prices as of March 31, 2018 and December 31, 2017.

There were no transfers of marketable securities between Levels 1, 2 or 3 for the three months ended March 31, 2018 and 2017.

The following table shows the Company's investments' gross unrealized losses and fair value, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at March 31, 2018.

	Less than 12 Months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate bonds	$ 35,407,491	$ (260,507)	$ 35,407,491	$ (260,507)
U.S. Treasury Securities	998,560	(112)	998,560	(112)
Total	**$ 36,406,051**	**$ (260,619)**	**$ 36,406,051**	**$ (260,619)**

The Company has determined that the unrealized losses are deemed to be temporary as of March 31, 2018. The Company believes that the unrealized losses generally are caused by increases in the risk premiums required by market participants rather than an adverse change in cash flows or a fundamental weakness in the credit quality of the issuer or underlying assets. Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, it does not consider the investment in corporate bonds to be other-than-temporarily impaired at March 31, 2018.

Note 4 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

	Useful life (Years)	March 31, 2018	December 31, 2017
Computer hardware and software	3	$ 114,683	$ 104,968
Lab equipment	3 to 5	369,827	369,827
Office equipment	7	55,199	25,354
Leasehold improvement	1 to 3.25	773,700	773,700
Total property, plant and equipment		1,313,409	1,273,849
Less: Accumulated depreciation and amortization		(581,909)	(413,823)
Property, plant and equipment, net		$ 731,500	$ 860,026

Depreciation expense for the three months ended March 31, 2018 and 2017 was $168,086 and $31,916, respectively, and was recorded in both research and development expense and general and administrative expense in the condensed consolidated statements of operations.

Note 5 - Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2018	December 31, 2017
Accrued expenses:		
Salaries, bonuses and employee benefits	$ 1,307,440	$ 4,518,128
Research and development expenses	2,310,505	674,686
General and administrative expenses	1,029,527	946,186
Total accrued expenses	$ 4,647,472	$ 6,139,000

Note 6 - Stockholders' Equity

Common Stock

For the three months ended March 31, 2018, the Company issued an aggregate of 248,762 shares of common stock, and received gross proceeds of approximately $1.5 million from the exercise of options.

Preferred Stock

On January 24, 2018, the Board authorized the filing of a Certificate of Elimination with the Secretary of State of the State of Delaware to remove the Certificate of Designation of Series A Non-Voting Convertible Preferred Stock (the Series A Preferred Stock) from the Company's Third Amended and Restated Certificate of Incorporation, as amended, because no shares of the Series A Preferred Stock were outstanding and no shares were available to be issued.

Options

In July 2010, the Company's stockholders approved the 2010 Equity Incentive Plan (the 2010 Plan) and on May 19, 2011, the Company's stockholders approved an amendment to the 2010 Plan increasing the authorized shares thereunder to 793,440, on a post-Split Effective Time basis. As of March 31, 2018, there were outstanding options to purchase an aggregate of 585,584 shares of common stock. Effective on June 2, 2016, the 2010 Plan was frozen and no further grants will be made under the 2010 Plan. Shares that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the Amended and Restated 2014 Plan (as defined below).

In July 2014, the Company's stockholders approved the 2014 Stock Incentive Plan (the 2014 Plan). On June 2, 2016, at the 2016 Annual Meeting of Stockholders, the Company's stockholders approved the amendment and restatement of the Company's 2014 Plan (the Amended and Restated 2014 Plan). Pursuant to the terms of the Amended and Restated 2014 Plan, the maximum number of shares reserved for issuance thereunder is 4,160,000. As of March 31, 2018, there were outstanding options to purchase an aggregate of 3,336,988 shares of common stock and 251,559 shares of common stock underlying outstanding restricted stock units (RSUs), and 181,078 shares available for grant under the Amended and Restated 2014 Plan.

On April 3, 2017, the Company's Board of Directors adopted the Assembly Biosciences, Inc. 2017 Inducement Award Plan (the Inducement Plan) pursuant to which the Company reserved 800,000 shares of common stock for issuance under the Inducement Plan. The only persons eligible to receive grants of awards under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM-5635-1. An "Award" is any right to receive Assembly common stock pursuant to the Inducement Plan, consisting of nonstatutory stock options, stock appreciation rights, dividend equivalent rights, restricted stock awards, restricted stock unit awards, or any other stock award. As of March 31, 2018, there were outstanding options to purchase an aggregate of 437,550 shares of common stock and 362,450 shares available for grant under the Inducement Plan.

On March 8, 2018, the Company appointed Graham Cooper as the Company's Chief Financial Officer and Chief Operating Officer. Mr. Cooper will also serve as the Company's principal financial officer and principal accounting officer. In connection with his appointment, Mr. Cooper also was granted a non-qualified stock option to purchase 220,000 shares of the Company's common stock. The option vests over three years as follows: one-third will vest on the first anniversary of the date of grant, March 8, 2019; and the remaining two-thirds will vest in 24 equal monthly installments, with the option becoming fully vested on March 8, 2021. The option is subject to Mr. Cooper's continued service with Assembly through the applicable vesting dates and to acceleration upon the occurrence of certain events as set forth in the option agreement and his employment agreement.

A summary of the Company's option activity and related information for the three-month period ended March 31, 2018 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Total Intrinsic Value
Outstanding as of December 31, 2017	4,551,819	$ 9.66	$ 162,002,439
Granted	534,804	53.06	-
Exercised	(248,762)	6.01	-
Forfeited	(11,500)	16.65	-
Outstanding as of March 31, 2018	4,826,361	$ 14.64	$ 168,652,906
Options vested and exercisable	3,150,559	$ 7.70	$ 130,548,017

The fair value of the options granted for the three months ended March 31, 2018 and 2017, were based on the following assumptions:

	Three Months Ended March 31,	
	2018	2017
Exercise price	$45.80 - $57.53	$12.81 - $25.34
Expected stock price volatility	77.0% - 86.1%	85.4% - 87.0%
Risk-free rate of interest	2.57% - 2.79%	2.19% - 2.23%
Term (years)	5.5 - 7.0	5.5 - 7.0

Estimated future stock-based compensation expense relating to unvested stock options is as follows:

	Future Stock Option Compensation Expenses
Nine Months Ending December 31, 2018	$ 12,899,608
Year Ending December 31, 2019	8,690,702
Year Ending December 31, 2020	3,254,762
Year Ending December 31, 2021	676,700
Year Ending December 31, 2022	25,487
Total	$ 25,547,259

The weighted average remaining contractual term of exercisable options is approximately 6.7 years at March 31, 2018.

Warrants

There was no warrant activity during the three months ended March 31, 2018. The weighted average remaining contractual life of outstanding warrants to purchase 15,296 shares of common stock at March 31, 2018 is approximately 2.4 years.

Restricted Stock Units

On December 8, 2017, the Company issued 120,000 RSUs to its Chief Scientific Officer, Richard Colonno. The RSUs will vest upon the occurrence of specified performance milestones; provided that none of these RSUs will vest prior to August 1, 2018. On March 29, 2018, the Company issued 131,559 RSUs to employees as annual performance awards, which RSUs will vest over four years assuming continuous service by the applicable employees through the vesting dates.

A summary of the Company's restricted stock units and related information is as follows:

	Number of units	Weighted average grant price
Unvested as of December 31, 2017	120,000	$ 44.28
Granted	131,559	49.14
Unvested as of March 31, 2018	251,559	$ 46.82

As of March 31, 2018, the Company had unrecognized stock-based compensation expense related to all unvested restricted stock units of $10.1 million. The weighted average remaining contractual term of unvested RSUs is approximately 9.9 years at March 31, 2018.

Stock-based compensation expense for the three months ended March 31, 2018 and 2017 is as follows:

	Three Months Ended March 31,	
	2018	2017
Research and development	$ 2,524,108	$ 951,926
General and administrative	1,558,659	272,721
Total stock-based compensation expense	$ 4,082,767	$ 1,224,647

Note 7 – Collaboration Agreement

On January 6, 2017, the Company entered into the Collaboration Agreement with Allergan to develop and commercialize select microbiome gastrointestinal programs. 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 ulcerative colitis (UC), Crohn's disease, and irritable bowel syndrome (IBS). Allergan and the Company will collaborate on research and development activities with respect to the licensed compounds in accordance with a mutually agreed upon research and development plan.

In connection with the closing of the transaction on February 10, 2017, Allergan paid the Company an upfront payment of $50 million. Additionally, the Company is eligible to receive variable consideration in the form of cost-sharing reimbursements, up to approximately $630 million in related to seven development milestones and up to approximately $2.15 billion in 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. There is significant uncertainty as to whether the stated milestones will be achieved, and the Company has not included the associated variable consideration in the transaction price as it is not probable that a significant reversal in the amount of cumulative revenue recognized would not occur.

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 development costs up to an aggregate of $75 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 million in the aggregate, the Company may elect either (a) to fund ⅓ of such costs in excess of $75 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 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 for convenience 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. 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.

The Company determined that it has four performance obligations under the Collaboration Agreement associated with the transfer of the license and the performance of the research and development services combined for each of the four indications; the license is not distinct because Allergan cannot obtain value from the license without the research and development services that the Company is uniquely able to perform. The deferred revenue associated with the $50 million upfront payment will be recorded proportionally over a ten-year service period as the research and development services are expected to be performed. As such, the Company recognized the upfront payment received of $50.0 million as approximately $5.0 million in short-term deferred revenue and $45.0 million in long-term deferred revenue as of the closing date. Given the early stage of development, the Company has determined the relative selling price for each of the four indications to be $12.5 million. For the three months ended March 31, 2018 and 2017, the Company recorded approximately $1.3 million and approximately $0.7 million, respectively, in revenue related to the amortization of deferred revenue. Short-term and long-term deferred revenue contract liabilities related to the Collaboration Agreement were approximately $5.2 million and approximately $39.3 million at March 31, 2018 and approximately $5.2 million and approximately $40.6 million at December 31, 2017.

Expense reimbursements will be recognized as collaboration revenue when the related expenses are incurred. The reimbursable expenses incurred in connection with the Collaboration Agreement during the three months ended March 31, 2018 and 2017 were approximately $2.3 million and nil, respectively, and recorded in collaboration revenue on the condensed consolidated statement of operations. In the condensed consolidated balance sheets, contract balances of approximately $2.3 million and approximately $2.3 million were recorded as accounts receivable from collaboration as of March 31, 2018 and December 31, 2017, respectively. As of January 1, 2018 and March 31, 2018, the Company had a contract liability balance of $0.2 million related to expense reimbursement performance obligations that were not satisfied.

Note 8 - Commitments and Contingencies

Real Property Leases and Equipment Leases

The Company leases office space for corporate functions in Carmel, Indiana under a lease agreement that expires in August 2023. The leased location in Carmel, Indiana supports both the HBV-cure and Microbiome programs. The Company leases office and laboratory space in San Francisco, California under a sublease that expires in December 2018 unless the Company requests a six-month extension. The leased location in San Francisco, California supports both the HBV-cure and Microbiome programs. The Company also conducts research activities for the Microbiome program at office and laboratory space in Groton, Connecticut under a lease that expires in March 2019.

The total leasing expenses for the three months ended March 31, 2018 and 2017 were approximately $0.4 million and $0.3 million, respectively.

Equipment Lease

Pursuant to a Master Lease agreement dated November 25, 2014, the Company leases certain equipment. The equipment lease expense for the three months ended March 31, 2018 and 2017 amounted to approximately $304,000 and $182,000, respectively. These equipment leases began to expire in 2017, with the final lease expiring in 2021. The sum of all future payments through termination is approximately $2.6 million.

Litigation

The Company is not a party to any material legal proceedings. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

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, 2017, 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, 2017 filed with the SEC on March 8, 2018 (2017 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. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our 2017 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 advancing two innovative platform programs: a new class of oral therapeutic candidates for the treatment of hepatitis B virus (HBV) infection and a novel class of oral synthetic live biotherapeutic candidates, which are designed to treat disorders 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 protein Allosteric Modifiers (CpAMs), which are small molecules that directly target and allosterically modulate the HBV core (HBc) protein. The lead product candidate from this program, ABI-H0731, has completed the Phase 1a portion of a Phase 1a/1b human clinical trial in New Zealand and as of April 2018, all HBV patients have completed dosing in the Phase 1b portion of the clinical trial (ABI-H0731-101b) in New Zealand and other 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.

The interim data from our completed Phase 1a (ABI-H0731-102) safety and PK study and Phase1b (ABI-H0731-101b) study of antiviral effects was presented as a poster at The International Liver Congress™, the Annual Meeting of the European Association for the Study of the Liver (EASL) on April 12, 2018. The poster presented data for two cohorts (100 mg and 200 mg) of HBV patients that had completed dosing in the Phase 1b trial. Initial results from two incomplete patient cohorts (300 mg and 400 mg) were also reported. The poster also presented the safety and PK from three additional cohorts (100 mg, 200 mg and 300 mg) from a Phase 1a study in healthy volunteers.

The Phase 1b (ABI-H0731-101b) patient study enrolled both HBV e-antigen (HBeAg) positive and negative patients. Potent antiviral activity was observed across patient cohorts in a dose dependent manner. Specifically, in the ongoing 300 mg dose cohort, the mean overall decline from baseline was reported as $\geq$2.8 $\log_{10}$ IU/mL, with $\geq$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). We intend to report complete results from this study at a scientific conference later in 2018.

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. Among the 62 patients and volunteers treated for 14-28 days, all treatment emergent adverse events were observed to be minor (Grade 1), with the exception of an isolated Grade 3 rash at the 400 mg dose that resolved with no intervention required other than treatment discontinuation. No other treatment discontinuations have occurred in these studies.

The interim study results from our Phase 1a (ABI-H0731-102) and 1b (ABI-H0731-101b) clinical studies support the advancement of ABI-H0731 into Phase 2a combination studies using the 300 mg dose. The Phase 2a clinical studies are expected to begin in mid-2018. The first study will enroll HBeAg positive patients on standard of care nucleos(t)ide therapy with suppressed viral loads. Patients will continue their nucleos(t)ide therapy and be randomized to either placebo or ABI-H0731 for six months. This study is designed to evaluate if adjunctive ABI-H0731 therapy can inhibit the generation of cccDNA molecules as compared to treatment with standard of care alone. We anticipate that a successful study will show a greater decline of HBV surface Antigen (a surrogate marker of cccDNA activity) in the combination therapy arm of the study as compared to the monotherapy arm of the study. A second Phase 2a study will enroll treatment naïve HBeAg positive patients and is designed to compare the antiviral activity of entecavir (standard of care nucleoside analogue inhibitor of the HBV polymerase) therapy alone compared to entecavir in combination with ABI-H0731 for six months. We anticipate that a successful study will show a greater decline in viral load per unit time in the combination therapy arm as compared to the monotherapy arm. We anticipate initial results from these studies during the first half of 2019.

Other Product Candidates

In the fourth quarter of 2017, we announced the selection of our second product candidate from this program, ABI-H2158, which is currently undergoing investigational new drug (IND) enabling studies. Pending the successful completion of IND-enabling studies and clearance of an IND, ABI-H2158 is expected to begin a Phase 1a human clinical trial in the fourth quarter of 2018. ABI-H2158 is an internally discovered and developed drug product candidate that is chemically distinct from ABI-H0731. We anticipate the selection of a third CpAM product candidate for this program in 2018.

Microbiome Program

Our Microbiome program consists of a fully integrated platform that includes a disease targeted strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practice (cGMP) conditions, and a 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. The Microbiome program is prioritizing efforts on optimizing our lead product candidates, ABI-M201 (Ulcerative Colitis) and ABI-M301 (Crohn's disease), in preparation for studies to support potential INDs. Using our microbiome platform, we are exploring additional product candidates for other disease indications, including irritable bowel syndrome, non-alcoholic steatohepatitis (NASH), immuno-oncology and Clostridium difficile infections (CDI), which indications we may pursue either internally or in collaboration with partners.

On January 6, 2017, we entered into the Research, Development, Collaboration and License Agreement (the Collaboration Agreement) with Allergan Pharmaceuticals International Limited (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 on February 10, 2017, Allergan paid us an upfront payment of $50 million. Additionally, we are eligible to receive up to approximately $630 million in payments related to seven development milestones and up to approximately $2.15 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 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 and research facilities in Groton, Connecticut and San Francisco, California.

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 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 2017 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2017 Annual Report, except for those accounting subjects mentioned in the section of the notes to the condensed consolidated financial statements titled Adoption of Recent Accounting Pronouncements.

Results of Operations

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

Revenue

For the three months ended March 31, 2018 and 2017, collaboration revenue was approximately $3.6 million and $0.7 million, respectively, which included the amortization of deferred revenue and reimbursement revenue in each case incurred under the Collaboration Agreement. This increase is the result of ramp-up in 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 $12.0 million for the three months ended March 31, 2018, an increase of approximately $2.4 million from approximately $9.6 million for the same period in 2017. The increase was primarily due to an increase of approximately $0.9 million in research expenses for our Microbiome program and an increase of approximately $1.6 million in research expenses for our HBV-cure program, which were offset by a decrease of $0.1 million in research expenses for outsourced chemistry.

Stock-based compensation expense was approximately $2.5 million for the three months ended March 31, 2018, an increase of approximately $1.5 million from approximately $1.0 million for the same period in 2017.

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 $4.1 million for the three months ended March 31, 2018, an increase of approximately $0.3 million from approximately $3.8 million for the same period in 2017. The increase was primarily due to an increase of approximately $1.1 million in salary and benefits expenses due to additional employees in Legal, IT, HR and Finance and $0.1 million of franchise tax expense, which were offset by a decrease of $0.6 million in legal expenses and $0.4 million in professional expenses.

Stock-based compensation expense was approximately $1.6 million for the three months ended March 31, 2018, an increase of approximately $1.3 million from approximately $0.3 million for the same period in 2017.

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, 2018 principally through equity financing, raising an aggregate of approximately $257.4 million in net proceeds, and a strategic partnership raising an aggregate of $50 million in upfront payments.

Cash Flows for the Three Months Ended March 31, 2018 and 2017

Net Cash from Operating Activities

Net cash used in operating activities was approximately $15.5 million for the three months ended March 31, 2018. It was primarily driven by 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 provided by operating activities was approximately $35.0 million for the three months ended March 31, 2017 and funded our research and development program activities and general and administrative expenses. It was primarily driven by $49.3 million of deferred revenue related to the Collaboration Agreement and $1.2 million of non-cash stock-based compensation expense, which were offset by a $13.9 million net loss, an increase of $0.7 million of operating assets and a decrease of $1.2 million in operating liabilities, excluding deferred revenue.

Net Cash from Investing Activities

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, which were offset by a $12.0 million redemption of marketable securities.

Net cash provided by investing activities from continuing operations for the three months ended March 31, 2017 was $6.7 million due to the 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, 2018 was $1.5 million, resulting from the exercise of stock options to purchase 248,762 shares of common stock.

Net cash provided by financing activities from continuing operations for the three months ended March 31, 2017 was $0.6 million, resulting from the exercise of stock options to purchase 71,290 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 trials of our product candidates. 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 will 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 multiple times since our initial public offering by issuing equity securities, most recently in November 2017. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

Based upon our cash position as of March 31, 2018, 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 discovery, nonclinical development, laboratory testing and clinical trials of our product candidates and any additional clinical trials we may conduct in the future;
- the extent to which we further acquire or in-license other medicines and technologies;
- the number and characteristics of product candidates that we pursue in preclinical and clinical development;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical trials 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, 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 preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our 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 financing to achieve our business objectives. Adequate additional financing 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 the holders of our common stock. 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 2017 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 2017 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 Securities Exchange Act of 1934, as amended (the Exchange Act), which 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 and our Chief 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). Based upon that evaluation, our Chief Executive Officer and Chief Financial 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, 2018 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 SEC. 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 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 or Phase 1a/1b 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 trials 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 trials 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 or build a sustainable or profitable business.

Nonclinical studies may not be representative of disease behavior in clinical trials. The outcomes of nonclinical testing and clinical trials are uncertain, and results of earlier nonclinical studies and clinical trials may not be predictive of future clinical trial 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 trials. In addition, the results of nonclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials, 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 trial processes due to inadequate performance of a drug candidate or inadequate adherence by patients or investigators to clinical trial protocols. Further, clinical trials 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 trials. Our failure to replicate earlier positive results in later-stage clinical trials 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 interim data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose top-line or interim 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, estimations, 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 interim 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 interim or preliminary data we previously published. As a result, top-line and interim 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, estimations, 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 study or clinical trial 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 interim 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.

In order to obtain FDA approval to market a new drug product, we must demonstrate safety and effectiveness in humans. To meet these requirements, we must conduct extensive nonclinical testing and sufficient adequate and well-controlled clinical trials. Conducting clinical trials 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 trials might cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials 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 trial sites;
- failure to demonstrate efficiency during clinical trials;
- the emergence of unforeseen safety issues;
- inability to manufacture sufficient quantities of qualified materials under cGMP for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- 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 trial protocols;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements for clinical trials;
- delays, suspension, or termination of clinical trials 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 trials. 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 trials and may fail to obtain regulatory approval for any of our product candidates.

The failure of nonclinical studies and clinical trials 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 trials 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 trials 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 trials or in the future, could cause us or regulatory authorities to interrupt, restrict, delay, or halt clinical trials. 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. In the Phase 1a portion of the trial recently completed in New Zealand and the Phase 1b interim data recently reported, the most common treatment-emergent adverse events that we observed were headaches and rashes, which were among the only adverse events deemed by clinical investigators to be probably or possibly related to the study drug, with the exception of a single isolated Grade 3 rash that resolved rapidly without intervention other than treatment discontinuation, which is the only study discontinuation to date.

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 trials 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 were established in October 2005, began active operations in the spring of 2007, terminated programs related to three prior product candidates, then 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, 2018 and December 31, 2017, the combined company had an accumulated deficit of approximately $267.3 million and $251.0 million, respectively, and net losses of approximately $42.8 million, $44.3 million and $28.5 million for the years ended December 31, 2017, 2016 and 2015, 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 trial 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 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 trials of ABI-H2158, our second HBV-cure product candidate;
- advance ABI-M201 and ABI-M301, the lead candidates from our Microbiome program, toward potential INDs;
- 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 trials 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 and achieve profitability will depend on, among other things:

- successful completion of research, nonclinical studies and clinical trials 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;
- 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 trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales, marketing and distribution activities.

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 any 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 requires 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 protein Allosteric Modifiers (CpAMS). The development of our CpAM technology is in early stages, and the commercial feasibility and acceptance of our CpAMs technology is unknown. More specifically, the theory that treatment with CpAMs may result in the 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 CpAMS. Additionally, even if CpAM 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. The technology for our microbiome therapy is in nonclinical 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 or build a sustainable or profitable business.

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 any 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. If that happens, we may need additional financing to continue the development of our HBV product candidates and our Microbiome program. There is no assurance that we will be able to generate sufficient revenue from our Collaboration Agreement with Allergan when needed to or that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If such event or other unforeseen circumstances occurred and we were unable to generate 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.

Our product candidates face significant development and regulatory hurdles prior to marketing, which could delay or prevent our receipt of licensing, sales and/or milestone revenue.

Before we or any commercial partners obtain the approvals necessary to sell any of our product candidates, we must show through nonclinical studies and human testing in clinical trials that each potential product is safe and effective. The rates at which we complete our scientific studies and clinical trials depend on many factors, including, but not limited to, our ability to obtain adequate supplies of the products to be tested and patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, and other potential drug candidates being studied. Delays in patient enrollment for our trials may result in increased costs and longer development times. In addition, we will need additional financing to develop our product candidates, which we might seek and receive from third-party commercial partners. Further, 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.

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.

On January 6, 2017, we entered into the Collaboration Agreement with Allergan 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. As of March 31, 2018, no performance milestone payments have been made. 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 ($25,000-$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, and collaborators to provide us with significant data and other information related to our projects, nonclinical studies and clinical trials, 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 trials, 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 trials, 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 trials 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 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 do not have our own manufacturing facilities and rely on third-party manufacturers to supply the quantities of ABI-H0731 used in our clinical trials, the quantities of ABI-H2158 used in our nonclinical studies and drug substance and drug product for our Microbiome program. In the past, we have relied exclusively on third-party manufacturers to supply drug substance and drug product materials for our Microbiome program. We are currently transitioning some of the third-party manufacturing to a small scale internal manufacturing facility to supply quantities of our microbiome drug substance and drug product for use in our planned nonclinical studies and early phase clinical trials. 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 trials 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 quality control 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 quality control 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 trials or to produce, store and distribute successfully 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 trials 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 trials;
- 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), immuno-oncology and C. difficile infections (CDI) 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, immuno-oncology and CDI 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.

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 Patient Protection and Affordable Care Act (ACA) signed into law on March 23, 2010, 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 trials 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 trials, 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, 2018, we had 85 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.

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 trials, 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 trials; 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 trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials 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 trials. 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 trials, 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 trials. 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 Patient Protection and 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;
- 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 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, 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, 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 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;

- the federal Health Insurance Portability and Accountability Act of 1996 (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 the Health Information Technology for Economic and Clinical Health Act of 2009, 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 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 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 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.

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.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), the Sarbanes-Oxley Act and the listing standards of NASDAQ, the exchange on which our common stock is listed. 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.

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 trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability/clinical trial 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. anti-bribery laws, the China anti-bribery laws 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 trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions, delays in clinical trials, 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 to increase in time. We engage third parties for clinical trials 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 are establishing international operations and conducting clinical trials outside of the United States, including in China, and 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, 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 war and terrorism, or natural disasters.

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, although our licensors have filed patent applications, we do not own or have any rights to any issued patents that cover any of our 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, customers 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 non-disclosure 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. Non-compliance 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 trials 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 trials 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 Capital Market.

Our common stock is listed on The NASDAQ Capital 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 Capital Market. A delisting of our common stock from The NASDAQ Capital 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, 2018, 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 trials 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.

At March 31, 2018, our executive officers and directors owned approximately 7.9% 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 60.2% 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, 2017, we had potentially utilizable gross Federal net operating loss carryforwards of approximately $153.2 million, State net operating loss carry-forwards of approximately $165.0 million and research and development credit carry forward of approximately $5.6 million, all of which expire between 2027 and 2037. 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 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 (calculate on a rolling basis). We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, some of which are outside our control. These ownership changes may subject our existing net operating losses or credits to substantial limitations under Sections 382 and 383. 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 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 Cuts and Jobs Act (the Tax Act), the amount of post 2017 NOLs 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 NOL to prior taxable years, while allowing post 2017 unused NOLs to be carried forward indefinitely. There is a risk that due to changes under the Tax Act, regulatory changes 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 NASDAQ Capital Market, each of which imposes additional reporting and other obligations on public companies. These rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. 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.

Additionally, the expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. 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. 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.

Not applicable.

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
10.1#	Employment Agreement, dated March 8, 2018, by and between Assembly Biosciences, Inc. and Graham Cooper.	X			
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2*	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	Financials in XBRL format.	X			

Represents management contracts or compensatory plans or arrangements.

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are 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.

SIGNATURES

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 7, 2018

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

Date: May 7, 2018

By: /s/ Graham Cooper
Graham Cooper
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.1

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into on March 8, 2018 (the "**Effective Date**"), by and between Assembly Biosciences, Inc., a Delaware corporation with principal executive offices at 11711 N. Meridian Street, Suite 310, Carmel, IN 46032 (the "**Company**"), and Graham Cooper (the "**Executive**").

WITNESSETH:

WHEREAS, the Company desires to employ the Executive as Chief Operating Officer and Chief Financial Officer as of the Effective Date, and the Executive desires to accept employment by the Company as of the Effective Date; and

WHEREAS, the parties desire to enter into this Agreement, setting forth the terms and conditions of the Executive's employment with the Company;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto hereby agree as follows:

1. Employment.

(a) Services. The Executive will be employed by the Company initially as its Chief Operating Officer and Chief Financial Officer, reporting to the Company's Chief Executive Officer, and shall perform such duties as are consistent with a position as Chief Operating Officer and Chief Financial Officer (the "**Services**"). The Executive agrees to perform such Services faithfully, to devote his full working time, attention and energies to the business of the Company and, while he remains employed and subject to the terms of this Agreement, not to engage in any other business activity that is in conflict with his duties and obligations to the Company. For avoidance of doubt, the Executive may engage in consulting and board activities for businesses that are not competitive with the Company so long as such activities do not interfere with his duties and obligations to the Company and otherwise comply with the Company's Code of Conduct. Commencing as of the Effective Date, the Executive shall not join any board of directors of any for profit entity or engage in outside consulting without the prior written consent of the Chief Executive Officer or the Company's Board of Directors.

(b) Acceptance. Executive hereby accepts such employment and agrees to render the Services.

2. Term. The Executive's employment under this Agreement shall commence as of the Effective Date and shall continue on an "at-will" basis until terminated pursuant to Section 8 of this Agreement (the "**Term**").

3. Best Efforts. The Executive shall devote his full business time, attention and energies (recognizing the exception described in 1(a) above for consulting and board work) to the business and affairs of the Company and shall use his best efforts to advance the best interests of the Company and during the Term shall not be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will interfere with the performance by the Executive of his duties hereunder or the Executive's availability to perform such duties or that will adversely affect, or negatively reflect upon, the Company.

4 . Compensation. During the Term, as full compensation for the performance by the Executive of his duties under this Agreement, the Company shall pay the Executive as follows:

(a) Base Salary. The Company shall pay Executive an annual base salary (the "**Base Salary**") initially equal to four hundred twenty-five thousand dollars ($425,000). Payment shall be made in accordance with the Company's normal payroll practices, as they may be changed from time to time. The Base Salary will be reviewed by the Chief Executive Officer and the Board of Directors (the "Board"), or a committee thereof, no less frequently than annually.

(b) Annual Performance Bonus. At the sole discretion of the Board (or a committee thereof), the Executive shall be eligible to receive an annual performance-based bonus during the Term (the "**Annual Performance Bonus**") targeted at forty percent (40%) of his then current Base Salary based on the attainment by the Executive of certain financial, clinical development and business objectives as established annually by the Board (or a committee thereof). Any Annual Performance Bonus earned with respect to the 2018 fiscal year will be prorated based upon the number of days the Executive is employed in the 2018 fiscal year. The Annual Performance Bonus shall be payable as a lump-sum payment as determined by the Board (or a committee thereof) in its sole discretion. Except as otherwise provided in this Agreement, to earn any particular Annual Performance Bonus or installment thereof, the Executive must, in additional to satisfying the performance objectives, remain employed on the date the Annual Performance Bonus is paid; *provided, further*, that the Annual Performance Bonus will be paid no later than seventy-five (75) days after the end of the period to which the Annual Performance Bonus pertains.

(c) Withholding. The Company shall withhold all applicable federal, state and local taxes, social security and such other amounts as may be required by law from all amounts payable to the Executive under this Agreement, including Section 4 and Section 9.

(d) Equity. As a material inducement to accept the Company's offer of employment, the Company will recommend to the Board (or a committee thereof) that the Executive be granted, subject to the Executive's acceptance of this Agreement and commencement of employment, an option to purchase 220,000 shares of common stock of the Company (the "**New Hire Stock Option**"). Subject to the Executive's continued employment and the terms of the Company's 2017 Inducement Award Plan (the " **Inducement Plan**") and the applicable non-qualified stock option agreement entered into by the Executive and the Company pursuant to the Inducement Plan, the option will have a term of ten years and the shares underlying the New Hire Stock Option shall vest in installments over three years with the first installment (representing approximately 33-1/3% of the shares) vesting on the first anniversary of grant date and the balance vesting over the next two years thereafter in approximately equal monthly installments. The New Hire Stock Option shall be subject to accelerated vesting in connection with a Change of Control as provided in Section 9(c). The New Hire Stock Option and any subsequently granted equity or stock-based awards under the Company's equity incentive plans, including stock options and restricted stock unit awards, will be collectively referred to in this Agreement as the "**Equity Awards**."

(e) Expenses. The Company shall provide the Executive with a corporate credit card for business use, and shall reimburse the Executive for all normal, usual and necessary expenses incurred by the Executive in furtherance of the business and affairs of the Company, including reasonable travel and entertainment, upon timely receipt by the Company of appropriate vouchers or other proof of the Executive's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company.

(f) Other Benefits. The Executive shall be entitled to all rights and benefits for which he shall be eligible under any benefit or other plans (including, without limitation, dental, medical, medical reimbursement and hospital plans, pension plans, employee stock purchase plans, profit sharing plans, bonus plans and other so-called "**Fringe Benefits**") as the Company shall make available to its senior executives from time to time, subject to the terms of such plans. In addition, if applicable, the Company shall reimburse the Executive for his reasonable licensing fees, continuing professional education, and other professional dues upon timely receipt by the Company of appropriate vouchers or other proof of the Executive's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company. The Company shall also name the Executive as a covered person under its Directors & Officers insurance policies.

(g) Vacation. The Executive will be entitled to paid vacation in accordance with the Company's vacation policy, as in effect from time to time.

5. Confidential Information and Inventions.

(a) The Executive recognizes and acknowledges that in the course of his duties he is likely to receive confidential or proprietary information owned by the Company or third parties with whom the Company has an obligation of confidentiality, relating to and used in the Company's business (collectively, "**Confidential and Proprietary Information**"). Confidential and Proprietary Information shall include, but shall not be limited to, confidential or proprietary scientific or technical information, data, formulas and related concepts, business plans (both current and under development), client lists, promotion and marketing programs, trade secrets, or any other confidential or proprietary business information relating to development programs, costs, revenues, marketing, investments, sales activities, promotions, credit and financial data, manufacturing processes, financing methods, plans or the business and affairs of the Company or of any affiliate, client or service provider of the Company, and any and all information relating to the operation of the Company's business which the Company may from time to time designate as confidential or proprietary or that the Executive reasonably knows should be, or has been, treated by the Company as confidential or proprietary. The Executive expressly acknowledges that the Confidential and Proprietary Information constitutes a protectable business interest of the Company. The Executive further agrees that if any information that the Company deems to be a trade secret is found by a court of competent jurisdiction not to be a trade secret, such information will, nevertheless, be considered Confidential and Proprietary Information for purposes of this Agreement. Confidential and Proprietary Information does not include any information that: (i) at the time of disclosure is generally known to, or readily ascertainable by, the public; (ii) becomes known to the public through no fault of the Executive or other violation of this Agreement; or (iii) is disclosed to the Executive by a third party under no obligation to maintain the confidentiality of the information. The Executive agrees, during and after the Term, except as reasonably necessary for the fulfillment of his duties under this Agreement: (i) not to use any such Confidential and Proprietary Information for himself or others; and (ii) to keep confidential and not disclose or make accessible to any other person or entity any Confidential and Proprietary Information. The Executive agrees to return immediately all Confidential and Proprietary Information and Company material and reproductions (including but not limited, to writings, correspondence, notes, drafts, records, invoices, technical and business policies, computer programs or disks) thereof in his possession to the Company upon termination of employment, or at any time upon the Company's request.

(b) Except with prior written authorization by the Company, the Executive agrees not to disclose or publish any of the Confidential and Proprietary Information, or any confidential, scientific, technical or business information of any other party to whom the Company owes an obligation of confidence, at any time during or after his employment with the Company. The restrictions in this Section 5(b) and in Section 5(a) above will not apply to any information that the Executive is required to disclose by law, *provided* that the Executive (i) notifies the Company of the existence and terms of such obligation, (ii) gives the Company a reasonable opportunity to seek a protective or similar order to prevent or limit such disclosure, and (iii) only discloses that information actually required to be disclosed.

(c) The Executive agrees that any and all inventions (whether or not patentable), discoveries, improvements, know-how, ideas, information and patentable or copyrightable works ("**Inventions**") initiated, conceived or made by him, either alone or in conjunction with others, during the course of his employment by the Company or that result from work performed by the Executive for the Company, shall be the sole property of the Company to the maximum extent permitted by applicable law and, to the extent permitted by law, shall be "works made for hire" as that term is defined in the United States Copyright Act (17 U.S.C.A., Section 101). The Company shall be the sole owner of all patents, copyrights, trade secret rights, and other intellectual property or other rights in connection therewith. The Executive hereby assigns to the Company all right, title and interest he may have or acquire in all such Inventions. The Executive further agrees to assist the Company in every proper way (but at the Company's expense) to obtain and from time to time enforce patents, copyrights or other rights on such Inventions in any and all countries, and to that end the Executive will execute all documents necessary:

(i) to apply for, obtain and vest in the name of the Company alone (unless the Company otherwise directs) letters patent, copyrights or other analogous protection in any country throughout the world and when so obtained or vested to renew and restore the same; and

(ii) to defend any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection.

To the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement to assign certain classes of inventions made by an employee, this Section 5 will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. As required pursuant to Section 2872 of the California Labor Code, Executive acknowledges that the Company has notified the Executive that the provisions of this Section 5 do not apply to an invention that qualified fully under the provisions of Section 2870 of the California Labor Code (attached hereto as Exhibit A).

(d) The Executive acknowledges that, while performing the services under this Agreement the Executive may locate, identify and/or evaluate patented or patentable inventions having commercial potential in the fields of pharmacy, pharmaceutical, biotechnology, healthcare, technology and other fields that may be of potential interest to the Company (the "**Third-Party Inventions**"). The Executive understands, acknowledges and agrees that all rights to, interests in or opportunities regarding, all Third-Party Inventions identified by the Company or its affiliates or either of the foregoing Persons' officers, directors, employees (including the Executive), agents or consultants during the Term shall be and remain the sole and exclusive property of the Company or such affiliate and the Executive shall have no rights whatsoever to such Third-Party Inventions and will not pursue for himself or for others any transaction relating to the Third-Party Inventions which is not on behalf of the Company.

(e) The provisions of this Section 5 shall survive any termination or expiration of this Agreement.

6. Non-Solicitation. The Executive understands and recognizes that his services to the Company are special and unique and that in the course of performing such services the Executive will have access to and knowledge of Confidential and Proprietary Information (as defined in Section 5) and will become knowledgeable of and familiar with the Company's customers and service providers as well as the Company's business. The Executive acknowledges that, due to the unique nature of the Company's business, the loss of any of its clients, service providers or business flow or the improper use of its Confidential and Proprietary Information could create significant instability and cause substantial damage to the Company and therefore the Company has a strong legitimate business interest in protecting the continuity of its business interests and the restrictions herein agreed to by the Executive narrowly and fairly serve such an important and critical business interest of the Company. Therefore, the Executive covenants and agrees as follows:

(a) Definitions. As used in this Agreement, the following terms have the meanings given to such terms below:

(i) "**Company Employee**" means (A) any person who is an employee of the Company at the time of the date of the Executive's termination of employment, and (B) any person who was an employee of the Company at any point during the six (6) month period prior to, the termination of the Executive's employment.

(ii) "**Person**" means any person, firm, partnership, joint venture, corporation or other business entity.

(iii) "**Restricted Period**" means the period commencing on the date of the Executive's termination of employment and ending twelve (12) months thereafter; *provided, however*, that this period will be tolled and will not run during any time Executive is in violation of this Section 6, it being the intent of the parties that the Restricted Period will be extended for any period of time in which the Executive is in violation of this Section 6.

(b) Non-Solicitation. During his employment with the Company and during the Restricted Period (other than for the benefit of the Company), the Executive will not, directly or indirectly, on the Executive's own behalf or on behalf of any other Person, solicit, induce, or attempt to solicit or induce any Company Employee or any independent contractor (who is then engaged by the Company or was engaged by the Company in the prior six (6) months) to terminate his or her employment or engagement with the Company or to accept employment or engagement with any Person.

(c) Enforcement. In the event that the Executive breaches or threatens to breach any provisions of Section 5 or this Section 6, then the Company will suffer irreparable harm and monetary damages would be inadequate to compensate the Company. Accordingly, in addition to any other rights which the Company may have, the Company shall (i) be entitled, without the posting of bond or other security, to seek injunctive relief to enforce the restrictions contained in such Sections and (ii) have the right to require the Executive to account for and pay over to the Company all compensation, profits, monies, accruals, increments and other benefits derived or received by the Executive as a result of any transaction constituting a breach of any of the provisions of Sections 5 or 6, to the maximum extent permitted by law.

(d) Reasonableness and Severability. Each of the rights and remedies enumerated in Section 6(c) shall be independent of the others and shall be in addition to and not in lieu of any other rights and remedies available to the Company at law or in equity. The Executive hereby acknowledges and agrees that the covenants provided for pursuant to Section 6 are essential elements of Executive's employment by the Company and are reasonable with respect to their duration, geographic area and scope and in all other respects. If, at the time of enforcement of this Section 6, a court of competent jurisdiction holds that the restrictions stated herein are unreasonable under the circumstances then existing, the parties hereto agree that the maximum duration, scope or geographic area legally permissible under such circumstances will be substituted for the duration, scope or area stated herein. If any of the covenants contained in this Section 6, or any part of any of them, is hereafter construed or adjudicated to be invalid or unenforceable, the same shall not affect the remainder of the covenant or covenants or rights or remedies which shall be given full effect without regard to the invalid portions. No such holding of invalidity or unenforceability in one jurisdiction shall bar or in any way affect the Company's right to the relief provided in this Section 6 or otherwise in the courts of any other state or jurisdiction within the geographical scope of such covenants as to breaches of such covenants in such other respective states or jurisdictions, such covenants being, for this purpose, severable into diverse and independent covenants.

(e) Defend Trade Secrets Act of 2016. The Executive understands that pursuant to the federal Defend Trade Secrets Act of 2016, the Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (x) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (y) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(f) Protected Disclosures. The Executive understands that nothing contained in this Agreement limits the Executive's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company. The Executive also understands that nothing in this Agreement limits the Executive's ability to share compensation information concerning the Executive or others, except that this does not permit the Executive to disclose compensation information concerning others that the Executive obtain because the Executive's job responsibilities require or allow access to such information.

(g) Remedies. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 5 or this Section 6, the Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available. The Executive agrees that he shall not raise in any proceeding brought to enforce the provisions of Section 5 or this Section 6 that the covenants contained in such Sections limit his ability to earn a living.

(h) Survival. The provisions of Section 6 shall survive any termination of this Agreement.

7. Representations and Warranties.

(a) The Executive hereby represents and warrants to the Company as follows:

(i) Neither the execution or delivery of this Agreement nor the performance by the Executive of his duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which the Executive is a party or by which he is bound.

(ii) The Executive has the full right, power and legal capacity to enter and deliver this Agreement and to perform his duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of the Executive enforceable against him in accordance with its terms. No approvals or consents of any persons or entities are required for the Executive to execute and deliver this Agreement or perform his duties and other obligations hereunder.

(b) The Company hereby represents and warrants to the Executive that this Agreement and the employment of the Executive hereunder have been duly authorized by and on behalf of the Company, including, without limitation, by all required action by the Board.

8. Termination. The Executive's employment hereunder shall be terminated immediately upon the Executive's death and may be otherwise terminated as follows:

(a) The Executive's employment hereunder may be terminated by the Company for Cause as determined by the Board. Any of the following actions by the Executive shall constitute "**Cause**":

(i) The willful failure, disregard or continuing refusal by the Executive to perform his duties hereunder;

(ii) Any act of willful or intentional misconduct, or a grossly negligent act by the Executive having the effect of injuring, in a material way (as determined in good-faith by the Board of Directors), the business or reputation of the Company, including but not limited to, any officer, director, or executive of the Company;

(iii) Willful misconduct by the Executive in carrying out his duties or obligations under this Agreement, including, without limitation, insubordination with respect to lawful directions received by the Executive from the Chief Executive Officer or from the Board;

(iv) The Executive's indictment of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea);

(v) The determination by the Company, based upon clear and convincing evidence, after a reasonable and good-faith investigation by the Company following a written allegation by another employee of the Company, that the Executive engaged in some form of harassment prohibited by law (including, without limitation, age, sex or race discrimination);

(vi) Any intentional misappropriation of the property of the Company, or embezzlement of its funds or assets (whether or not a misdemeanor or felony);

(vii) Breach by the Executive of any of the provisions of Sections 5, 6, or 7 of this Agreement; and

(viii) Breach by the Executive of any provision of this Agreement other than those contained in Sections 5, 6, or 7 which is not cured by the Executive within thirty (30) business days after notice thereof is given to the Executive by the Company.

Except for a failure, misconduct, breach, or refusal which, by its nature, cannot reasonably be expected to be cured, the Executive shall have ten (10) business days from the delivery of written notice by the Company within which to cure any acts constituting Cause, unless a longer cure period is provided in the act constituting Cause described above; provided however, that, if the Company reasonably expects irreparable injury from a delay of ten (10) business days, the Company may give the Executive notice of such shorter period within which to cure as is reasonable under the circumstances, which may include the termination of the Executive's employment for Cause without notice and with immediate effect.

(b) The Executive's employment hereunder may be terminated by the Board due to the Executive's Disability. For purposes of this Agreement, a termination for "**Disability**" shall occur (i) when the Board has provided a written termination notice to the Executive supported by a written statement from a reputable independent physician mutually selected by the Company and the Executive, or the Executive's legal representatives in the event he is unable to make such selection due to mental incapacity, to the effect that the Executive shall have become so physically or mentally incapacitated as to be unable to resume, even with reasonable accommodation as may be required under the Americans With Disabilities Act, within the ensuing twelve (12) months, his employment hereunder by reason of physical or mental illness or injury, or (ii) upon rendering of a written termination notice by the Company after the Executive has been unable to substantially perform his duties hereunder, even with reasonable accommodation as may be required under the Americans With Disabilities Act, for one hundred twenty (120) or more consecutive days, or more than one hundred eighty (180) days in any consecutive twelve (12) month period, by reason of any physical or mental illness or injury. For purposes of this Section 8(b), the Executive agrees to make himself available and to cooperate in any reasonable examination by a reputable independent physician mutually selected by the Company and the Executive, and paid for by the Company. Notwithstanding the foregoing, nothing herein shall give the Company the right to terminate the Executive prior to discharging its obligations to the Executive, if any, under the Family and Medical Leave Act, the Americans With Disabilities Act, or any other applicable law. The Company shall reimburse the Executive for his actual cost of maintaining a supplementary long-term disability insurance policy during the Term up to a maximum reimbursement of $10,000 per year.

(c) The Executive's employment hereunder may be terminated by the Company (or its successor) by written notice to the Executive upon the occurrence of a Change of Control. For purposes of this Agreement, "**Change of Control**" means (i) the acquisition, directly or indirectly, following the Effective Date by any person (as such term is defined in Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended), in one transaction or a series of related transactions, of securities of the Company representing in excess of fifty percent (50%) of the combined voting power of the Company's then outstanding securities if such person or his or its affiliate(s) do not own in excess of 50% of such voting power on the Effective Date of this Agreement, (ii) the future disposition by the Company (whether direct or indirect, by sale of assets or stock, merger, consolidation or otherwise) of all or substantially all of its business and/or assets in one transaction or series of related transactions other than a merger effected exclusively for the purpose of changing the domicile of the Company, or (iii) a "corporate transaction" as defined in the Company equity incentive plans under which the Executive has been granted Equity Awards. Notwithstanding the foregoing, if the Change of Control does not constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the assets of the Company, within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**"), the amount of cash severance payable pursuant to Section 9(b), if any, shall be paid in equal installments in accordance with the Company's then payroll practice over a 18-month period. Solely for purposes of Section 409A of the Code, each installment payment is considered a separate payment.

(d) The Executive's employment hereunder may be voluntarily terminated by the Executive for Good Reason. For purposes of this Agreement, "**Good Reason**" shall mean any of the following: (i) any material reduction by the Company of the Executive's duties, or responsibilities or authority; (ii) any material reduction by the Company of the Executive's Base Salary and/or target Annual Performance Bonus payable hereunder (it being understood that an across-the-board reduction applicable to all similarly situated employees of the Company, including the Executive, shall not be deemed a reduction for purposes of this definition); (iii) the Executive no longer reports to the Chief Executive Officer or Board of Directors of the Company or its successor; (iv) any requirement by the Company, without the Executive's prior written consent, that the Executive locate the Executive's residence or primary place of employment to a location outside a 50-mile radius of such location mutually agreed upon between the Company and the Executive as of the Effective Date, or such other location that the Company and the Executive may mutually agree upon and designate from time to time during the Term; or (v) a material breach by the Company of Section 7(b) of this Agreement which is not cured by the Company within 30 days after written notice thereof is given to the Company by the Executive. However, notwithstanding the above, Good Reason shall not exist unless: (x) the Executive notifies the Board within thirty (30) days of the initial existence of one of the adverse events described above, and (y) the Company fails to correct the adverse event within thirty (30) days of such notice, and (z) the Executive's voluntary termination because of the existence of one or more of the adverse events described above occurs within two hundred seventy (270) days of the initial existence of the event.

(e) The Executive's employment may be terminated by the Company without Cause by delivery of written notice to the Executive effective the date of delivery of such notice. For the avoidance of doubt, termination of the Executive's employment due to his death or Disability does not constitute a termination for Cause.

(f) The Executive's employment may be terminated by the Executive in the absence of Good Reason by delivery of written notice to the Company effective fifteen (15) days after the date of delivery of such notice.

9. Compensation upon Termination.

(a) Accrued Benefits. Upon termination of the Executive's employment by either party regardless of the cause or reason, the Executive shall be entitled to the following, referred to herein as the "**Accrued Benefits**": (i) payment for any accrued, unpaid Base Salary through the termination date; (ii) if provided for under the Company's vacation plan or policy or required by applicable law, payment for any accrued, unused vacation days through the termination date; and (iii) reimbursement for any approved business expenses that the Executive has timely submitted for reimbursement in accordance with the Company's business expense reimbursement policy or practice. Except as otherwise expressly provided by this Agreement, the Company shall have no further payment obligations to the Executive and all Equity Awards that have not vested as of the termination date shall be forfeited to the Company as of such date. Subject to this Section 9, the vested portion of any stock options held by the Executive as of the Executive's termination date shall remain exercisable for ninety (90) days following such termination.

(b) Change of Control Separation Benefits. If the Executive's employment is terminated due to death, by the Company due to Disability pursuant to Section 8(b), by the Company without Cause pursuant to Section 8(e) or by the Executive for Good Reason pursuant to Section 8(d) and such termination occurs during the period beginning one (1) month immediately preceding the Change of Control and ending twelve (12) months immediately following such Change of Control (the "**COC Period**"), *provided* that the Executive signs and does not revoke a general release of claims against the Company within the time period specified therein (which time period shall not exceed sixty (60) days), in form and substance satisfactory to the Company (the "**Release**"), and *provided further* that such termination is a "separation from service" within the meaning of Treasury Regulation § 1.409A-1(h), then the Company shall provide the following benefits to the Executive, referred to herein as the "**Change of Control Separation Benefits**": (i) a lump sum payment equal to eighteen (18) months of the Executive's then-current Base Salary; (ii) the full Annual Performance Bonus for the year in which such termination occurs multiplied by 1.5, less any installments paid in advance (items (i) and (ii) being the "**Change of Control Separation Pay**"); (iii) immediate vesting in full of all Equity Awards; provided, however, that (A) in the event that a termination without Cause or termination for Good Reason or termination due to death or Disability occurs during the one (1) month immediately preceding a Change of Control (i.e., the first month of a COC Period), any Equity Awards outstanding as of the Executive's termination shall not accelerate in connection with such termination but instead will remain outstanding and eligible to vest pursuant to this provision immediately prior to the consummation of such Change of Control (assuming the timely execution and non-revocation of a Release) and (B) in the event that Termination without Cause or a Termination for Good Reason occurs prior to a Change of Control and such Change of Control is not consummated on or prior to the one (1) month anniversary of such termination, no vesting shall occur pursuant to this provision and any Equity Awards outstanding as of the Executive's termination shall terminate in accordance with its terms; (iv) extension of the exercise period for all vested stock options held by the Executive as of the termination date until the end of their term; and (v) if the Executive properly and timely elects to continue his health insurance benefits under COBRA or applicable state continuation coverage after the termination date, reimbursement for the portion of Executive's health continuation coverage premiums that the Company would have paid had the Executive remained employed by the Company until the earlier of (A) the eighteen (18) month period following the month in which the Executive's termination date occurs, or (B) the maximum period permitted by applicable law, provided that the Company's obligation to pay a portion of the Executive's health continuation coverage premiums will terminate if he becomes eligible for health insurance benefits from another employer during the reimbursement period, The Change of Control Separation Pay will be paid within sixty (60) days after the termination date.

(c) Base Separation Benefits. If the Executive's employment is terminated during the Term and outside of the COC Period as a result of the Executive's Disability pursuant to Section 8(b), by the Company without Cause pursuant to Section 8(e), or by the Executive for Good Reason pursuant to Section 8(d), *provided* that the Executive signs and does not revoke the Release within the time period specified therein (which time period shall not exceed sixty (60) days), and *provided further* that such termination is a "separation from service" within the meaning of Treasury Regulation § 1.409A-1(h), then the Company shall provide the following benefits to the Executive, referred to herein as the "Base **Separation Benefits**": (i) the continued payment in installments of the Executive's then-current Base Salary for a period of twelve (12) months following the termination date (the "**Base Separation Pay**") ; (ii) all Equity Awards which would have time vested during the twelve (12) months following the termination date shall accelerate and vest; (iii) extension of the exercise period for all vested stock options held by the Executive as of the termination date until the first anniversary of the termination date; and (iv) if the Executive properly and timely elects to continue his health insurance benefits under COBRA or applicable state continuation coverage after the termination date, reimbursement for the portion of Executive's health continuation coverage premiums that the Company would have paid had the Executive remained employed by the Company until the earlier of (A) the twelve (12) month period following the month in which the Executive's termination date occurs, or (B) the maximum period permitted by applicable law, provided that the Company's obligation to pay a portion of the Executive's health continuation coverage premiums will terminate if he becomes eligible for health insurance benefits from another employer during the reimbursement period. The first installment of the Base Separation Pay will be paid on the Company's first regular payday occurring following the effectiveness of the Release in an amount equal to the sum of payments of Base Salary that would have been paid if he had remained in employment for the period from the termination date through the payment date. The remaining installments will be paid until the end of the 12-month period at the same rate as the Base Salary in accordance with the Company's normal payroll practices for its employees. The Executive understands that if he is eligible to receive the Base Separation Benefits, such Base Separation Benefits shall be in lieu of and not in addition to the Change of Control Separation Benefits described in Section 9(b) of this Agreement. Notwithstanding the foregoing, if the Executive is entitled to receive the Base Separation Benefits but violates any provisions of this Agreement or any other agreement entered into by the Executive and the Company after termination of employment, the Company will be entitled to immediately stop paying any further installments of the Base Separation Benefits. If the Executive's employment is terminated during the Term as a result of the Executive's death, then the Company shall provide to the Executive's estate the continued payment of Executive's then-current Base Salary for a period of twelve (12) months following the termination date, beginning on the Company's first regular payday following the such termination date.

(d) This Section 9 sets forth the only obligations of the Company with respect to the termination of the Executive's employment with the Company, except as otherwise required by law, and the Executive acknowledges that, upon the termination of his employment, he shall not be entitled to any payments or benefits which are not explicitly provided in Section 9.

(e) Upon termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned as director and or officer of the Company, to the extent applicable, effective as of the date of such termination, unless otherwise requested by the Board.

(f) The provisions of this Section 9 shall survive any termination of this Agreement.

10. Section 409A. The intent of the parties to this Agreement is that the payments, compensation and benefits under this Agreement be exempt from or comply with Section 409A of the Code and the regulations and guidance promulgated thereunder (collectively, "**Section 409A**") and, in this connection, the following shall be applicable:

(a) To the greatest extent possible, this Agreement shall be interpreted to be exempt from or in compliance with Section 409A.

(b) If any severance, compensation, or benefit required by this Agreement is to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A.

(c) If any severance, compensation, or benefit required by this Agreement that constitutes "nonqualified deferred compensation" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A, and the Executive is a "specified employee" within the meaning of Section 409A, no payments of any of such severance, compensation, or benefit shall be made until the earlier of six (6) months plus one (1) day after such separation from service or the Executive's death (the "**New Payment Date**"). The aggregate amount of any such payments that would have otherwise been paid during the period between the date of separation from service and the New Payment Date shall be paid to the Executive or his estate in a lump sum payment on the New Payment Date. Thereafter, any severance, compensation, or benefit required by this Agreement that remains outstanding as of the day immediately following the New Payment Date shall be paid without delay over the time period originally scheduled, in accordance with the terms of this Agreement.

(d) The provisions of this Section 10 shall survive any termination of this Agreement.

11. Section 280G.

(a) Notwithstanding any other provision of this Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by the Company or its affiliates to the Executive or for the Executive's benefit pursuant to the terms of this Agreement or otherwise ("**Covered Payments**") constitute parachute payments ("**Parachute Payments**") within the meaning of Section 280G of the Code and would, but for this Section 11 be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the "**Excise Tax**"), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "**Reduced Amount**"). "**Net Benefit**" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

(b) Any such reduction shall be made in accordance with Section 409A of the Code and the following: (i) the Covered Payments which do not constitute nonqualified deferred compensation subject to Section 409A of the Code shall be reduced first; and (ii) all other Covered Payments shall then be reduced as follows: (A) cash payments shall be reduced before non-cash payments; and (B) payments to be made on a later payment date shall be reduced before payments to be made on an earlier payment date.

(c) Any determination required under this Section 11 shall be made in writing in good faith by the accounting firm that was the Company's independent auditor immediately before the Change of Control (the "**Accounting Firm**"). The Accounting Firm shall provide detailed supporting calculations to the Company and the Executive as requested by the Company or the Executive. The Company and the Executive shall provide the Accounting Firm with such information and documents as the Accounting Firm may reasonably request in order to make a determination under this Section 11. For purposes of making the calculations and determinations required by this Section 11, the Accounting Firm may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accounting Firm's determinations shall be final and binding on the Company and the Executive. The Company shall be responsible for all fees and expenses incurred by the Accounting Firm in connection with the calculations required by this Section 11.

(d) It is possible that after the determinations and selections made pursuant to this Section 11 the Executive will receive Covered Payments that are in the aggregate more than the amount provided under this Section 11 ("**Overpayment**") or less than the amount provided under this Section 11 ("**Underpayment**").

(i) In the event that: (A) the Accounting Firm determines, based upon the assertion of a deficiency by the Internal Revenue Service against either the Company or the Executive which the Accounting Firm believes has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then the Executive shall pay any such Overpayment to the Company.

(i i) In the event that: (A) the Accounting Firm, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment will be paid promptly by the Company to or for the benefit of the Executive.

12. Miscellaneous.

(a) This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of California, without giving effect to its principles of conflicts of laws.

(b) In the event of any dispute arising out of, or relating to, this Agreement or the breach thereof (other than Sections 5 or 6 hereof), or regarding the interpretation thereof, the parties agree to submit any differences to nonbinding mediation prior to pursuing resolution through the courts. The parties hereby submit to the exclusive jurisdiction of the state and federal courts situated in San Francisco County, California, and agree that service of process in such court proceedings shall be satisfactorily made upon each other if sent by registered mail addressed to the recipient at the address referred to in Section 12(g) below.

(c) This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective heirs, legal representatives, successors and permitted assigns.

(d) This Agreement, and the Executive's rights and obligations hereunder, may not be assigned by the Executive. The rights and obligations of the Company under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of the Company, including any successors or assigns in connection with any sale, transfer or other disposition of all or substantially all of its business or assets.

(e) This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the parties hereto.

(f) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

(g) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally or by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the parties at the addresses set forth on the first page of this Agreement, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, five days after the date of deposit in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this Section 12(g).

(h) This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter hereof. No representation, promise or inducement has been made by either party that is not embodied in this Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

(i) As used in this Agreement, "affiliate" of a specified person or entity shall mean and include any person or entity controlling, controlled by or under common control with the specified person or entity.

(j) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

(k) This Agreement may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

[*Remainder of Page Intentionally Left Blank – Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement and intend it to be effective as of the Effective Date by proper person thereunto duly authorized.

ASSEMBLY BIOSCIENCES, INC.

By: /s/ Derek Small
Name: Derek Small
Title: Chief Executive Officer and President

EXECUTIVE

/s/ Graham Cooper
Name: Graham Cooper

[Signature Page to Graham Cooper Employment Agreement]

EXHIBIT A

California Labor Code Section 2870. Application of provision providing that employee shall assign or offer to assign rights in invention to employer.

(a) Any provision in an employment agreement which provides that an employee shall assign, or offer to assign, any of his or her rights in an invention to his or her employer shall not apply to an invention that the employee developed entirely on his or her own time without using the employer's equipment, supplies, facilities, or trade secret information except for those inventions that either:

(1) Relate at the time of conception or reduction to practice of the invention to the employer's business, or actual or demonstrably anticipated research or development of the employer; or

(2) Result from any work performed by the employee for his employer.

(b) To the extent a provision in an employment agreement purports to require an employee to assign an invention otherwise excluded from being required to be assigned under subdivision (a), the provision is against the public policy of this state and is unenforceable.

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 7, 2018

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

EXHIBIT 31.2

CERTIFICATION

I, Graham Cooper, 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 7, 2018

By: /s/ Graham Cooper
Graham Cooper
Chief Financial Officer and Chief Operating Officer
(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, 2018 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

Date: May 7, 2018

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended March 31, 2018 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Graham Cooper, Chief Financial 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/ Graham Cooper
Graham Cooper
Chief Financial Officer and Chief Operating Officer

Date: May 7, 2018