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 September 30, 2017

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, IN	**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 October 27, 2017, there were 17,397,731 shares of registrant's common stock outstanding.

Index

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 27,247,232	$ 28,575,085
Marketable securities, at fair value	39,052,821	24,388,403
Accounts receivable from collaboration	1,400,374	-
Prepaid expenses and other current assets	951,334	611,176
Total current assets	68,651,761	53,574,664
Long-term assets		
Marketable securities, at fair value	1,004,310	2,435,753
Property, plant and equipment, net	593,126	214,687
Security deposits	425,789	255,366
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	43,661,361	44,543,942
Total assets	**$ 112,313,122**	**$ 98,118,606**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 870,607	$ 2,368,131
Accrued expenses	6,352,512	4,752,823
Deferred revenue - short-term	4,995,894	-
Total current liabilities	12,219,013	7,120,954
Long-term liabilities		
Deferred tax liabilities	11,146,312	11,119,651
Deferred revenue - long-term	41,814,946	-
Total long-term liabilities	52,961,258	11,119,651
Total liabilities	**65,180,271**	**18,240,605**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,385,773 and 17,246,754 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	17,386	17,247
Additional paid-in capital	295,532,797	288,688,990
Accumulated other comprehensive loss	(388,389)	(600,769)
Accumulated deficit	(248,028,943)	(208,227,467)
Total stockholders' equity	47,132,851	79,878,001
Total liabilities and stockholders' equity	**$ 112,313,122**	**$ 98,118,606**

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration revenue	$ 2,659,613	$ -	$ 5,703,293	$ -
Operating expenses:				
Research and development	10,929,436	8,833,027	33,628,196	24,470,634
General and administrative	4,180,357	2,845,898	12,022,357	8,939,573
Total operating expenses	15,109,793	11,678,925	45,650,553	33,410,207
Loss from operations	**(12,450,180)**	**(11,678,925)**	**(39,947,260)**	**(33,410,207)**
Other income (expenses)				
Interest and other income	241,326	378,381	617,668	1,313,407
Realized loss from marketable securities	(99,068)	(273,573)	(577,300)	(618,075)
Total other income	142,258	104,808	40,368	695,332
Loss before income taxes	**(12,307,922)**	**(11,574,117)**	**(39,906,892)**	**(32,714,875)**
Income tax benefit	35,903	-	105,416	-
Net loss	**$ (12,272,019)**	**$ (11,574,117)**	**$ (39,801,476)**	**$ (32,714,875)**
Other comprehensive (loss) income				
Unrealized loss recognized in accumulated other comprehensive loss before reclassification, net of tax benefit of $31,844, $0, $89,281 and $0, respectively	(51,203)	(270,779)	(143,562)	(633,058)
Reclassification adjustment of unrealized loss included in net loss, net of tax expense of $37,987, $0, $221,358 and $0, respectively	61,081	273,573	355,942	618,075
Comprehensive loss	**$ (12,262,141)**	**$ (11,571,323)**	**$ (39,589,096)**	**$ (32,729,858)**
Net loss per share, basic and diluted	$ (0.71)	$ (0.67)	$ (2.30)	$ (1.90)
Weighted average common shares outstanding, basic and diluted	17,367,523	17,225,554	17,326,506	17,225,625

See Notes to Condensed Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (39,801,476)	$ (32,714,875)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	124,676	55,250
Stock-based compensation	5,833,010	4,033,036
Realized loss from marketable securities	577,300	618,075
Deferred income tax benefit	(105,416)	-
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	(1,400,374)	-
Prepaid expenses and other current assets	(340,158)	94,936
Accounts payable	(1,497,524)	2,474,266
Accrued expenses	1,599,689	1,605,078
Deferred revenue	46,810,840	-
Security deposits	(170,423)	(8,186)
Net cash provided by (used in) operating activities	11,630,144	(23,842,420)
Cash flows from investing activities		
Purchases of fixed assets and construction in progress	(503,115)	(35,094)
Purchases of marketable securities	(40,022,384)	(7,951,256)
Redemptions of marketable securities	26,556,566	28,515,332
Net cash (used in) provided by investing activities	(13,968,933)	20,528,982
Cash flows from financing activities		
Proceeds from the exercise of stock options	1,010,936	-
Net cash provided by financing activities	1,010,936	-
Net decrease in cash and cash equivalents	(1,327,853)	(3,313,438)
Cash and cash equivalents at the beginning of the period	28,575,085	27,107,526
Cash and cash equivalents at the end of the period	**$ 27,247,232**	**$ 23,794,088**
Supplemental disclosure of cash flow information:		
Shares issued for option exercise - receivable	$ 8	$ -
Change in unrealized gain (loss) on marketable securities available-for-sale, before tax expense	$ 344,457	$ (14,983)

See Notes to Condensed Consolidated Financial Statements.

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

	Common Stock		Additional	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Comprehensive Loss	Deficit	Equity
Balance as of December 31, 2016	**17,246,754**	**$ 17,247**	**$ 288,688,990**	**$ (600,769)**	**$ (208,227,467)**	**$ 79,878,001**
Proceeds from the exercise of stock options	131,519	131	1,010,805	-	-	1,010,936
Shares issued for option exercise - receivable	7,500	8	(8)	-	-	-
Change in unrealized gain on marketable securities, net of income tax expense of $132,077	-	-	-	212,380	-	212,380
Stock-based compensation	-	-	5,833,010	-	-	5,833,010
Net loss	-	-	-	-	(39,801,476)	(39,801,476)
Balance as of September 30, 2017	**17,385,773**	**$ 17,386**	**$ 295,532,797**	**$ (388,389)**	**$ (248,028,943)**	**$ 47,132,851**

See Notes to Condensed Consolidated Financial Statements.

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc. (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 aimed at pursuing multiple product candidates that inhibit the HBV lifecycle and increasing the current low cure rate for patients with HBV. Assembly has discovered several 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 commenced the Phase 1b portion of the clinical trial in the second quarter of 2017 in New Zealand and other countries outside the United States. We have also filed an investigational new drug application, or IND, under which an additional Phase 1a pharmacokinetic, safety and tolerability study of ABI-H0731 in the United States has been initiated. The second product candidate from this program, ABI-H2158, is currently undergoing IND enabling studies and is expected to begin a Phase 1a human clinical trial in the second half of 2018. 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 Practice (cGMP) conditions, and a patent pending delivery system that the Company calls GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. Using 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), immune-oncology and *Clostridium difficile* infections (CDI), which the Company will 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 September 30, 2017, condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2017 and 2016, condensed consolidated statements of cash flows for the nine months ended September 30, 2017 and 2016, and condensed consolidated statement of changes in stockholders' equity for the nine months ended September 30, 2017 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 and nine months ended September 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017 or for any future interim period. The consolidated balance sheet at December 31, 2016 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, 2016, and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 2, 2017 (the 2016 Annual Report).

Use of Estimates

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

Significant estimates inherent in the preparation of the accompanying financial statements include recoverability and useful lives (indefinite or finite) of intangible assets, assessment of impairment of goodwill, and the fair value of stock options and warrants granted to employees, consultants, directors, investors, licensors, placement agents and underwriters. In addition, with the Company entering into the Collaboration Agreement, the Company believes its condensed consolidated financial statements are also impacted by the following accounting estimates and judgments: (i) identifying deliverables under collaboration agreements involving multiple elements and determining whether such deliverables are separable from other aspects of the contractual relationship; (ii) estimating the selling price of deliverables for the purpose of allocating arrangement consideration for revenue recognition; and (iii) estimating the periods over which the allocated consideration for deliverables is recognized.

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 2016 Annual Report other than the adoption of the following revenue recognition policy.

Revenue Recognition

The Company recognizes revenue when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

The Company recognizes revenue under the Collaboration Agreement based on the relevant accounting literature. Under this guidance, multiple elements or deliverables may include (i) grants of licenses, or options to obtain licenses, to intellectual property, (ii) research and development services, (iii) participation on joint research and/or joint development committees, and/or (iv) manufacturing or supply of services. The payments entities may receive under these arrangements typically include one or more of the following: non-refundable, upfront license fees; option exercise fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

Multiple-element arrangements require the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit using the relative selling price method. The relative selling price for each deliverable is determined using vendor specific objective evidence (VSOE), of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The allocated consideration for each unit of accounting is recognized based on the method most appropriate for that unit of account and in accordance with the revenue recognition criteria detailed above.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Collaboration Agreement provides for non-refundable milestone payments. The Company recognizes revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered substantive when the consideration payable to the Company for such milestone (i) is consistent with the Company's performance necessary to achieve the milestone or the increase in value to the collaboration resulting from the Company's performance, (ii) relates solely to the Company's past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, the Company considers all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

The Collaboration Agreement provides Allergan with options to license additional intellectual property rights, or purchase additional research, development, or supply services. The Company concluded that these were "substantive options" under the multiple-element arrangement guidance, and accordingly, associated fees have not been considered in allocating contract consideration among deliverables with stand-alone value. If Allergan exercises one or more of these options, the associated revenue would be recognized using the method most appropriate for the particular deliverable.

The Company will periodically review the estimated performance periods under the Collaboration Agreement, which provides for non-refundable upfront payments and fees. The Company will adjust the periods over which revenue should be recognized when appropriate to reflect changes in assumptions relating to the estimated performance periods. The Company could accelerate revenue recognition in the event of early termination of programs or if the Company's expectations change. Alternatively, the Company could decelerate revenue recognition if programs are extended or delayed. While such changes to the Company's estimates have no impact on the Company's reported cash flows, the amount of revenue recorded in future periods could be materially impacted.

The Company records revenues related to the reimbursement of costs incurred under the Collaboration Agreement where the Company acts as a principal, controls the research and development activities and bears credit risk. Under the Collaboration Agreement, the Company is reimbursed for associated out-of-pocket costs. The gross amount of these pass-through reimbursed costs is reported as revenue in the accompanying statements of operations, while the actual expenses for which the Company is reimbursed are reflected as research and development costs. The Company has also accounted for the milestone payments under ASC 605 *Revenue Recognition - Milestone Method*. See Note 7 for further information.

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 September 30, 2017 and 2016 are as follows:

	September 30,	
	2017	**2016**
Warrants to purchase common stock	16,909	16,909
Options to purchase common stock	4,859,680	4,377,201
Total	**4,876,589**	**4,394,110**

Adoption of Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. Under ASU 2016-09, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital (APIC). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement and the APIC pools will be eliminated. In addition, ASU 2016-09 eliminates the requirement that excess tax benefits be realized before companies can recognize them. ASU 2016-09 also requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Furthermore, ASU 2016-09 will increase the amount an employer can withhold to cover income taxes on awards and still qualify for the exception to liability classification for shares used to satisfy the employer's statutory income tax withholding obligation. An employer with a statutory income tax withholding obligation will now be allowed to withhold shares with a fair value up to the amount of taxes owed using the maximum statutory tax rate in the employee's applicable jurisdiction(s). ASU 2016-09 requires a company to classify the cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation as a financing activity on the statement of cash flows. Under current GAAP, it is not specified how these cash flows should be classified. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The Company adopted ASU 2016-09 on January 1, 2017, as required. The adoption did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which requires entities to recognize revenue in a way that depicts the transfer of promised 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. The new guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has subsequently issued ASU 2016-10, *Revenue from Contracts with Customers: (Topic 606) Identifying Performance Obligations and Licensing* to address issues arising from implementation of the new revenue recognition standard. ASU 2014-09 and ASU 2016-10 are effective for interim and annual periods beginning January 1, 2018, and may be adopted earlier, but not before January 1, 2017. The revenue standards are required to be adopted by taking either a full retrospective or a modified retrospective approach. The Company is continuing to assess the impact of the new guidance on its accounting policies and procedures and is evaluating the new requirements as applied to existing revenue contracts. While this assessment is still in progress, the Company believes the most significant impact will relate to the timing of collaboration revenues, where the recognition of variable consideration such as milestone payments may be accelerated. In conjunction with its continuing assessment of the impact of the new guidance, the Company is also evaluating its method of adoption and reviewing and updating its internal controls over financial reporting to ensure that information required to implement the new standard is appropriately captured and recorded. The Company will implement any changes as required to facilitate adoption of the new guidance beginning in the first fiscal quarter of 2018. In addition, the Company continues to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB or others, which may impact its current expectations.

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. The Company is currently evaluating the impact that ASU 2016-01 will have on its condensed consolidated financial statements and related disclosures.

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 similarly to existing guidance for operating leases. 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 impact that ASU 2016-02 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 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. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its condensed consolidated statements of cash flows and related disclosures.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805) Clarifying the Definition of a Business*, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company is currently evaluating the impact of adopting this guidance.

In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit’s carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. This standard, which will be effective for the Company beginning in the first quarter of fiscal year 2021, is required to be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact this standard will have on its condensed consolidated financial statements.

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. This ASU is effective for fiscal years beginning after December 15, 2017, including interim periods within those years. The Company is currently evaluating the impact this standard will have on its condensed consolidated financial statements.

Note 3 - Marketable Securities

Marketable securities consist of the following as of September 30, 2017 and December 31, 2016:

	September 30, 2017			
	Amortized Cost	Gross Unrealized Gain [1]	Gross Unrealized Loss [1]	Fair Value
Short-term available-for-sale securities				
Corporate bonds	$ 39,170,010	$ 10,689	$ (127,878)	$ 39,052,821
Long-term available-for-sale securities				
Corporate bonds	$ 1,006,110	$ -	$ (1,800)	$ 1,004,310
Total	$ 40,176,120	$ 10,689	$ (129,678)	$ 40,057,131

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gain [1]	Gross Unrealized Loss [1]	Fair Value
Short-term available-for-sale securities				
Corporate bonds	$ 22,032,191	$ 3,190	$ (473,056)	$ 21,562,325
Government and agency obligations	1,225,000	661	-	1,225,661
Municipal bonds	1,596,160	4,257	-	1,600,417
	24,853,351	8,108	(473,056)	24,388,403
Long-term available-for-sale securities				
Corporate bonds	2,434,251	1,502	-	2,435,753
	2,434,251	1,502	-	2,435,753
Total	$ 27,287,602	$ 9,610	$ (473,056)	$ 26,824,156

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

The contractual term to maturity of short-term marketable securities held by the Company as of September 30, 2017 is less than one year. The weighted average contractual term to maturity of long-term marketable securities held by the Company is approximately 1.1 years as of September 30, 2017.

The fair value of marketable securities was classified into fair value measurement categories as of September 30, 2017 and December 31, 2016 as follows:

	September 30, 2017	December 31, 2016
Quoted prices in active markets for identical assets (Level 1)	$ -	$ -
Quoted prices for similar assets observable in the marketplace (Level 2)	40,057,131	26,824,156
Significant unobservable inputs (Level 3)	-	-
Total	$ 40,057,131	$ 26,824,156

The fair values of marketable securities are determined using quoted market prices from daily exchange traded markets based on the closing prices as of September 30, 2017 and December 31, 2016.

There were no transfers of marketable securities between Levels 1, 2 or 3 for the nine months ended September 30, 2017 and 2016.

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 September 30, 2017.

	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate bonds	$ 4,504,310	$ (3,130)	$ 28,616,806	$ (126,548)	$ 33,121,116	$ (129,678)
Total	**$ 4,504,310**	**$ (3,130)**	**$ 28,616,806**	**$ (126,548)**	**$ 33,121,116**	**$ (129,678)**

The Company has determined that the unrealized losses are deemed to be temporary as of September 30, 2017. 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 September 30, 2017.

Note 4 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

	Useful life (Years)	September 30, 2017	December 31, 2016
Computer hardware and software	3	$ 86,228	$ 86,228
Lab equipment	3 to 5	282,101	253,735
Office equipment	3 to 5	1,109	1,109
Leasehold improvement	1	68,213	68,213
Construction in progress [(1)]	N/A	474,749	-
Total property, plant and equipment		912,400	409,285
Less: Accumulated depreciation and amortization		(319,274)	(194,598)
Property, plant and equipment, net		$ 593,126	$ 214,687

(1) Construction in progress include the buildout and completion of the manufacturing facility for microbiome platform.

Depreciation expense for the three months ended September 30, 2017 and 2016 was approximately $42,000 and $18,000, respectively, and was recorded in both research and development expense and general and administrative expense in the condensed consolidated statements of operations.

Depreciation expense for the nine months ended September 30, 2017 and 2016 was approximately $125,000 and $55,000, 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:

	September 30, 2017	December 31, 2016
Accrued expenses:		
Salaries, bonuses and employee benefits	$ 3,588,019	$ 2,884,000
Accrued severance expenses	-	241,737
Research and development expenses	2,166,699	916,674
General and administrative expenses	597,794	710,412
Total accrued expenses	$ 6,352,512	$ 4,752,823

Note 6 - Stockholders' Equity

Common Stock

For the nine months ended September 30, 2017, the Company issued an aggregate of 139,019 shares of common stock and received gross proceeds of approximately $1.0 million from the exercise of options.

Options

In July 2010, the Company's stockholders approved the 2010 Equity Incentive Plan (the 2010 Plan). As of September 30, 2017, there were outstanding options to purchase an aggregate of 609,334 shares of common stock under the 2010 Plan. 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 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 (representing an increase of 1,600,000). As of September 30, 2017, there were outstanding options to purchase an aggregate of 3,506,157 shares of common stock and 495,305 shares available for grant under the Amended and Restated 2014 Plan. Additionally, 73,876 shares of common stock forfeited under the 2010 Plan are available for issuance 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 September 30, 2017, there were outstanding options to purchase an aggregate of 147,950 shares of common stock and 652,050 shares available for grant under the Inducement Plan.

Pursuant to the terms of the merger of Assembly Pharmaceuticals, Inc. with a wholly-owned subsidiary of the Company in 2014, the options to purchase shares of Assembly Pharmaceuticals' common stock issued and outstanding immediately prior to the merger were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company's common stock. As of September 30, 2017, assumed options to purchase an aggregate of 596,239 shares of common stock were outstanding.

A summary of the Company's option activity and related information for the nine-month period ended September 30, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value
Outstanding as of December 31, 2016	4,457,251	$ 7.14	$ 23,258,604
Granted	645,750	22.77	7,844,114
Exercised	(142,911)	8.15	-
Forfeited	(100,410)	10.74	-
Outstanding as of September 30, 2017	4,859,680	$ 9.12	$ 125,399,870
Options vested and exercisable	3,273,721	$ 6.71	$ 92,348,773

The fair value of the options granted for the nine months ended September 30, 2017 and 2016, were based on the following assumptions:

	Nine Months Ended September 30,	
	2017	2016
Exercise price	$12.81 - $25.96	$5.84 - $8.14
Expected stock price volatility	83.3% - 87.0%	86.5% - 91.8%
Risk-free rate of interest	2.02% - 2.23%	1.36% - 1.94%
Term (years)	5.5 - 7.0	5.4 - 7.0

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

	Future Stock Option Compensation Expenses
Three Months Ended December 31, 2017	$ 2,345,132
Year Ended December 31, 2018	5,134,745
Year Ended December 31, 2019	1,507,901
Year Ended December 31, 2020	511,557
Year Ended December 31, 2021	27,595
Total	$ 9,526,930

Unamortized stock-based compensation expense amounted to approximately $9.5 million at September 30, 2017. The weighted average remaining amortization period is approximately 1.4 years at September 30, 2017. Effective on January 1, 2017, the Company elected to account for forfeited awards as they occur as permitted by ASU 2016-09. Ultimately, the actual expenses recognized over the vesting period will be for those shares that vested. Prior to making this election, the Company estimated a forfeiture rate for awards at 0%, as the Company did not have a significant history of forfeitures.

Stock-based compensation expense for the three and nine months ended September 30, 2017 and 2016 is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development	$ 1,557,298	$ 772,835	$ 3,735,494	$ 2,341,842
General and administrative	1,039,803	282,208	2,097,516	1,691,194
Total stock-based compensation expense	$ 2,597,101	$ 1,055,043	$ 5,833,010	$ 4,033,036

Warrants

There was no warrant activity for the nine months ended September 30, 2017. The weighted average remaining contractual life of outstanding warrants to purchase 16,909 shares of common stock at September 30, 2017 is approximately 2.7 years.

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).

Under the Collaboration Agreement, 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.

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. At the time of execution of the Collaboration Agreement, there was significant uncertainty as to whether the stated milestones would be achieved. In conjunction with this uncertainty, the Company has determined that the milestones are substantive in nature as they are commensurate with the enhancement of value of the delivered license as they relate to clinical success and advancement within the FDA product development platform. 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 Collaboration Agreement meets the definition of a collaborative arrangement and a multiple-element arrangement. The Company concluded that there were two significant deliverables under the Collaboration Agreement for each of four indicators—the licenses and the research and development services—but that the license does not have stand-alone value as Allergan cannot obtain value from the license without the research and development services, which the Company is uniquely able to perform. The deferred revenue will be amortized over a 10-year service period. 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 indicators to be $12.5 million and expects the elements to deliver over similar times. For the three and nine months ended September 30, 2017, the Company recorded approximately $1.3 million and $3.2 million, respectively, in revenue related to the amortization of deferred revenue. 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 and nine months ended September 30, 2017 were approximately $1.4 million and $2.5 million and recorded in collaboration revenue on the condensed consolidated statement of operations. In the condensed consolidated balance sheet, $1.4 million is recorded as accounts receivable from collaboration as of September 30, 2017.

Note 8 - Commitments and Contingencies

Real Property 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 was to expire December 31, 2017. The Company exercised its right to extend the term of the sublease until June 30, 2018. The Company will document the terms of the extension in the fourth quarter of 2017 and anticipates that the lease will be extended until December 31, 2018. The Company also conducted research activities for the HBV-cure program at laboratory space leased from Indiana University at Bloomington, Indiana until May 2017. The Company transferred the activities that it performed at Indiana University to its Carmel, Indiana and San Francisco, California locations. 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 2018. The Company ceased leasing office and laboratory space from the University of Florida Research Foundation in Alachua, Florida in May 2017.

The total leasing expenses for the three months ended September 30, 2017 and 2016 were approximately $0.4 million and $0.3 million, respectively. The total leasing expenses for the nine months ended September 30, 2017 and 2016 were approximately $1.1 million and $1.1 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 September 30, 2017 and 2016 amounted to approximately $200,000 and $227,000, respectively. The equipment lease expense for the nine months ended September 30, 2017 and 2016 amounted to approximately $560,000 and $483,000, respectively. These equipment leases began to expire in 2017, with the final lease expiring in 2020. The sum of all future payments through termination is approximately $1.9 million.

Litigation

The Company is not a party to any material legal proceedings and is not aware of any claims or actions pending or threatened against it. 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, 2016, 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, 2016 filed with the SEC on March 2, 2017 (2016 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 2016 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.

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 several 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, was observed to be active in primary human hepatocytes and exhibited antiviral potency against all HBV genotypes tested (A, B, C and D) as well as nucleoside resistant mutants. ABI-H0731has completed the Phase 1a portion of a Phase 1a/1b human clinical trial in New Zealand, and commenced the Phase 1b portion of the clinical trial in the second quarter of 2017 in New Zealand and other countries outside the United States. We expect topline interim data from the Phase 1b portion of the clinical trial in the first quarter of 2018 and full results in the first half of 2018. Assuming a successful Phase 1b monotherapy clinical trial, we expect to initiate a longer Phase 2a combination clinical trial in mid-2018 and have initial data in the second half of 2018. A larger Phase 2b combination clinical trial is anticipated for 2019. We have also successfully filed an Investigational New Drug application, or IND, and have initiated an additional Phase 1a pharmacokinetic, safety and tolerability study of ABI-H0731 in the United States.

Our clinical strategy encompasses initial testing of CpAMs as a monotherapy, as required by regulatory agencies, to demonstrate their intrinsic antiviral activity and safety in healthy volunteers and patients. Thereafter, subsequent clinical trials in patients are anticipated to be in combination with other classes of HBV therapies. In the Phase 1a dose ranging portion of our Phase 1a/1b clinical trial of ABI-H0731 in New Zealand, we assessed the safety, tolerability and pharmacokinetics of ABI-H0731 in 48 healthy volunteers. In this clinical trial, single ascending doses between 100-1,000 mg per day were evaluated in addition to 7-day repeat dosing with 800 mg once daily as well as 800 mg twice daily. ABI-H0731 was reported to be well tolerated at all doses. No serious adverse events, no clinically significant adverse events, no withdrawals due to adverse events nor clinically significant changes in vital signs or electrocardiography findings were observed. Treatment emergent laboratory abnormalities were transient, minor and/or deemed not clinically significant. Treatment-related adverse events deemed by the clinical investigator to be possibly or probably related to the study drug included headaches and rashes, which were reported to be mild and transient and only observed at the highest doses. Pharmacokinetic data from the Phase 1a portion of the trial exhibited dose-dependent increases in plasma exposure levels, low subject-to-subject variability and a half-life supporting the potential for once daily dosing. ABI-H0731 was observed to be well absorbed and associated with plasma concentrations that we believe will be sufficient to suppress viral replication and cccDNA generation.

The Phase 1b portion of the clinical trial commenced in the second quarter of 2017 at sites outside the United States. The Phase 1b trial is intended to assess the safety, tolerability and pharmacokinetics, as well as antiviral efficacy of ABI-H0731 in patients with chronic HBV infection. We expect to commence a separate Phase 2a combination clinical trial in mid-2018 in combination with other approved therapies that will treat patients for several months. This Phase 2a clinical trial will assess safety over a prolonged treatment period and monitor surrogate markers of cccDNA. We expect to commence a larger Phase 2b combination clinical trial in 2019 that is intended to be registrational in nature and monitor both surrogate markers of cccDNA and sustained off-therapy antiviral responses in various patient populations.

We recently announced the selection of our second product candidate from this program, ABI-H2158, which is currently undergoing IND enabling studies. ABI-H2158 is an internally discovered and developed drug product candidate. In preclinical studies, we observed increased potency of ABI-H2158 compared to ABI-H0731 while ABI-H2158 maintained a favorable pharmacokinetic profile. Pending the successful completion of IND-enabling studies, this product candidate is expected to begin a Phase 1a human clinical trial in the second half of 2018. We anticipate the selection of a third CpAM product candidate from this program by the end of 2017 or the first quarter of 2018.

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 patent pending delivery system that we call GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. In September 2017, we elected not to initiate a Phase 1b clinical trial of our initial product candidate, ABI-M101, in patients with *Clostridium difficile* infections (CDI) who have relapsed after two or three standard antibiotic regimens. We will continue to assess development activities with respect to ABI-M101 over the next twelve months. 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 IND enabling studies. Using our microbiome platform, we are developing additional product candidates for other disease indications, including irritable bowel syndrome, non-alcoholic steatohepatitis (NASH), immuno-oncology and CDI, which indications we will develop 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.

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 2016 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2016 Annual Report, except for revenue recognition. Our critical accounting policy for revenue recognition is detailed in Note 2.

Results of Operations

Comparison of the Three Months Ended September 30, 2017 and 2016

Revenue

For the three months ended September 30, 2017, collaboration revenue was approximately $2.7 million, which included the amortization of deferred revenue and reimbursement revenue in each case incurred under the Collaboration Agreement. There was no revenue during the same period in 2016.

Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was approximately $9.4 million for the three months ended September 30, 2017, an increase of approximately $1.3 million from approximately $8.1 million for the same period in 2016. The increase was primarily due to an increase of approximately $1.2 million in research expenses for our Microbiome program and an increase of approximately $0.3 million in research expenses for our HBV-cure program.

Stock-based compensation expense was approximately $1.6 million for the three months ended September 30, 2017, an increase of approximately $0.8 million from approximately $0.8 million for the same period in 2016.

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 $3.1 million for the three months ended September 30, 2017, an increase of approximately $0.5 million from approximately $2.6 million for the same period in 2016. The increase was primarily due to an increase of approximately $0.7 million in salary expenses and $0.1 million in professional expenses, and offset by decrease of $0.4 million in legal expenses.

Stock-based compensation expense was approximately $1.0 million for the three months ended September 30, 2017, an increase of approximately $0.7 million from approximately $0.3 million for the same period in 2016.

Comparison of the Nine Months Ended September 30, 2017 and 2016

Revenue

For the nine months ended September 30, 2017, collaboration revenue was approximately $5.7 million, which included the amortization of deferred revenue and reimbursement revenue in each case incurred under the Collaboration Agreement. There was no revenue during the same period in 2016.

Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was approximately $29.9 million for the nine months ended September 30, 2017, an increase of approximately $7.8 million from approximately $22.1 million for the same period in 2016. The increase was primarily due to an increase of approximately $5.1 million in research expenses for our Microbiome program and an increase of approximately $2.7 million in research expenses for our HBV-cure program. The increase in research and development expense for the HBV-cure program and Microbiome program was due to increased expenses incurred under agreements with third parties, including contract research organizations (CRO) that conduct research, pre-clinical activities and clinical trials on our behalf as well as contract manufacturing organizations that manufacture drug and biological products or biologics for use in our pre-clinical and clinical trials.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expense will continue to increase in the foreseeable future as we advance the clinical development of ABI-H0731, ABI-H2158 and our Microbiome program therapeutics.

Stock-based compensation expense was approximately $3.7 million for the nine months ended September 30, 2017, an increase of approximately $1.4 million from approximately $2.3 million for the same period in 2016.

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 $9.9 million for the nine months ended September 30, 2017, an increase of approximately $2.7 million from the $7.2 million expense for the same period in 2016. The increase was primarily due to an increase of $1.6 million in salary expenses, $0.8 million in professional expenses and $0.3 million in legal expenses.

Stock-based compensation expense was approximately $2.1 million for the nine months ended September 30, 2017, an increase of approximately $0.4 million from approximately $1.7 million for the same period in 2016.

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 September 30, 2017 principally through equity financing, raising an aggregate of approximately $192.5 million in net proceeds, and a strategic partnership raising an aggregate of $50 million in upfront payments.

Cash Flows for the Nine Months Ended September 30, 2017 and 2016

Net Cash from Operating Activities

Net cash provided by operating activities was approximately $11.6 million for the nine months ended September 30, 2017 and funded our research and development program build out and general and administrative expenses. It was primarily driven by $46.8 million of deferred revenue related to the Collaboration Agreement, $5.8 million of non-cash stock-based compensation expense and $0.6 million of realized loss from marketable securities, and offset by a $39.8 million of net loss, a $1.8 million of changing in operating assets and liabilities, excluding deferred revenue, and a $0.1 million of deferred income tax benefit.

Net cash used in operating activities was $23.8 million for the nine months ended September 30, 2016. Net cash used in continuing operations for the nine months ended September 30, 2016 was primarily driven by a $32.7 million net loss, and offset by a $4.0 million non-cash expense recorded for stock-based compensation, $4.1 million increase in accounts payable and accrued expenses and $0.6 million realized loss from marketable securities.

Net Cash from Investing Activities

Net cash used in investing activities from continuing operations for the nine months ended September 30, 2017 was $14.0 million and primarily due to a purchase of $40.0 million marketable securities and $0.5 million of fixed assets and construction in progress, and offset by $26.6 million of redemptions of marketable securities.

Net cash provided by investing activities from continuing operations for the nine months ended September 30, 2016 was approximately $20.5 million primarily due to a purchase of $8.0 million of marketable securities and offset by the redemption of $28.5 million of marketable securities during the year.

Net Cash from Financing Activities

Net cash provided by financing activities from continuing operations for the nine months ended September 30, 2017 was $1.0 million, resulting from the exercise of stock options to purchase 142,911 shares of common stock (139,019 shares of common stock on a net exercise basis).

There was no net cash flow provided by financing activities for the nine months ended September 30, 2016.

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 March and April 2015. 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 September 30, 2017, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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 2016 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 September 30, 2017 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, and we are not aware of any claims or actions pending or threatened against us. 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 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 in an early stage of 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 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 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, or BLA, or New Drug Application, or 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 U.S. 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. Any failure to achieve favorable results in clinical development would materially harm our business, 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 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 drug 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;
- the lack of effectiveness 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 for the desired indications could harm the development of that product candidate and 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, 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.

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 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 September 30, 2017, the combined company had an accumulated deficit of approximately $248.0 million, and net losses of approximately $39.8 million and $32.7 million for the nine months ended September 30, 2017 and 2016, respectively. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to incur substantial additional losses over the next several years as we continue to pursue our research, development, nonclinical studies and clinical 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 of ABI-H2158, our second HBV-cure product candidate;
- 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 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 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 accelerated 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 designed to treat disorders associated with the microbiome. To our knowledge, no companies have received regulatory approval for, or manufactured on a commercial scale, a microbiome-based therapeutics. The technology for our microbiome therapy is in nonclinical development and our GEMICEL® dual-targeted release drug formulation is novel and has not yet shown to deliver successfully live bacteria in patients. The ability to deliver effectively and reliably bacteria 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. As a result, our Microbiome program is subject to risks associated with treatment programs lacking precedent.

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 therapy 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 therapy and our Microbiome program. Thereafter, we will need additional capital to fund our operations in the future. There is no assurance that we will be able to generate sufficient revenue from our Collaboration Agreement with Allergan (as defined below) 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 a Research, Development, Collaboration and License Agreement (the Collaboration Agreement) with Allergan Pharmaceuticals International Limited (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 therapy 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 September 30, 2017, 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 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 time frames 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 most 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. Although we intend to establish our own manufacturing capabilities for our microbiome drug substance and drug products, we currently lack the physical plant to formulate and manufacture our own product candidates for use in our planned nonclinical studies and 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 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 FDA approval, 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), c. difficile infections (CDI), nonalcoholic steatohepatitis disease (NASH) and immune-oncology is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We will compete with organizations that have existing treatments and that are or will be developing treatments for the indications that our product candidates target. If our competitors develop effective treatments for HBV, UC, IBD, IBS, CDI, NASH and immune-oncology or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects might be materially harmed, due to intense competition in these markets.

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, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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 payers 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 payers 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 September 30, 2017, we had 80 employees, 10 temporary contractors and various consultants and multiple contract research organizations with whom we have contracted. 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, the EMA 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 U.S. and approvals from the FDA-equivalent 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 a NDA, in the case of our HBV 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 U.S.

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 year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In guidance issued by the Office of Information and Regulatory Affairs within OMB on April 5, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents, and 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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.

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, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices, and the Public Health Service Act, or 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 preclinical 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 U.S. 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 U.S. 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 U.S. 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 U.S. for disease treatments that prove successful; and
- Countries other than the U.S. 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 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 U.S. 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 U.S., the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The U.S. 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 U.S. 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, 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 partner. 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 U.S. 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 U.S., and we may encounter significant problems in securing and defending our intellectual property rights outside the U.S.

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 U.S. 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 or clinical studies or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical 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 September 30, 2017, the closing price of our common stock has fluctuated between $4.54 and $34.92. 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 September 30, 2017, our executive officers, directors and one of our founders beneficially owned approximately 16.7% 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 59.3% 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, 2016, we had potentially utilizable gross Federal net operating loss carryforwards of approximately $146.5 million, State net operating loss carry-forwards of approximately $174.0 million and research and development credit carry forward of approximately $4.0 million, all of which expire between 2027 and 2036. 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.

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, one financial analyst publishes reports about us and our business. We do not control this analyst 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 the analyst who covers us downgrades our stock, our stock price would likely decline rapidly. If this analyst ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On October 12, 2017, the Company reported that Miguel S. Barbosa, Ph.D., Chief Scientific Officer, Head of Microbiome Program, will step down from all of his positions at the Company effective as of the close of business on October 31, 2017. On October 27, 2017, the Compensation Committee of the Board of the Directors, approved (i) the terms and conditions of a Consulting Agreement, which was executed on October 30, 2017 and is effective as of November 1, 2017 (the "Consulting Agreement") under which Dr. Barbosa will provide consulting services to the Company as a strategic advisor until March 31, 2018, and thereafter on a month to month basis, unless earlier terminated by either party. As a consultant to the Company, Dr. Barbosa will receive a fee of $6,000 per month (pro-rated for any partial month) and (ii) an amendment to Dr. Barbosa's stock option grant dated September 26, 2016 (the "Option Amendment"), effective as of November 1, 2017, which (a) reduces the total number of shares underlying the stock option from 190,000 to 62,500, with the remaining 15,000 shares of common stock that are unvested as of the date of the Option Amendment vesting in equal increments of 5,000 shares on each of September 26, 2018, September 26, 2019 and September 26, 2020, provided that Dr. Barbosa is providing services under the Consulting Agreement as of such vesting date and neither party has terminated the Consulting Agreement and (ii) eliminates provisions relating to acceleration of vesting and the extension of the exercise term in connection with a termination of employment. The Consulting Agreement and Option Amendment were executed by the Company and Dr. Barbosa on October 30, 2017. While performing services under the Consulting Agreement, Dr. Barbosa will be deemed to be in "continuous service" such that he will have 90 days following the conclusion of his consulting period to exercise any of his vested options. Except for the foregoing, all other rights and obligations with respect to Dr. Barbosa's equity will be as set forth in the applicable stock option agreement, grant notice and plan documents.

The descriptions of the Consulting Agreement and Option Amendment contained herein do not purport to be complete and are qualified in their entirety by reference to the complete text of the Consulting Agreement and Option Amendment, which will be filed as exhibits to the Company's Annual Report on Form 10-K for the period ended December 31, 2017.

Item 6. Exhibits

Exhibit Number	Description of Document	Filed Herewith	Incorporated by Reference from	Date	Number
10.1	Form of Restricted Stock Award Notice and Restricted Stock Unit Award Agreement under the Amended and Restated 2014 Stock Incentive Plan.	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			

* 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: November 1, 2017

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

Date: November 1, 2017

By: /s/ David J. Barrett
David J. Barrett
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 10.1

ASSEMBLY BIOSCIENCES, INC.
AMENDED AND RESTATED 2014 STOCK INCENTIVE PLAN
RESTRICTED STOCK UNIT AWARD NOTICE

_____ _____
Grant Number

_____

_____

You have been granted Restricted Stock Units ("RSUs") of Assembly Biosciences, Inc. (the "Company"), as follows:

Effective Date:	[ ], 201__
Vesting Commencement Date:	[ ], 201__
Total Number of RSUs Granted:	[ ]
Term/Expiration Date:	[ ]
Vesting Schedule:	[One-third to vest on the first anniversary of the Vesting Commencement Date; Remainder to vest in equal installments on the second and third anniversary of the Vesting Commencement Date.] [Specify Performance Metrics] [Specify Perfomance Metrics + Corporate Transaction and/or Separation of Service triggers]
Payment Date:	The Company shall deliver, to the Grantee named below, one Share (as defined in the Plan) in respect of each vested RSU. Delivery shall be made as soon as practicable following the vesting date and in no event later than 30 days following the applicable vesting date.

By your signature and the signature of the Company's representative below, you and the Company agree that this RSU is granted under and governed by the terms and conditions of the Assembly Biosciences, Inc. Amended and Restated 2014 Stock Incentive Plan (the "Plan") and the Restricted Stock Unit Agreement, all of which are attached and made a part of this document.

Dated: _____

GRANTEE:

_____
[ ]

ASSEMBLY BIOSCIENCES, INC.

By: _____

Name: _____

Title: _____

ASSEMBLY BIOSCIENCES, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT
UNDER THE AMENDED AND RESTATED 2014 STOCK INCENTIVE PLAN

THIS RESTRICTED STOCK UNIT AWARD AGREEMENT (this "Award Agreement") is made and entered into by and between Assembly Biosciences, Inc. (the "Company") and the individual named in the Restricted Stock Unit Award Notice (the "Grantee") under the Company's Amended and Restated 2014 Stock Incentive Plan (the "Plan"). The Award Notice also establishes the Effective Date of the Award, the number of Restricted Stock Units awarded, vesting conditions, and the Payment Date of the Award.

WHEREAS, the Grantee is expected to provide valuable services to the Company;

[Add additional recitals as desired];

WHEREAS, the Company considers it desirable and in the best interests of the Company that the Grantee be given an opportunity to acquire a proprietary interest in the Company as an incentive to advance the interests of the Company and to perform future services that will contribute materially to the successful operation of the Company; and

WHEREAS, the Company, acting through the Board of Directors of the Company (the "Board") or (ii) the Committee appointed by the Board under the Plan (the "Committee"), desires to grant the Grantee a Restricted Stock Unit Award measured in shares of common stock of the Company (the "Common Stock"), in accordance with the Plan. Capitalized terms used herein which are not otherwise defined herein shall have the meanings ascribed to them under the Plan.

NOW, THEREFORE, in consideration of the premises, it is agreed by and between the parties as follows:

1. Grant of Restricted Stock Unit Award. The Company awards the Grantee Restricted Stock Units in a number that is specified in the Award Notice provided to the Grantee. The Award is subject to the vesting, payment and other provisions of this Award Agreement, the Award Notice and the Plan. Each Restricted Stock Unit represents one (1) Share of Common Stock of the Company. The Company will account for the Restricted Stock Units in a bookkeeping account on the Grantee's behalf until they become payable or are forfeited. The number of Restricted Stock Units shall be adjusted if the Common Stock is split, combined, if stock dividends are paid on Common Stock, or upon a similar event in the same manner that the Common Stock is adjusted.

2. Dividend Equivalents. For each Restricted Stock Unit that is granted and credited to the Grantee's account, the Grantee's account will also be credited with a Dividend Equivalent Rights in an amount equal to any cash dividends paid by the Company upon one Share of Common Stock after the Effective Date and before the Payment Date (as provided in the Award Notice) for the Restricted Stock Unit, subject to the vesting and other provisions of this Award Agreement and the Award Notice.

3. Vesting. The Restricted Stock Units (and Dividend Equivalent Rights associated with the Restricted Stock Units) shall be unvested and shall be subject to the restrictions set forth in this Award Agreement and the Award Notice. Unless sooner forfeited in accordance with Section 5, the Restricted Stock Units and Dividend Equivalent Rights associated with the Restricted Stock Unit shall be vested for a Grantee as set forth in the Grantee's Award Notice.

4. Settlement of Vested Restricted Stock Units and Restricted Dividend Equivalents. If any of the Restricted Stock Units vest on a Vesting Date, the Company shall settle such Restricted Stock Units (the "Vested Restricted Stock Units") and Dividend Equivalent Rights attributable to such Vested Restricted Stock Units ("Vested Dividend Equivalents") on the Payment Date established in the Award Notice (the "Payment Date") by delivering to the Grantee (a) a certificate for shares of Common Stock of the Company and (b) cash, determined as follows:

(a) *Number of Shares of Common Stock*. The Company will determine the value as of the Payment Date of the Vested Restricted Stock Units and the Vested Dividend Equivalent Rights (together, the "Total Amount"). For this purpose, the Vested Dividend Equivalents shall be valued at their original value and shall not be increased or decreased by an interest or earnings factor. The Total Amount will be reduced by any tax withholding that is not paid by the Grantee under the procedure in Section 6 below (the amount after the reduction is the "Net Amount"). The Net Amount will be divided by the value of one (1) Common Share of the Company as of the Vesting Date, and the resulting whole number (without remainder) shall be the number of shares of Common Stock that will be delivered to the Grantee, and

(b) *Cash*. The remainder resulting from the division in (a) above to determine the number of shares of Common Stock will be the dollar amount of the cash payable to the Grantee, and such amount shall be paid to the Grantee by check.

The Vested Restricted Stock Units and Vested Dividend Equivalents will be settled by the Company within thirty (30) days of the Payment Date.

5. Forfeiture of Restricted Stock Units (and Dividend Equivalent Rights Attributable to Restricted Stock Units). In the event of Termination of Employment of the Grantee from the Company for any reason (including Disability), any Restricted Stock Units and Dividend Equivalent Rights attributable to such Restricted Stock Units that were not already vested on the termination of Employment shall be forfeited on that date.

6. Certain Tax Matters. The Grantee acknowledges that the Grantee understands the federal, state and local income, employment and foreign (if applicable) tax consequences of the Restricted Stock Unit Award, and the issuance, vesting and forfeiture provisions relating to the Restricted Stock Unit Award.

The Grantee understands that, at the time that the Grantee realizes any compensation income in respect of the Restricted Stock Unit Award, the Company will be required to withhold federal, state and local income and employment taxes on the full amount of the compensation income realized by the Grantee, and if the Grantee is located outside of the United States, the Company may be required to withhold to meet tax, employment, or other obligations imposed by the tax jurisdiction that may be applicable to the Grantee. It is understood that all matters with respect to the total amount of taxes to be withheld in respect of such compensation income shall be determined by the Board (or the Committee) in its reasonable discretion. It is understood that although the Company may pay withheld amounts for the taxing jurisdiction that may be credited to the Grantee against taxes due by the Grantee, the Grantee is responsible for payment of all taxes due as a result of compensation arising under this Award Agreement.

The Board (or the Committee) may make such provisions and take such steps as it may deem necessary or appropriate for the withholding of taxes by the Company on compensation income the Grantee realizes. The Company shall accept payment by the Grantee of an amount in cash for all or part of the withholding obligation of the Company on the compensation income, so that the payment(s) to the Grantee under this Award Agreement are not reduced for tax withholding to the extent of the payment. Such payment by the Grantee must be made to the Company by the time that the Company is required to pay the withholding to the taxing authority, but in any event not later than thirty (30) days from the Payment Date. If the Grantee does not make a payment for the full withholding obligation, the Company shall withhold part of the payment due for redemption of the Vested Restricted Stock Units and Vested Dividend Equivalent Rights in the amount needed by the Company to meet its withholding obligations, with the result that the payment amount for the Vested Restricted Stock Units and Vested Dividend Equivalent Rights will be reduced as provided in Section 4(a) above by the amount needed to meet the Company's withholding obligations.

7. Rights Prior to Vesting. The Restricted Stock Units and Dividend Equivalent Rights represent a right to payment from the Company if the conditions of this Award Agreement are met and do not give the Grantee ownership of any Common Stock prior to delivery as provided in Section 4. No assets have been set aside by the Company or otherwise to pay the amounts promised by this Award Agreement, the right to payment is unsecured, and the Grantee is a general creditor of the Company for payment under this Award Agreement.

8. Investment Representation. The Grantee represents and warrants to the Company that the Grantee has read this Award Agreement carefully, and to the extent believed necessary, has discussed this Award Agreement and its impact and limitations upon the Grantee with counsel.

9. Transferability. The right to payment under this Award Agreement may not be sold, exchanged, transferred, pledged, hypothecated, encumbered or otherwise disposed of except as provided in the Plan. The Company shall have the right to assign to any of its affiliates any of its rights, or to delegate to any of its affiliates any of its obligations under this Award Agreement.

10. Binding Effect. This Award Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns.

11. Gender and Number. All terms used in this Award Agreement shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the context may require.

12. Terms and Conditions of Plan. The terms and conditions included in the Plan and the Award Notice are incorporated by reference herein, and to the extent that any conflict may exist between any term or provision of this Award Agreement and any term or provision of the Plan as in effect from time to time, such term or provision of the Plan shall control.

13. Certain Remedies. Without intending to limit the remedies available to the Company, the Grantee agrees that damages at law will be an insufficient remedy in the event the Grantee violates the terms of this Award Agreement. The Grantee agrees that the Company may apply for and have injunctive or other equitable relief in any court of competent jurisdiction to restrain the breach or threatened breach of, or otherwise specifically to enforce, any of the provisions hereof.

14. Waiver. The waiver by either party of compliance with any provision of this Award Agreement by the other party shall not operate or be construed as a waiver of any other provision of this Award Agreement, or of any subsequent breach by such party of a provision of this Award Agreement.

15. No Restriction on Right of Company to Effect Corporate Changes. Neither the Plan nor this Award Agreement shall affect in any way the right or power of the Company or its stockholders to make or authorize any or all adjustments, recapitalizations, reorganizations or other changes in the capital structure or business of the Company, or any merger or consolidation of the Company, or any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of the assets or business of the Company, or any other corporate act or proceeding, whether of a similar character or otherwise.

16. Entire Agreement. This Award Agreement (including the Award Notice, and the Plan which is incorporated herein by reference and all additional riders incorporated herein) sets forth all of the promises, agreements, conditions and understandings between the parties hereto with respect to the Award, and there are no promises, agreements, conditions, understandings, warranties or representations, oral or written, express or implied, between them with respect to the Restricted Stock Unit Award other than as set forth therein or herein. This Award Agreement supersedes and replaces any and all prior agreements between the parties hereto with respect to Restricted Stock Units and Dividend Equivalent Rights. This Award Agreement is, and is intended by the parties to be, an integration of any and all prior agreements or understandings, oral or written, with respect to Restricted Stock Units and Dividend Equivalent Rights. No modification, amendment or waiver of any of the provisions of this Award Agreement shall be effective unless approved in writing by both parties.

17. Invalid or Unenforceable Provision. The invalidity or unenforceability of any particular provision of this Award Agreement shall not affect the other provisions hereof, and this Award Agreement shall be construed in all respects as if such invalid or unenforceable provision was omitted.

18. Governing Law. This Award Agreement shall be construed and enforced in accordance with the laws of Delaware, without giving effect to principles of conflicts of laws.

19. Miscellaneous.

(a) Neither the granting or vesting of the Restricted Stock Units and Dividend Equivalent Rights nor any other provision of this Award Agreement shall be construed as conferring upon the Grantee any right to continue in the employment of the Company, or as interfering with or restricting in any way the right of the Company to terminate such employment at any time.

(b) The Company, the Board (or the Committee) and any employees or agents thereof are relieved from any liability for the non-issuance or non-transfer, or any delay in the issuance or transfer, of any Common Stock which results from the inability of the Company to obtain, or in any delay in obtaining, from each regulatory body having jurisdiction all requisite authority to issue or transfer the Common Stock in satisfaction of this Award Agreement if counsel for the Company deems such authorization necessary for the lawful issuance or transfer of any of the Common Stock.

(c) No Common Stock shall be sold or otherwise disposed of in violation of any federal or state securities law or regulations.

(d) All decisions of the Board (or the Committee) with respect to the interpretation, construction and application of the Plan and/or this Award Agreement shall be conclusive and binding upon the Grantee and all other persons.

(e) This Award Agreement has been drafted with the intent that payments (and the right to payments) under it comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations thereunder applicable to nonqualified deferred compensation. This Award Agreement shall be interpreted in a manner consistent with such intent.

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: November 1, 2017

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

EXHIBIT 31.2

CERTIFICATION

I, David J. Barrett, 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: November 1, 2017

By: /s/ David J. Barrett
David J. Barrett
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 September 30, 2017 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: November 1, 2017

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 September 30, 2017 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, David J. Barrett, 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/ David J. Barrett
David J. Barrett
Chief Financial Officer and Chief Operating Officer

Date: November 1, 2017