

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 June 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

(State or other jurisdiction of
incorporation or organization)

20-8729264

(I.R.S. Employer Identification No.)

11711 N. Meridian St., Suite 310

Carmel, IN

(Address of principal executive offices)

46032

(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

Non-accelerated Filer (Do not check if smaller reporting company)

Emerging growth company

Accelerated Filer

Smaller Reporting 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 August 3, 2017, there were 17,364,439 shares of registrant's common stock outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

**ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS**

	June 30, 2017	December 31, 2016
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 39,452,737	\$ 28,575,085
Marketable securities, at fair value	36,123,684	24,388,403
Accounts receivable	1,113,759	-
Prepaid expenses and other current assets	978,356	611,176
Total current assets	77,668,536	53,574,664
Long-term assets		
Marketable securities, at fair value	3,008,840	2,435,753
Property, plant and equipment, net	131,857	214,687
Security deposits	327,250	255,366
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	45,106,083	44,543,942
Total assets	\$ 122,774,619	\$ 98,118,606
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 687,908	\$ 2,368,131
Accrued expenses	6,305,547	4,752,823
Deferred revenue - short-term	4,995,894	-
Total current liabilities	11,989,349	7,120,954
Long-term liabilities		
Deferred tax liabilities	11,176,072	11,119,651
Deferred revenue - long-term	43,074,186	-
Total long-term liabilities	54,250,258	11,119,651
Total liabilities	66,239,607	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; 17,360,689 and 17,246,754 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	17,361	17,247
Additional paid-in capital	292,672,842	288,688,990
Accumulated other comprehensive loss	(398,267)	(600,769)
Accumulated deficit	(235,756,924)	(208,227,467)
Total stockholders' equity	56,535,012	79,878,001
Total liabilities and stockholders' equity	\$ 122,774,619	\$ 98,118,606

See Notes to Condensed Consolidated Financial Statements.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Collaboration revenue	\$ 2,359,311	\$ -	\$ 3,043,680	\$ -
Operating expenses:				
Research and development	12,125,021	7,519,031	22,698,760	15,637,607
General and administrative	3,801,541	2,935,099	7,842,000	6,093,675
Total operating expenses	<u>15,926,562</u>	<u>10,454,130</u>	<u>30,540,760</u>	<u>21,731,282</u>
Loss from operations	<u>(13,567,251)</u>	<u>(10,454,130)</u>	<u>(27,497,080)</u>	<u>(21,731,282)</u>
Other income (expenses)				
Interest and other income	239,858	444,605	376,342	935,026
Realized loss from marketable securities	(340,984)	(142,675)	(478,232)	(344,502)
Total other income	<u>(101,126)</u>	<u>301,930</u>	<u>(101,890)</u>	<u>590,524</u>
Loss before income taxes	<u>(13,668,377)</u>	<u>(10,152,200)</u>	<u>(27,598,970)</u>	<u>(21,140,758)</u>
Income tax benefit	69,513	-	69,513	-
Net loss	<u>\$ (13,598,864)</u>	<u>\$ (10,152,200)</u>	<u>\$ (27,529,457)</u>	<u>\$ (21,140,758)</u>
Other comprehensive (loss) income				
Unrealized loss recognized in accumulated other comprehensive loss before reclassification, net of tax benefit of \$57,437, \$0, \$57,437 and \$0, respectively	(31,203)	(232,542)	(92,359)	(362,279)
Reclassification adjustment of unrealized loss included in net loss, net of tax expense of \$183,371, \$0, \$183,371 and \$0, respectively	157,613	142,675	294,861	344,502
Comprehensive loss	<u>\$ (13,472,454)</u>	<u>\$ (10,242,067)</u>	<u>\$ (27,326,955)</u>	<u>\$ (21,158,535)</u>
Net loss per share, basic and diluted	<u>\$ (0.78)</u>	<u>\$ (0.59)</u>	<u>\$ (1.59)</u>	<u>\$ (1.23)</u>
Weighted average common shares outstanding, basic and diluted	<u>17,342,623</u>	<u>17,225,660</u>	<u>17,305,657</u>	<u>17,225,661</u>

See Notes to Condensed Consolidated Financial Statements.

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

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	\$ (27,529,457)	\$ (21,140,758)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	82,830	37,093
Stock-based compensation	3,235,908	2,977,993
Realized loss from marketable securities	478,232	344,503
Deferred income tax benefit	(69,513)	-
Changes in operating assets and liabilities:		
Accounts receivable	(1,113,759)	-
Prepaid expenses and other current assets	(367,180)	147,643
Accounts payable	(1,680,223)	1,050,224
Accrued expenses	1,552,724	591,742
Deferred revenue	48,070,080	-
Security deposits	(71,884)	13,460
Net cash provided by (used in) operating activities	<u>22,587,758</u>	<u>(15,978,100)</u>
Cash flows from investing activities		
Purchases of fixed assets	-	(2,163)
Purchases of marketable securities	(32,591,164)	(7,951,257)
Redemptions of marketable securities	20,133,000	17,165,332
Net cash (used in) provided by investing activities	<u>(12,458,164)</u>	<u>9,211,912</u>
Cash flows from financing activities		
Proceeds from the exercise of stock options	748,058	-
Net cash provided by financing activities	<u>748,058</u>	<u>-</u>
Net increase (decrease) in cash and cash equivalents	10,877,652	(6,766,188)
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	<u>\$ 39,452,737</u>	<u>\$ 20,341,338</u>
Supplemental disclosure of cash flow information:		
Change in unrealized gain (loss) on marketable securities available-for-sale, before tax expense	\$ 328,436	\$ (17,777)

See Notes to Condensed Consolidated Financial Statements.

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

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
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	113,935	114	747,944	-	-	748,058
Change in unrealized gain on marketable securities, net of income tax expense of \$125,934	-	-	-	202,502	-	202,502
Stock-based compensation	-	-	3,235,908	-	-	3,235,908
Net loss	-	-	-	-	(27,529,457)	(27,529,457)
Balance as of June 30, 2017	17,360,689	\$ 17,361	\$ 292,672,842	\$ (398,267)	\$(235,756,924)	\$ 56,535,012

See Notes to Condensed Consolidated Financial Statements.

ASSEMBLY BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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 therapeutics for the treatment of hepatitis B virus (HBV) infection and a novel class of oral synthetic live biotherapeutics, which are designed to restore health to a dysbiotic microbiome. The Company's HBV-cure program is aimed at increasing the current low cure rate for patients with HBV and is pursuing multiple drug candidates that inhibit multiple steps of the HBV lifecycle. Assembly has discovered several novel Core protein Allosteric Modulators (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 a Phase 1a human clinical trial, and the Phase 1b/2a portion of the clinical trial commenced in the second quarter of 2017. 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 allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. The lead product candidate from this platform, ABI-M101, is in development for the treatment of *clostridium difficile* infections (CDI). Using its microbiome platform, the Company is developing additional product candidates for other disease indications, 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 ¾, ½ 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.

ASSEMBLY BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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 June 30, 2017, condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2017 and 2016, condensed consolidated statements of cash flows for the six months ended June 30, 2017 and 2016, and condensed consolidated statement of changes in stockholders' equity for the six months ended June 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 six months ended June 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 as 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 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.

ASSEMBLY BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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 June 30, 2017 and 2016 are as follows:

	Six Months Ended June 30,	
	2017	2016
Warrants to purchase common stock	16,909	16,909
Options to purchase common stock	4,837,464	4,097,952
Total	4,854,373	4,114,861

ASSEMBLY BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

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. As of June 30, 2017, the Company has not elected early adoption and has not concluded on an adoption method. The Company is in the process of analyzing the Company's collaboration agreement and the potential impact the standard may have on previously reported revenues and future revenues. The Company is still evaluating the impact on the condensed consolidated financial statements and related disclosures.

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.

ASSEMBLY BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UnAUDITED)

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, and interim periods within those years, beginning after December 15, 2017. 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 June 30, 2017 and December 31, 2016:

	June 30, 2017			
	<u>Amortized Cost</u>	<u>Gross Unrealized Gain ⁽¹⁾</u>	<u>Gross Unrealized Loss ⁽¹⁾</u>	<u>Fair Value</u>
Short-term available-for-sale securities				
Corporate bonds	\$ 36,255,433	\$ 10,173	\$ (141,922)	\$ 36,123,684
Long-term available-for-sale securities				
Corporate bonds	\$ 3,012,100	\$ -	\$ (3,260)	\$ 3,008,840
Total	<u>\$ 39,267,533</u>	<u>\$ 10,173</u>	<u>\$ (145,182)</u>	<u>\$ 39,132,524</u>

(1) pre-tax

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	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
	<u>24,853,351</u>	<u>8,108</u>	<u>(473,056)</u>	<u>24,388,403</u>
Long-term available-for-sale securities				
Corporate bonds	2,434,251	1,502	-	2,435,753
	<u>2,434,251</u>	<u>1,502</u>	<u>-</u>	<u>2,435,753</u>
Total	<u>\$ 27,287,602</u>	<u>\$ 9,610</u>	<u>\$ (473,056)</u>	<u>\$ 26,824,156</u>

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

The contractual term to maturity of short-term marketable securities held by the Company as of June 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 June 30, 2017.

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

	June 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)	39,132,524	26,824,156
Significant unobservable inputs (Level 3)	-	-
Total	<u>\$ 39,132,524</u>	<u>\$ 26,824,156</u>

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

There were no transfers of marketable securities between Levels 1, 2 or 3 for the six months ended June 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 June 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	\$ 4,152,931	\$ (4,413)	\$ 29,289,584	\$ (140,769)	\$ 33,442,515	\$ (145,182)
Total	<u>\$ 4,152,931</u>	<u>\$ (4,413)</u>	<u>\$ 29,289,584</u>	<u>\$ (140,769)</u>	<u>\$ 33,442,515</u>	<u>\$ (145,182)</u>

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

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Note 4 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

	<u>Useful life (Years)</u>	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Computer hardware and software	3	\$ 86,228	\$ 86,228
Lab equipment	3 to 5	253,735	253,735
Office equipment	3 to 5	1,109	1,109
Leasehold improvement	1	68,213	68,213
Total property, plant and equipment		<u>409,285</u>	<u>409,285</u>
Less: Accumulated depreciation and amortization		<u>(277,428)</u>	<u>(194,598)</u>
Property, plant and equipment, net		<u>\$ 131,857</u>	<u>\$ 214,687</u>

Depreciation expense for the three months ended June 30, 2017 and 2016 was approximately \$51,000 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 six months ended June 30, 2017 and 2016 was approximately \$83,000 and \$37,000, 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:

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Accrued expenses:		
Salaries, bonuses and employee benefits	\$ 2,585,127	\$ 2,884,000
Accrued severance expenses	310,298	241,737
Research and development expenses	2,771,227	916,674
General and administrative expenses	638,895	710,412
Total accrued expenses	<u>\$ 6,305,547</u>	<u>\$ 4,752,823</u>

Note 6 - Stockholders' Equity

Common Stock

For the six months ended June 30, 2017, the Company issued an aggregate of 113,935 shares of common stock and received gross proceeds of approximately \$0.7 million from the exercise of options.

Options

In July 2010, the stockholders approved the 2010 Equity Incentive Plan (the 2010 Plan). As of June 30, 2017, there were outstanding options to purchase an aggregate of 610,334 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 stockholders approved the 2014 Stock Incentive Plan (the 2014 Plan). On June 2, 2016, at the 2016 Annual Meeting of Stockholders, the stockholders of the Company approved the amendment and restatement of the Company's 2014 Plan (the Amended and Restated 2014 Plan). Pursuant to the terms of the Amended and Restated 2014 Plan, the maximum number of shares reserved for issuance thereunder is 4,160,000 (representing an increase of 1,600,000). As of June 30, 2017, there were outstanding options to purchase an aggregate of 3,541,141 shares of common stock and 485,155 shares available for grant under the Amended and Restated 2014 Plan. Additionally, 73,126 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 Board of Directors of the Company 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 June 30, 2017, there were outstanding options to purchase an aggregate of 89,750 shares of common stock and 710,250 shares available for grant under the Inducement Plan.

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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 June 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 six-month period ended June 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	583,250	22.93	784,000
Exercised	(117,827)	7.13	-
Forfeited	(85,210)	9.71	-
Outstanding as of June 30, 2017	<u>4,837,464</u>	<u>\$ 9.00</u>	<u>\$ 58,428,762</u>
Options vested and exercisable	<u>3,200,688</u>	<u>\$ 6.70</u>	<u>\$ 44,640,661</u>

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

	Six Months Ended June 30,	
	2017	2016
Exercise price	\$12.81 - \$25.96	\$5.84 - \$7.03
Expected stock price volatility	84.4% - 87.0%	88.2% - 91.8%
Risk-free rate of interest	2.02% - 2.23%	1.36% - 1.94%
Expected 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
Six Months Ended December 31, 2017	\$ 4,648,866
Year Ended December 31, 2018	4,775,098
Year Ended December 31, 2019	1,355,710
Year Ended December 31, 2020	441,243
Year Ended December 31, 2021	15,854
Total	<u>\$ 11,236,771</u>

Unamortized stock-based compensation expense amounted to approximately \$11.2 million at June 30, 2017. The weighted average remaining amortization period is approximately 1.5 years at June 30, 2017. Effective on January 1, 2017, the Company elected to account for forfeitures 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 their forfeiture rate at 0%, or they did not have a significant history of forfeitures.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	\$ 1,226,269	\$ 850,851	\$ 2,178,195	\$ 1,569,007
General and administrative	784,992	667,287	1,057,713	1,408,986
Total stock-based compensation expense	<u>\$ 2,011,261</u>	<u>\$ 1,518,138</u>	<u>\$ 3,235,908</u>	<u>\$ 2,977,993</u>

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Warrants

There was no warrant activity for the six months ended June 30, 2017. The weighted average remaining contractual life of outstanding warrants to purchase 16,909 shares of common stock at June 30, 2017 is approximately 2.9 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 drug 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 $\frac{2}{3}$, $\frac{1}{3}$ 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 $\frac{1}{3}$ of such costs in excess of \$75 million or (b) to allow Allergan to deduct from future development milestone payments $\frac{1}{3}$ 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 United States 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 six months ended June 30, 2017, the Company recorded approximately \$1.2 million and \$1.9 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 six months ended June 30, 2017 were \$1.1 million and recorded in collaboration revenue on the condensed consolidated statement of operations.

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 expires in December 2017, unless the Company requests a six month extension by October 2, 2017. 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.

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The total leasing expenses for the three months ended June 30, 2017 and 2016 were approximately \$0.3 million and \$0.4 million, respectively. The total leasing expenses for the six months ended June 30, 2017 and 2016 were approximately \$0.6 million and \$0.8 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 June 30, 2017 and 2016 amounted to approximately \$180,000 and \$165,000, respectively. The equipment lease expense for the six months ended June 30, 2017 and 2016 amounted to approximately \$359,000 and \$256,000, 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 \$1.3 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 therapeutics for the treatment of hepatitis B virus (HBV) infection and novel class of oral synthetic live biotherapeutics, which are designed to restore health to a dysbiotic microbiome. Our HBV-cure program is aimed at increasing the current low cure rate for patients with HBV and is pursuing multiple drug candidates that inhibit multiple steps of the HBV lifecycle. We have discovered several novel Core protein Allosteric Modulators (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 a Phase 1a human clinical trial, and the Phase 1b/2a portion of the clinical trial commenced in the second quarter of 2017. 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 allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. The lead product candidate from this platform, ABI-M101, is in development for the treatment of *clostridium difficile* infections (CDI). Using our microbiome platform, we are developing additional product candidates for other disease indications, which 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 2/3, 1/3 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. We closed our research facilities in Alachua, Florida and Bloomington, Indiana in May 2017. Research activities for the HBV-cure program are also being conducted at Indiana University at Bloomington, under the aegis of Adam Zlotnick, Ph.D., co-founder of Assembly Pharmaceuticals, Inc. and head of our HBV Scientific Advisory Board.

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 June 30, 2017 and 2016

For the three months ended June 30, 2017, collaboration revenue was approximately \$2.4 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 \$10.9 million for the three months ended June 30, 2017, an increase of approximately \$4.2 million from approximately \$6.7 million for the same period in 2016. The increase was primarily due to an increase of approximately \$2.9 million in research expenses for our Microbiome program and an increase of approximately \$1.3 million in research expenses for our HBV-cure program.

Stock-based compensation expense was approximately \$1.2 million for the three months ended June 30, 2017, an increase of approximately \$0.3 million from approximately \$0.9 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 \$3.0 million for the three months ended June 30, 2017, an increase of approximately \$0.7 million from approximately \$2.3 million for the same period in 2016. The increase was primarily due to an increase of approximately \$0.6 million in salary expenses and \$0.1 million in legal expenses.

Stock-based compensation was approximately \$0.8 million for the three months ended June 30, 2017, an increase of approximately \$0.1 million from approximately \$0.7 million for the same period in 2016.

Comparison of the Six Months Ended June 30, 2017 and 2016

For the six months ended June 30, 2017, collaboration revenue was approximately \$3.0 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 \$20.5 million for the six months ended June 30, 2017, an increase of approximately \$6.4 million from approximately \$14.1 million for the same period in 2016. The increase was primarily due to an increase of approximately \$3.9 million in research expenses for our Microbiome program and an increase of approximately \$2.5 million in research expenses for our HBV-cure program.

Stock-based compensation expense was approximately \$2.2 million for the six months ended June 30, 2017, an increase of approximately \$0.6 million from approximately \$1.6 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 \$6.8 million for the six months ended June 30, 2017, an increase of approximately \$2.1 million from approximately \$4.7 million for the same period in 2016. The increase was primarily due to an increase of approximately \$0.9 million in salary expenses, \$0.7 million in professional expenses and \$0.5 million in legal expenses.

Stock-based compensation was approximately \$1.1 million for the six months ended June 30, 2017, a decrease of approximately \$0.3 million from approximately \$1.4 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 June 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 Six Months Ended June 30, 2017 and 2016

Net Cash from Operating Activities

Net cash provided by operating activities was approximately \$22.6 million for the six months ended June 30, 2017 and funded our research and development program build out and general and administrative expenses. It was primarily driven by \$48.1 million of deferred revenue related to the Collaboration Agreement, \$3.2 million of non-cash stock-based compensation expense and \$0.5 million of realized loss from marketable securities, and offset by a \$27.5 million of net loss, an increase of \$1.5 million of operating assets and a decrease of \$0.2 million in operating liabilities, excluding deferred revenue.

Net cash used in operating activities was \$16.0 million for the six months ended June 30, 2016 and funded our research and development and general and administrative expenses. Net cash used in continuing operations for the six months ended June 30, 2016 was primarily driven by a \$21.1 million net loss, and offset by a \$3.0 million non-cash expense recorded for the stock-based compensation, \$1.6 million increase in accounts payable and accrued expenses and \$345,000 realized loss from marketable securities.

Net Cash from Investing Activities

Net cash used in investing activities from continuing operations for the six months ended June 30, 2017 was \$12.5 million and primarily due to a purchase of \$32.6 million marketable securities, and offset by \$20.1 million of the redemption of marketable securities.

Net cash provided by investing activities from continuing operations for the six months ended June 30, 2016 was \$9.2 million and primarily due to a purchase of \$8.0 million of marketable securities and offset by the redemption of \$17.2 million of marketable securities.

Net Cash from Financing Activities

Net cash provided by financing activities from continuing operations for the six months ended June 30, 2017 was \$0.7 million, resulting from the exercise of stock options to purchase 113,935 shares of common stock.

There was no net cash flow provided by financing activities for the six months ended June 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 June 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 drug 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, which 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 June 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 hepatitis B virus (HBV) and microbiome therapies. 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 or nonclinical studies. We cannot predict when or if any one of our product candidates will prove effective or safe 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, which has one product candidate in early clinical development, and our Microbiome program, which has one product candidate in late nonclinical development. We cannot be certain that we 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.

ABI-H0731 and ABI-M101 are our lead product candidates for our HBV-cure and Microbiome program, respectively. We have completed the Phase 1a portion of a Phase 1a/1b clinical trial for ABI-H0731, our novel oral agent for the treatment of chronic HBV. We initiated the Phase 1b/2a portion of the trial in the second quarter of 2017. Our lead microbiome biotherapeutic product candidate, ABI-M101, is in late nonclinical development and we plan to initiate a Phase 1b clinical trial of ABI-M101 in *clostridium difficile* infections (CDI) patients who have relapsed after two or three standard antibiotic regimens in the second half of 2017. 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.

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 New Drug Applications (NDAs) or Biologics License Applications (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 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.

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 June 30, 2017, the combined company had an accumulated deficit of approximately \$235.8 million, and net losses of approximately \$27.5 million and \$21.1 million for the six months ended June 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 HBV-cure candidate, through clinical development and initiate and conduct clinical trials of ABI-M101, our microbiome product candidate;
- continue to undertake research and development to identify potential additional product candidates;
- 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;
- 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 successfully commercialize 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, as a result, we may not be able to successfully develop products for commercial use.

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins with Core protein Allosteric Modulators (CpAMs), which is a clinically unproven mechanism of action. The development of our CpAM technology is in the early stages, and the commercial feasibility and acceptance of our CpAM technology are unknown. Similarly, to our knowledge, no companies have received regulatory approval for microbiome-based therapeutics. The technology for our microbiome therapy is in nonclinical development and our GEMICEL®, dual targeted release drug formulation, is novel and not yet shown to successfully deliver live bacteria in patients. As a result, our Microbiome program is subject to risks associated with treatment programs lacking precedent.

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. More specifically, the theory that CpAMs can selectively lower covalently closed circular DNA (cccDNA) and viral antigen levels in HBV patients and achieve a functional cure is unproven. Thus, even if CpAM technology is successful at targeting the HBV core protein and 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, with respect to our Microbiome program, the ability to effectively and reliably deliver 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 successfully develop commercial products, we will be unable to generate revenue or build a sustainable or profitable business.

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

We anticipate that we will incur operating losses for the next several years as we continue to develop our HBV 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. However, 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 are 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 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 our HBV therapy, requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to our HBV therapy. 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 June 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. Also, 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.

Unforeseen safety issues could hinder the development of our product candidates and their adoption, if approved.

Safety issues could arise during development of our product candidates, which might delay testing or prevent further development entirely. Unforeseen safety issues could emerge in any future study or trial of our HBV or microbiome product candidates, which could severely hamper the likelihood of FDA or other regulatory approval of any such product candidate. If any of these events were to occur, the development of any product candidate could be significantly delayed and become more expensive than anticipated, and could lead us to abandon our development efforts entirely, any of which would have a significant adverse effect on our business.

If a product is approved, any limitation on use that might be necessary due to safety issues, such as labeling warnings or distributions and use restrictions under a risk evaluation mitigation strategy (REMS) could hinder its adoption in the marketplace. In addition, if any product is approved, it could be used against any instructions that we publish that limit its use, which could subject us to litigation.

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 successfully develop our product candidates. In addition, any failures by third parties to adequately perform 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, 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.

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 Phase 1 clinical trials and drug substance and drug product for ABI-M101. 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 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.
- 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 successfully produce, store and distribute our products.
- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. Any internal manufacturing facilities we establish may fail to comply, and we would not have complete control over any third-party manufacturers' compliance, with these regulations and requirements.

- We may be required to obtain additional intellectual property rights from third parties in order to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors.
- We may be required to share our trade secrets and know-how with third parties, thereby risking the misappropriation or disclosure of our intellectual property by or to third parties.
- If we contract with third-party manufacturers, we might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

Each of these risks could delay our development efforts, nonclinical studies and clinical 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 cannot compete successfully for market share against other drug 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 therapies 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 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, CDI, ulcerative colitis (UC), irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) 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, CDI, UC, IBS or IBD 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.

If we 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;
- 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 Chief Executive Officer and President, Derek A. Small; our Chief Scientific Officer, Richard J. Colonno, Ph.D.; our Chief Scientific Officer - Microbiome and Head of Microbiome Program, Miguel S. Barbosa, Ph.D.; our Chief Medical Officer and Vice President of Research and Development, Uri Lopatin, M.D.; our Chief Development Officer, Thomas E. Rollins; and our Chief Financial Officer and Chief Operating Officer, David J. Barrett. Our employment agreements with Mr. Small, Dr. Lopatin, Dr. Colonno, Dr. Barbosa, Mr. Rollins and Mr. Barrett do not ensure their retention. This is also true for our other management team members, both present and future.

Furthermore, our future success also depends, in part, on our ability to identify, hire, and retain additional management team members as our operations grow. 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 June 30, 2017, we had 78 employees, 13 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 biotherapeutics 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 successfully develop 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 efficiently integrate 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 subject to extensive and costly government regulation.

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. The FDA regulates the research, development, nonclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical and biological products. 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 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.

We might not obtain the necessary U.S. or foreign regulatory approvals to commercialize any product candidate.

We 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 New Drug Application (NDA) or biologics license application (BLA) 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 approved, our product candidates will be subject to extensive post-approval regulation.

Once a product candidate is approved, numerous post-approval requirements apply. Among other things, the holder of an approved NDA 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. 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.

Even if we are able to commercialize any product candidates, those products may become subject to unfavorable pricing regulations, third-party 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 successfully commercialize 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 promptly obtain 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 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 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 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 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 employee 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 and other anti-bribery laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, 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. 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, as 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 effectively maintain 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 effectively enforce 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 June 30, 2017, the closing price of our common stock has fluctuated between \$4.54 and \$27.54. 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.

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 June 30, 2017, our executive officers, directors and one of our founders beneficially owned approximately 17.0% of our outstanding voting common stock, and this group together with other stockholders holding beneficially 5% or more of our outstanding voting common stock, owned approximately 60.0% 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 Amended and Restated Certificate of Incorporation and Bylaws 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 Amended and Restated Certificate of Incorporation and Bylaws 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:

- 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;
- 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, two financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If any of the analysts who cover us downgrade our stock, our stock price would likely decline rapidly. If these analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

Exhibit Number	Description of Document	Filed Herewith	Incorporated by Reference from	Date	Number
10.1	Assembly Biosciences, Inc. 2017 Inducement Award Plan (the 2017 Inducement Award Plan).	X			
10.2	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2017 Inducement Award Plan.	X			
10.3	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2017 Inducement Award 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: August 9, 2017

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

Date: August 9, 2017

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

ASSEMBLY BIOSCIENCES, INC.

2017 INDUCEMENT AWARD PLAN

1. **Purposes of the Plan.** The purposes of this Plan are to attract and retain the best available personnel, to provide an inducement material for such persons to enter into employment with the Company or a Related Party within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules and to promote the success of the Company's business.

2. **Definitions.** The following definitions shall apply as used herein and in the individual Award Agreements except as defined otherwise in an individual Award Agreement. In the event a term is separately defined in an individual Award Agreement, such definition shall supersede the definition contained in this Section 2.

(a) "**Administrator**" means the Board or any of the Committees appointed to administer the Plan.

(b) "**Affiliate**" and "**Associate**" shall have the respective meanings ascribed to such terms in Rule 12b-2 promulgated under the Exchange Act.

(c) "**Applicable Laws**" means the legal requirements relating to the Plan and the Awards under applicable provisions of federal and state securities laws, the corporate laws of California and, to the extent other than California, the corporate law of the state of the Company's incorporation, the Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to Awards granted to residents therein.

(d) "**Assumed**" means that pursuant to a Corporate Transaction either (i) the Award is expressly affirmed by the Company or (ii) the contractual obligations represented by the Award are expressly assumed (and not simply by operation of law) by the successor entity or its Parent in connection with the Corporate Transaction with appropriate adjustments to the number and type of securities of the successor entity or its Parent subject to the Award and the exercise or purchase price thereof which at least preserves the compensation element of the Award existing at the time of the Corporate Transaction as determined in accordance with the instruments evidencing the agreement to assume the Award.

(e) "**Award**" means the grant of an Option, SAR, Dividend Equivalent Right, Restricted Stock, Restricted Stock Unit or other right or benefit under the Plan.

(f) "**Award Agreement**" means the written agreement evidencing the grant of an Award executed by the Company and the Grantee, including any amendments thereto.

(g) "**Board**" means the Board of Directors of the Company.

(h) “**Cause**” means, with respect to the termination by the Company or a Related Entity of the Grantee’s Continuous Service, that such termination is for “Cause” as such term (or word of like import) is expressly defined in a then-effective written agreement between the Grantee and the Company or such Related Entity, or in the absence of such then-effective written agreement and definition, is based on, in the determination of the Administrator, the Grantee’s: (i) performance of any act or failure to perform any act in bad faith and to the detriment of the Company or a Related Entity; (ii) dishonesty, intentional misconduct or material breach of any agreement with the Company or a Related Entity; or (iii) commission of a crime involving dishonesty, breach of trust, or physical or emotional harm to any person; provided, however, that with regard to any agreement that defines “Cause” on the occurrence of or in connection with a Corporate Transaction, such definition of “Cause” shall not apply until a Corporate Transaction actually occurs.

(i) “**Code**” means the Internal Revenue Code of 1986, as amended, or any successor statute.

(j) “**Committee**” means any committee composed of members of the Board appointed by the Board to administer the Plan.

(k) “**Common Stock**” means the Company’s Common Stock, par value \$0.001 per share.

(l) “**Company**” means Assembly Biosciences, Inc., a Delaware corporation, or any successor entity that adopts the Plan in connection with a Corporate Transaction.

(m) “**Continuous Service**” means that the provision of services to the Company or a Related Entity in any capacity of Employee, Director or Consultant is not interrupted or terminated. In jurisdictions requiring notice in advance of an effective termination as an Employee, Director or Consultant, Continuous Service shall be deemed terminated upon the actual cessation of providing services to the Company or a Related Entity notwithstanding any required notice period that must be fulfilled before a termination as an Employee, Director or Consultant can be effective under Applicable Laws. A Grantee’s Continuous Service shall be deemed to have terminated either upon an actual termination of Continuous Service or upon the entity for which the Grantee provides services ceasing to be a Related Entity. Continuous Service shall not be considered interrupted in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Related Entity, or any successor in any capacity of Employee, Director or Consultant, or (iii) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director or Consultant (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave.

(n) “**Corporate Transaction**” means any of the following transactions, provided, however, that the Administrator shall determine under parts (iv) and (v) whether multiple transactions are related, and its determination shall be final, binding and conclusive:

(i) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated;

(ii) the sale, transfer or other disposition of all or substantially all of the assets of the Company;

(iii) the complete liquidation or dissolution of the Company;

(iv) any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the shares of Common Stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger; or

(v) acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities.

(o) "**Director**" means a member of the Board or the board of directors of any Related Entity.

(p) "**Disability**" means as defined under the long-term disability policy of the Company or the Related Entity to which the Grantee provides services regardless of whether the Grantee is covered by such policy. If the Company or the Related Entity to which the Grantee provides service does not have a long-term disability plan in place, "Disability" means that a Grantee is unable to carry out the responsibilities and functions of the position held by the Grantee by reason of any medically determinable physical or mental impairment for a period of not less than ninety (90) consecutive days. A Grantee will not be considered to have incurred a Disability unless he or she furnishes proof of such impairment sufficient to satisfy the Administrator in its discretion.

(q) "**Dividend Equivalent Right**" means a right entitling the Grantee to compensation measured by dividends paid with respect to Common Stock.

(r) "**Employee**" means any person, including an Officer or Director, who is in the employ of the Company or any Related Entity, subject to the control and direction of the Company or any Related Entity as to both the work to be performed and the manner and method of performance. The payment of a director's fee by the Company or a Related Entity shall not be sufficient to constitute "employment" by the Company.

(s) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

(t) "**Fair Market Value**" means, as of any date, the value of Common Stock determined as follows.

(i) If the Common Stock is listed on one or more established stock exchanges or national market systems, including without limitation The NASDAQ Global Select Market, The NASDAQ Global Market or The NASDAQ Capital Market of The NASDAQ Stock Market LLC, its Fair Market Value shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on the principal exchange or system on which the Common Stock is listed (as determined by the Administrator) on the date of determination (or, if no closing sales price or closing bid was reported on that date, as applicable, on the last trading date such closing sales price or closing bid was reported), as reported in The Wall Street Journal or such other source as the Administrator deems reliable;

(ii) If the Common Stock is regularly quoted on an automated quotation system (including the OTC Bulletin Board) or by a recognized securities dealer, its Fair Market Value shall be the closing sales price for such stock as quoted on such system or by such securities dealer on the date of determination, but if selling prices are not reported, the Fair Market Value of a share of Common Stock shall be the mean between the high bid and low asked prices for the Common Stock on the date of determination (or, if no such prices were reported on that date, on the last date such prices were reported), as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or

(iii) In the absence of an established market for the Common Stock of the type described in (i) and (ii), above, the Fair Market Value thereof shall be determined by the Administrator in a manner in compliance with Section 409A of the Code.

(u) “**Grantee**” means an individual who receives an Award under the Plan.

(v) “**Non-Qualified Stock Option**” means an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.

(w) “**Officer**” means a person who is an officer of the Company or a Related Entity within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(x) “**Option**” means a Non-Qualified Stock Option to purchase Shares pursuant to an Award Agreement granted under the Plan.

(y) “**Parent**” means a “parent corporation,” whether now or hereafter existing, as defined in Section 424(e) of the Code.

(z) “**Plan**” means this Assembly Biosciences, Inc. 2017 Inducement Award Plan.

(aa) “**Post-Termination Exercise Period**” means the period specified in the Award Agreement of not less than thirty (30) days commencing on the date of termination (other than termination by the Company or any Related Entity for Cause) of the Grantee’s Continuous Service, or such longer period as may be applicable upon death or Disability.

(bb) “**Related Entity**” means any Parent or Subsidiary of the Company.

(cc) “**Replaced**” means that pursuant to a Corporate Transaction the Award is replaced with a comparable stock award or a cash incentive program of the Company, the successor entity (if applicable) or Parent of either of them which preserves the compensation element of such Award existing at the time of the Corporate Transaction and provides for subsequent payout in accordance with the same (or a more favorable) vesting schedule applicable to such Award. The determination of Award comparability shall be made by the Administrator and its determination shall be final, binding and conclusive.

(dd) “**Restricted Stock**” means Shares issued under the Plan to the Grantee for such consideration, and subject to such restrictions on transfer, rights of first refusal, repurchase provisions, forfeiture provisions, and other terms and conditions as established by the Administrator.

(ee) “**Restricted Stock Units**” means an Award which may be earned in whole or in part upon the passage of time or the attainment of performance criteria established by the Administrator and which may be settled for cash, Shares or other securities or a combination of cash, Shares or other securities as established by the Administrator.

(ff) “**Rule 16b-3**” means Rule 16b-3 promulgated under the Exchange Act or any successor thereto.

(gg) “**SAR**” means a stock appreciation right entitling the Grantee to Shares or cash compensation, as established by the Administrator, measured by appreciation in the value of Common Stock.

(hh) “**Share**” means a share of the Common Stock.

(ii) “**Subsidiary**” means a “subsidiary corporation,” whether now or hereafter existing, as defined in Section 424(f) of the Code.

3. Stock Subject to the Plan.

(a) Subject to the provisions of Sections 3(b) and 12 below, the maximum aggregate number of Shares which may be issued pursuant to all Awards is Eight Hundred Thousand (800,000) Shares. The Shares granted under the Plan may be authorized, but unissued, or reacquired Common Stock.

(b) Any Shares covered by an Award (or portion of an Award) which is forfeited, canceled or expires (whether voluntarily or involuntarily) shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares which may be issued under the Plan. Shares that actually have been issued under the Plan pursuant to an Award shall not be returned to the Plan and shall not become available for future issuance under the Plan, except that if Options or other Awards granted under this Plan are forfeited or repurchased by the Company, such Shares shall become available for future grant under the Plan. In the event any Option or other Award granted under the Plan is exercised through the tendering of shares of Common Stock (either actually or through attestation), or in the event tax withholding obligations are satisfied by tendering or withholding shares of Common Stock, any shares of Common Stock so tendered or withheld shall not again be available for awards under the Plan. Shares of Common Stock subject to an SAR granted pursuant to Section 6(l) of this Plan that are not issued in connection with cash or stock settlement of the exercise of the SAR shall not again be available for award under the Plan. Shares of Common Stock reacquired by the Company on the open market or otherwise using cash proceeds from the exercise of Options shall not be available for awards under the Plan.

4. Administration of the Plan.

(a) Plan Administrator.

(i) Administration – General. The Plan shall be administered by (A) the Board or (B) a Committee designated by the Board, which Committee shall be constituted in such a manner as to satisfy the Applicable Laws and to permit such grants and related transactions under the Plan to be exempt from Section 16(b) of the Exchange Act in accordance with Rule 16b-3. Once appointed, such Committee shall continue to serve in its designated capacity until otherwise directed by the Board.

(ii) Administration With in Compliance with Rule 5605(a)(2) of the NASDAQ Listing Rules. Notwithstanding the foregoing or anything in the Plan to the contrary, the grant of Awards will be approved by the Company's independent compensation committee or a majority of the Company's independent directors (as defined in Rule 5605(a)(2) of the NASDAQ Listing Rules) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the NASDAQ Listing Rules.

(b) Powers of the Administrator. Subject to Applicable Laws and the provisions of the Plan (including any other powers given to the Administrator hereunder), and except as otherwise provided by the Board, the Administrator shall have the authority, in its discretion:

(i) to select the individuals to whom Awards may be granted from time to time hereunder; provided that Awards may only be granted to individuals who satisfy the standards for inducement grants under Rule 5635(c)(4) of the NASDAQ Listing Rules;

(ii) to determine whether and to what extent Awards are granted hereunder;

(iii) to determine the number of Shares or the amount of other consideration to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the type, terms and conditions of any Award granted hereunder;

(vi) to establish additional terms, conditions, rules or procedures to accommodate the rules or laws of applicable non-U.S. jurisdictions and to afford Grantees favorable treatment under such rules or laws; provided, however, that no Award shall be granted under any such additional terms, conditions, rules or procedures with terms or conditions which are inconsistent with the provisions of the Plan;

(vii) to amend the terms of any outstanding Award granted under the Plan, provided that any amendment that would adversely affect the Grantee's rights under an outstanding Award shall not be made without the Grantee's written consent;

(viii) to construe and interpret the terms of the Plan and Awards, including without limitation, any notice of award or Award Agreement, granted pursuant to the Plan;

(ix) to institute an option exchange program; and

(x) to take such other action, not inconsistent with the terms of the Plan, as the Administrator deems appropriate.

The express grant in the Plan of any specific power to the Administrator shall not be construed as limiting any power or authority of the Administrator; provided that the Administrator may not exercise any right or power reserved to the Board. Any decision made, or action taken, by the Administrator or in connection with the administration of this Plan shall be final, conclusive and binding on all persons having an interest in the Plan.

(c) Indemnification. In addition to such other rights of indemnification as they may have as members of the Board or as Officers or Employees of the Company or a Related Entity, members of the Board and any Officers or Employees of the Company or a Related Entity to whom authority to act for the Board, the Administrator or the Company is delegated shall be defended and indemnified by the Company to the extent permitted by law on an after-tax basis against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any claim, investigation, action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any Award granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by the Company) or paid by them in satisfaction of a judgment in any such claim, investigation, action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such claim, investigation, action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct; provided, however, that within thirty (30) days after the institution of such claim, investigation, action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at the Company's expense to defend the same.

5. Eligibility. Awards may be granted to individuals who become employees of the Company and any Related Entity who satisfy the standards for inducement grants under Rule 5635(c)(4) of the NASDAQ Listing Rules and where the Award is an inducement material to the individual's entering into employment with the Company or a Related Entity. A person who previously served as an Employee or Director will not be eligible to receive Awards under the Plan, other than following a bona fide period of non-employment. Subject to the foregoing, Awards may be granted to such individuals who are residing in non-U.S. jurisdictions as the Administrator may determine from time to time. For clarity, Awards may not be granted to (1) Consultants or Directors for service in such capacity, or (2) any individual who was previously an Employee or Director, other than following a bona fide period of non-employment. All Awards must be granted either by a majority of the Company's independent directors or by the Company's compensation committee comprised of independent directors within the meaning of Rule 5605(a)(2) of the NASDAQ Listing Rules.

6. Terms and Conditions of Awards.

(a) Types of Awards. The Administrator is authorized under the Plan to award any type of arrangement to individuals who become an employee that is not inconsistent with the provisions of the Plan and that by its terms involves or might involve the issuance of (i) Shares, (ii) cash or (iii) an Option, an SAR, or similar right with a fixed or variable price related to the Fair Market Value of the Shares and with an exercise or conversion privilege related to the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. Such awards include, without limitation, Options, SARs, Restricted Stock, Restricted Stock Units or Dividend Equivalent Rights, and an Award may consist of one such security or benefit, or two (2) or more of them in any combination or alternative.

(b) Designation of Award. Each Award shall be designated in the Award Agreement. In the case of an Option, the Option shall be designated as a Non-Qualified Stock Option.

(c) Conditions of Award. Subject to the terms of the Plan, the Administrator shall determine the provisions, terms, and conditions of each Award including, but not limited to, the Award vesting schedule, repurchase provisions, rights of first refusal, forfeiture provisions, form of payment (cash, Shares, or other consideration) upon settlement of the Award, payment contingencies, and satisfaction of any performance criteria. The performance criteria established by the Administrator may be based on any one of, or combination of, increase in share price, earnings per share, total stockholder return, return on equity, return on assets, return on investment, net operating income, cash flow, revenue, economic value added, initiation or completion of clinical trials, results of clinical trials, regulatory approval, regulatory submissions, drug development or commercialization milestones, collaboration milestones or strategic partnerships. Partial achievement of the specified criteria may result in a payment or vesting corresponding to the degree of achievement as specified in the Award Agreement.

(d) Acquisitions and Other Transactions. The Administrator may issue Awards under the Plan in settlement, assumption or substitution for, outstanding awards or obligations to grant future awards in connection with the Company or a Related Entity acquiring another entity, an interest in another entity or an additional interest in a Related Entity whether by merger, stock purchase, asset purchase or other form of transaction.

(e) Deferral of Award Payment. The Administrator may establish one or more programs under the Plan to permit selected Grantees the opportunity to elect to defer receipt of consideration upon exercise of an Award, satisfaction of performance criteria, or other event that absent the election would entitle the Grantee to payment or receipt of Shares or other consideration under an Award. The Administrator may establish the election procedures, the timing of such elections, the mechanisms for payments of, and accrual of interest or other earnings, if any, on amounts, Shares or other consideration so deferred, and such other terms, conditions, rules and procedures that the Administrator deems advisable for the administration of any such deferral program.

(f) Separate Programs. The Administrator may establish one or more separate programs under the Plan for the purpose of issuing particular forms of Awards to one or more classes of Grantees on such terms and conditions as determined by the Administrator from time to time.

(g) Early Exercise. The Award Agreement may, but need not, include a provision whereby the Grantee may elect at any time while an Employee, Director or Consultant to exercise any part or all of the Award prior to full vesting of the Award. Any unvested Shares received pursuant to such exercise may be subject to a repurchase right in favor of the Company or a Related Entity or to any other restriction the Administrator determines to be appropriate.

(h) Term of Option or SAR. The term of each Option or SAR shall be the term stated in the Award Agreement, provided, however, that the term shall be no more than ten (10) years from the date of grant thereof.

(i) Transferability of Awards. Unless the Administrator provides otherwise, in its sole discretion, no Award may be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Grantee, only by the Grantee. Notwithstanding the foregoing, the Grantee may designate one or more beneficiaries of the Grantee's Award in the event of the Grantee's death on a beneficiary designation form provided by the Administrator.

(j) Time of Granting Awards. The date of grant of an Award shall for all purposes be the date on which the Administrator makes the determination to grant such Award, or such other later date as is determined by the Administrator.

(k) Stock Appreciation Rights. An SAR may be granted (i) with respect to any Option granted under this Plan, either concurrently with the grant of such Option or at such later time as determined by the Administrator (as to all or any portion of the shares of Common Stock subject to the Option), or (ii) alone, without reference to any related Option. Each SAR granted by the Administrator under this Plan shall be subject to the following terms and conditions. Each SAR granted to any participant shall relate to such number of shares of Common Stock as shall be determined by the Administrator, subject to adjustment as provided in Section 12. In the case of an SAR granted with respect to an Option, the number of shares of Common Stock to which the SAR pertains shall be reduced in the same proportion that the holder of the Option exercises the related Option. The exercise price of an SAR will be determined by the Administrator, in its discretion, at the date of grant but may not be less than 100% of the Fair Market Value of the shares of Common Stock subject thereto on the date of grant. Subject to the right of the Administrator to deliver cash in lieu of shares of Common Stock (which, as it pertains to Officers and Directors of the Company, shall comply with all requirements of the Exchange Act), the number of shares of Common Stock which shall be issuable upon the exercise of an SAR shall be determined by dividing:

(i) the number of shares of Common Stock as to which the SAR is exercised multiplied by the amount of the appreciation in such shares (for this purpose, the “appreciation” shall be the amount by which the Fair Market Value of the shares of Common Stock subject to the SAR on the exercise date exceeds (1) in the case of an SAR related to an Option, the exercise price of the shares of Common Stock under the Option or (2) in the case of an SAR granted alone, without reference to a related Option, an amount which shall be determined by the Administrator at the time of grant, subject to adjustment under Section 12); by

(ii) the Fair Market Value of a share of Common Stock on the exercise date.

In lieu of issuing shares of Common Stock upon the exercise of an SAR, the Administrator may elect to pay the holder of the SAR cash equal to the Fair Market Value on the exercise date of any or all of the shares which would otherwise be issuable. No fractional shares of Common Stock shall be issued upon the exercise of an SAR; instead, the holder of the SAR shall be entitled to receive a cash adjustment equal to the same fraction of the Fair Market Value of a share of Common Stock on the exercise date or to purchase the portion necessary to make a whole share at its Fair Market Value on the date of exercise. The exercise of an SAR related to an Option shall be permitted only to the extent that the Option is exercisable under Section 10 on the date of surrender.

(l) Compliance with Section 409A of the Code. Notwithstanding anything to the contrary set forth herein, any Award that is not exempt from the requirements of Section 409A of the Code shall contain such provisions so that such Award will comply with the requirements of Section 409A of the Code. Such restrictions, if any, shall be determined by the Administrator and contained in the Award Agreement evidencing such Award.

(m) Minimum Vesting. Awards granted to Employees under the Plan that are subject to time vesting shall not vest or become exercisable until at least one year after the date of grant, except in the case of death, Disability or a Corporate Transaction.

7. Award Exercise or Purchase Price, Consideration and Taxes.

(a) Exercise or Purchase Price. The exercise or purchase price, if any, for an Award shall be as follows.

(i) In the case of an Option, the per Share exercise price shall be not less than one-hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(ii) In the case of other Awards, such price as is determined by the Administrator.

(iii) Notwithstanding the foregoing provisions of this Section 7(a), in the case of an Award issued pursuant to Section 6(d), above, the exercise or purchase price for the Award shall be determined in accordance with the provisions of the relevant instrument evidencing the agreement to issue such Award.

(b) Consideration. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued upon exercise or purchase of an Option or upon the issuance of another Award, including the method of payment, shall be determined by the Administrator. In addition to any other types of consideration the Administrator may determine, the Administrator is authorized to accept as consideration for Shares issued under the Plan the following:

(i) cash;

(ii) check;

(iii) delivery of Grantee's promissory note with such recourse, interest, security, and redemption provisions as the Administrator determines as appropriate (but only to the extent that the acceptance or terms of the promissory note would not violate an Applicable Law); provided, however, that interest shall compound at least annually and shall be charged at the minimum rate of interest necessary to avoid (i) the imputation of interest income to the Company and compensation income to the Grantee under any applicable provisions of the Code, and (B) the classification of the Award as a liability for financial accounting purposes;

(iv) surrender of Shares or delivery of a properly executed form of attestation of ownership of Shares as the Administrator may require which have a Fair Market Value on the date of surrender or attestation equal to the aggregate exercise price of the Shares as to which said Award shall be exercised;

(v) payment through a broker-dealer sale and remittance procedure pursuant to which the Grantee (A) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates (or other evidence satisfactory to the Company to the extent that the Shares are uncertificated) for the purchased Shares directly to such brokerage firm in order to complete the sale transaction;

(vi) with respect to Options, payment through a "net exercise" such that, without the payment of any funds, the Grantee may exercise the Option and receive the net number of Shares equal to (i) the number of Shares as to which the Option is being exercised, multiplied by (ii) a fraction, the numerator of which is the Fair Market Value per Share (on such date as is determined by the Administrator) less the Exercise Price per Share, and the denominator of which is such Fair Market Value per Share; or

(vii) future services to be rendered to the Company or a Related Entity; or

(viii) any combination of the foregoing methods of payment.

The Administrator may at any time or from time to time, by adoption of or by amendment to the standard forms of Award Agreement described in Section 4(c) (iv), or by other means, grant Awards which do not permit all of the foregoing forms of consideration to be used in payment for the Shares or which otherwise restrict one or more forms of consideration.

8. [Intentionally Omitted].

9. Withholding of Additional Income Taxes.

(a) Upon the exercise of an Option or SAR, the grant of any other Award for less than the Fair Market Value of the Common Stock or the vesting of restricted Common Stock acquired on the exercise of an Award hereunder, the Company, in accordance with Section 3402(a) of the Code and any applicable state statute or regulation, may require the Grantee to pay to the Company additional withholding taxes in respect of the amount that is considered compensation includable in such person's gross income. With respect to (i) the exercise of an Option, (ii) the grant of any other Award for less than its Fair Market Value, (iv) the vesting of restricted Common Stock acquired by exercising an Award, or (v) the exercise of an SAR, the Committee in its discretion may condition such event on the payment by the Grantee of any such additional withholding taxes.

(b) At the sole and absolute discretion of the Administrator, the holder of Awards may pay all or any part of the total estimated federal and state income tax liability arising out of the exercise or receipt of such Awards or the vesting of restricted Common Stock acquired on the exercise of an Award hereunder (each of the foregoing, a "**Tax Event**") by tendering already-owned shares of Common Stock or by directing the Company to withhold shares of Common Stock otherwise to be transferred to the Grantee as a result of the exercise or receipt thereof in an amount equal to the estimated federal and state income tax liability arising out of such event, provided that no more Shares may be withheld than are necessary to satisfy the Grantee's actual minimum withholding obligation with respect to the exercise of Awards unless excess share withholding would not result in liability accounting treatment for Awards granted under the Plan under applicable accounting rules. In such event, the Grantee must, however, notify the Administrator of his or her desire to pay all or any part of the total estimated federal and state income tax liability arising out of a Tax Event by tendering already-owned shares of Common Stock or having shares of Common Stock withheld prior to the date that the amount of federal or state income tax to be withheld is to be determined. For purposes of this Section 9, shares of Common Stock shall be valued at their Fair Market Value on the date that the amount of the tax withholdings is to be determined.

10. Exercise of Award.

(a) Procedure for Exercise: Rights as a Stockholder.

(i) Any Award granted hereunder shall be exercisable at such times and under such conditions as determined by the Administrator under the terms of the Plan and specified in the Award Agreement.

(ii) An Award shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award by the person entitled to exercise the Award and full payment for the Shares with respect to which the Award is exercised has been made, including, to the extent selected, use of the broker-dealer sale and remittance procedure to pay the purchase price as provided in Section 7(b)(v).

(b) Exercise of Award Following Termination of Continuous Service. In the event of termination of a Grantee's Continuous Service for any reason other than Disability or death (but not in the event of a Grantee's change of status from Employee to Consultant), such Grantee may, but only during the Post-Termination Exercise Period (but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Administrator. The Grantee's Award Agreement may provide that upon the termination of the Grantee's Continuous Service for Cause, the Grantee's right to exercise the Award shall terminate concurrently with the termination of Grantee's Continuous Service. To the extent that the Grantee's Award was unvested at the date of termination, or if the Grantee does not exercise the vested portion of the Grantee's Award within the Post-Termination Exercise Period, the Award shall terminate.

(c) Disability of Grantee. In the event of termination of a Grantee's Continuous Service as a result of his or her Disability, such Grantee may, but only within twelve (12) months from the date of such termination (or such longer period as specified in the Award Agreement but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination. To the extent that the Grantee's Award was unvested at the date of termination, or if Grantee does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(d) Death of Grantee. In the event of a termination of the Grantee's Continuous Service as a result of his or her death, or in the event of the death of the Grantee during the Post-Termination Exercise Period or during the twelve (12) month period following the Grantee's termination of Continuous Service as a result of his or her Disability, the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance may exercise the portion of the Grantee's Award that was vested as of the date of termination, within twelve (12) months from the date of death (or such longer period as specified in the Award Agreement but in no event later than the expiration of the term of such Award as set forth in the Award Agreement). To the extent that, at the time of death, the Grantee's Award was unvested, or if the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(e) Extension if Exercise Prevented by Law. Notwithstanding the foregoing, if the exercise of an Award within the applicable time periods set forth in this Section 10 is prevented by the provisions of Section 11 below, the Award shall remain exercisable until one (1) month after the date the Grantee is notified by the Company that the Award is exercisable, but in any event no later than the expiration of the term of such Award as set forth in the Award Agreement.

11. Conditions Upon Issuance of Shares.

(a) If at any time the Administrator determines that the delivery of Shares pursuant to the exercise, vesting or any other provision of an Award is or may be unlawful under Applicable Laws, the vesting or right to exercise an Award or to otherwise receive Shares pursuant to the terms of an Award shall be suspended until the Administrator determines that such delivery is lawful and shall be further subject to the approval of counsel for the Company with respect to such compliance. The Company shall have no obligation to effect any registration or qualification of the Shares under federal or state laws.

(b) As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any Applicable Laws.

12. Adjustments. Subject to any required action by the stockholders of the Company, the number of Shares covered by each outstanding Award, and the number of Shares which have been authorized for issuance under the Plan but as to which no Awards have yet been granted or which have been returned to the Plan, the exercise or purchase price of each such outstanding Award, as well as any other terms that the Administrator determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares, (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company, or (iii) any other transaction with respect to the Company's Common Stock including a corporate merger, consolidation, acquisition of property or stock, separation (including a spin-off or other distribution of stock or property), reorganization, liquidation (whether partial or complete) or any similar transaction; provided, however that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Administrator and its determination shall be final, binding and conclusive. Except as the Administrator determines, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award. No adjustments shall be made for dividends paid in cash or in property other than Common Stock of the Company, nor shall cash dividends or dividend equivalents accrue or be paid in respect of unexercised Options or unvested Awards hereunder.

13. Corporate Transactions.

(a) Termination of Award to Extent Not Assumed in Corporate Transaction. Effective upon the consummation of a Corporate Transaction, all outstanding Awards under the Plan shall terminate. However, all such Awards shall not terminate to the extent they are Assumed in connection with the Corporate Transaction.

(b) Acceleration of Award Upon Corporate Transaction. The Administrator shall have the authority, exercisable either in advance of any actual or anticipated Corporate Transaction or at the time of an actual Corporate Transaction and exercisable at the time of the grant of an Award under the Plan or any time while an Award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding unvested Awards under the Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such Awards in connection with a Corporate Transaction on such terms and conditions as the Administrator may specify. The Administrator also shall have the authority to condition any such Award vesting and exercisability or release from such limitations upon the subsequent termination of the Continuous Service of the Grantee within a specified period following the effective date of the Corporate Transaction. The Administrator may provide that any Awards so vested or released from such limitations in connection with a Corporate Transaction shall remain fully exercisable until the expiration or sooner termination of the Award.

14. Effective Date and Term of Plan. The Plan shall become effective upon its adoption by the Board. It shall continue in effect for a term of ten (10) years from the date of its adoption.

15. Amendment, Suspension or Termination of the Plan.

(a) The Board may at any time amend, suspend or terminate the Plan in any respect, except that it may not, without the approval of the stockholders obtained within twelve (12) months before or after the Board adopts a resolution authorizing any of the following actions, do any of the following:

(i) increase the total number of shares that may be issued under the Plan (except by adjustment pursuant to Section 12);

(ii) the provisions of Section 7(a) regarding the exercise price at which shares may be offered pursuant to Options may not be modified (except by adjustment pursuant to Section 12);

(iii) extend the expiration date of the Plan; and

(iv) except as provided in Section 12 (including, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, or exchange of shares), the Company may not amend an Award granted under the Plan to reduce its exercise price per share, cancel and regrant new Awards with lower prices per share than the original prices per share of the cancelled Awards, or cancel any Awards in exchange for cash or the grant of replacement Awards with an exercise price that is less than the exercise price of the original Awards, essentially having the effect of a repricing, without approval by the Company's stockholders.

(b) No Award may be granted during any suspension of the Plan or after termination of the Plan.

(c) No suspension or termination of the Plan (including termination of the Plan under Section 15, above) shall adversely affect any rights under Awards already granted to a Grantee without his or her consent.

16. Reservation of Shares.

(a) The Company, during the term of the Plan, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan.

(b) The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

17. No Effect on Terms of Employment/Consulting Relationship. The Plan shall not confer upon any Grantee any right with respect to the Grantee's Continuous Service, nor shall it interfere in any way with his or her right or the right of the Company or a Related Entity to terminate the Grantee's Continuous Service at any time, with or without Cause, and with or without notice. The ability of the Company or any Related Entity to terminate the employment of a Grantee who is employed at will is in no way affected by its determination that the Grantee's Continuous Service has been terminated for Cause for the purposes of this Plan.

18. No Effect on Retirement and Other Benefit Plans. Except as specifically provided in a retirement or other benefit plan of the Company or a Related Entity, Awards shall not be deemed compensation for purposes of computing benefits or contributions under any retirement plan of the Company or a Related Entity, and shall not affect any benefits under any other benefit plan of any kind or any benefit plan subsequently instituted under which the availability or amount of benefits is related to level of compensation. The Plan is not a "Retirement Plan" or "Welfare Plan" under the Employee Retirement Income Security Act of 1974, as amended.

19. Electronic Delivery. The Administrator may, in its sole discretion, decide to deliver any documents related to any Award granted under the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company or to request a Grantee's consent to participate in the Plan by electronic means. Each Grantee hereunder consents to receive such documents by electronic delivery and agrees to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company, and such consent shall remain in effect throughout Grantee's term of employment or service with the Company and any Related Entity and thereafter until withdrawn in writing by Grantee.

20. Data Privacy. The Administrator may, in its sole discretion, decide to collect, use and transfer, in electronic or other form, personal data as described in this Plan or any Award for the exclusive purpose of implementing, administering and managing participation in the Plan. Each Grantee hereunder acknowledges that the Company holds certain personal information about Grantee, including, but not limited to, name, home address and telephone number, date of birth, social security number or other identification number, salary, nationality, job title, details of all Awards awarded, cancelled, exercised, vested or unvested, for the purpose of implementing, administering and managing the Plan (the "*Data*"). Each Grantee hereunder further acknowledges that Data may be transferred to any third parties assisting in the implementation, administration and management of the Plan and that these third parties may be located in jurisdictions that may have different data privacy laws and protections, and Grantee authorizes such third parties to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the recipient or the Company may elect to deposit any shares of Common Stock acquired upon any Award.

21. Compliance with Section 409A. To the extent that the Administrator determines that any Award granted hereunder is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued or amended after the effective date of the Plan. Notwithstanding any provision of the Plan to the contrary, in the event that following the effective date of the Plan the Administrator determines that any Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the effective date of the Plan), the Administrator may adopt such amendments to the Plan and the applicable Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (1) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (2) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance.

22. Unfunded Obligation. Grantees shall have the status of general unsecured creditors of the Company. Any amounts payable to Grantees pursuant to the Plan shall be unfunded and unsecured obligations for all purposes, including, without limitation, Title I of the Employee Retirement Income Security Act of 1974, as amended. Neither the Company nor any Related Entity shall be required to segregate any monies from its general funds, or to create any trusts, or establish any special accounts with respect to such obligations. The Company shall retain at all times beneficial ownership of any investments, including trust investments, which the Company may make to fulfill its payment obligations hereunder. Any investments or the creation or maintenance of any trust or any Grantee account shall not create or constitute a trust or fiduciary relationship between the Administrator, the Company or any Related Entity and a Grantee, or otherwise create any vested or beneficial interest in any Grantee or the Grantee's creditors in any assets of the Company or a Related Entity. The Grantees shall have no claim against the Company or any Related Entity for any changes in the value of any assets that may be invested or reinvested by the Company with respect to the Plan.

23. Construction. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

As approved by the Board of Directors on April 3, 2017

ASSEMBLY BIOSCIENCES, INC.
2017 Inducement Award Plan
NOTICE OF STOCK OPTION GRANT

Grant Number 2017-

You have been granted an option to purchase Common Stock of Assembly Biosciences, Inc. (the "Company"), as follows:

Date of Grant [_____]
Vesting Commencement Date [_____]
Exercise Price per Share \$ ____
Total Number of Shares Granted _____
Total Exercise Price \$ _____
Type of Option: _____ Nonstatutory Stock Option
Term/Expiration Date: 10 years

Vesting Schedule: [1/4 to vest on the first anniversary of the vesting commencement date; and thereafter 1/36 of remaining option shares (approximately ____ shares) to vest each month thereafter for 36 months; in each case subject to your Continuous Services through each vesting date and otherwise in accordance with the terms and conditions of the Plan (as defined below) and the Stock Option Agreement attached hereto. Shares to vest on any vesting date shall be rounded down to nearest whole number. Monthly installments shall take into effect prior rounding so that each monthly installment including the last installment is approximately the same. On the fourth anniversary of the vesting commencement date, the options shall be fully vested. Upon the occurrence of a Corporate Transaction and the termination of your employment by the Company other than for Cause within 6 months of such Corporate Transaction, all unvested options shall vest.]

Termination Period: Option may be exercised for up to 90 days after termination of Continuous Service. By your signature and the signature of the Company's representative below, you and the Company agree that this option is granted under and governed by the terms and conditions of the Assembly Biosciences, Inc. 2017 Inducement Award Plan (the "Plan") and the Stock Option Agreement, all of which are attached and made a part of this document. Capitalized terms used in this Notice of Stock Option Grant and not otherwise defined herein shall have the meaning assigned to such term in the Plan.

Dated: _____

OPTIONEE: ASSEMBLY BIOSCIENCES, INC.
By: _____
Name: _____
Title: _____

[Name]

ASSEMBLY BIOSCIENCES, INC.

STOCK OPTION AGREEMENT

1. Grant of Option. Assembly Biosciences, Inc. (the "Company"), hereby grants to the Optionee named in the Notice of Grant (the "Optionee") an option (the "Option") to purchase a total number of shares of Common Stock (the "Shares") set forth in the Notice of Grant, at the exercise price per share set forth in the Notice of Grant (the "Exercise Price") subject to the terms, definitions and provisions of the Assembly Biosciences, Inc. 2017 Inducement Award Plan (the "Plan") adopted by the Company, which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Option.

2. Exercise of Option. This Option shall be exercisable during its term in accordance with the Vesting Schedule set out in the Notice of Grant and with the provisions of Sections 10 and 11 of the Plan as follows:

(a) Right to Exercise.

(i) This Option may not be exercised for a fraction of a share.

(ii) In no event may this Option be exercised after the date of expiration of the term of this Option as set forth in the Notice of Grant.

(b) Method of Exercise. This Option shall be exercisable by written notice (in the form attached hereto as *Exhibit A*) which shall state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised, and such other representations and agreements as to the holder's investment intent with respect to such shares of Common Stock as may be required by the Company pursuant to the provisions of the Plan. Such written notice shall be signed by the Optionee and shall be delivered in person, by certified mail or by electronic mail (with confirmation of receipt) to the Secretary of the Company. The written notice shall be accompanied by payment of the Exercise Price. This Option shall be deemed to be exercised upon receipt by the Company of such written notice accompanied by the Exercise Price.

Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act of 1933, as amended (the "Securities Act"), or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations. No Shares will be issued pursuant to the exercise of an Option unless such issuance and such exercise shall comply with all relevant provisions of law and the requirements of any stock exchange upon which the Shares may then be listed. Assuming such compliance, for income tax purposes the Shares shall be considered transferred to the Optionee on the date on which the Option is exercised with respect to such Shares.

3. Method of Payment. Payment of the Exercise Price shall be by any of the following, or a combination thereof, at the election of the Optionee:
- (i) cash; or
 - (ii) check; or
 - (iii) surrender of other shares of Common Stock of the Company, or attestation of ownership of such shares, as described in Section 7(b) of the Plan; or
 - (iv) "net exercise" as described in Section 7(b)(vi) of the Plan; or
 - (v) a broker-assisted exercise as described in Section 7(b)(v) of the Plan; or
 - (vi) promissory note as described in Section 7(b)(iii) of the Plan to the extent not prohibited by applicable law; or
 - (vii) any combination of the foregoing methods of payment.

4. Nontransferability of Option. This Option may not be transferred in any manner other than as set forth in the Plan. The terms of this Option shall be binding upon the executors, administrators, heirs, successors transferees and assigns of the Optionee as if such persons were the Optionee.

5. Termination of Relationship. In the event of termination of Optionee's employment or consulting relationship with the Company, Optionee may, to the extent otherwise so entitled at the date of such termination (the "Termination Date"), exercise this Option during the Termination Period set out in the Notice of Grant. To the extent that Optionee was not entitled to exercise this Option at the date of such termination, or if Optionee does not exercise this Option within the time specified herein, the Option shall terminate.

6. Term of Option. This Option may be exercised only within the term set out in the Notice of Grant and the Plan, and may be exercised during such term only in accordance with the Plan and the terms of this Option.

7. Disability of Optionee. Notwithstanding the provisions of Section 5 above, in the event of termination of Optionee's consulting or employment relationship as a result of his total and permanent disability (as defined in Section 22(e)(3) of the Code or any successor provision), Optionee may, but only within twelve (12) months from the date of termination of employment or consulting relationship (but in no event later than the date of expiration of the term of this Option as set forth in the Notice of Grant), exercise this Option to the extent Optionee was entitled to exercise it at the date of such termination. To the extent that Optionee was not entitled to exercise the Option at the date of termination, or if Optionee does not exercise such Option (which Optionee was entitled to exercise) within the time specified herein, the Option shall terminate.

8. Death of Optionee. In the event of the death of Optionee during the term of this Option and, with respect to a consultant, during such consultant's continuing consulting relationship with the Company or within 90 days of termination of consultant's relationship with the Company and, with respect to an employee, during such employee's employment relationship with the Company or within 90 days of termination of such employee's relationship with the Company, the Option may be exercised at any time within twelve (12) months following the date of termination (but in no event later than the date of expiration of the term of this Option as set forth in the Notice of Grant), by Optionee's estate or by a person who acquired the right to exercise the Option by bequest or inheritance, but only to the extent of the right to exercise that Optionee was entitled to at the date of death.

9. Taxation Upon Exercise of Option. Pursuant to Section 9 of the Plan, the Company may require the Optionee to pay to the Company amounts necessary to satisfy any applicable Company withholding obligations. The Optionee shall satisfy his or her tax withholding obligation arising upon the exercise of this Option by one or some combination of the following methods: (i) by cash payment, or (ii) out of Optionee's current compensation, or (iii) if permitted by the Board or Committee, in its discretion, by surrendering to the Company already-owned Shares or by directing the Company to withhold shares otherwise to be transferred to the Optionee, in each case in accordance with Section 9(b) of the Plan. For this purpose, the fair market value of the Shares to be withheld shall be determined on the date that the amount of tax to be withheld is to be determined (the "Tax Date").

If the Optionee is subject to Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (an "Insider"), any surrender of previously owned Shares to satisfy tax withholding obligations arising upon exercise of this Option must comply with the applicable provisions of Rule 16b-3 promulgated under the Exchange Act ("Rule 16b-3") and shall be subject to such additional conditions or restrictions as may be required thereunder to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

All elections by an Optionee to have Shares withheld to satisfy tax-withholding obligations shall be made in writing in a form acceptable to the Committee and shall be subject to the following restrictions:

- (1) the election must be made on or prior to the applicable Tax Date;
- (2) once made, the election shall be irrevocable as to the particular Shares of the Option as to which the election is made;
- (3) all elections shall be subject to the consent or disapproval of the Board or Committee;
- (4) if the Optionee is an Insider, the election must comply with the applicable provisions of Rule 16b-3 and shall be subject to such additional conditions or restrictions as may be required thereunder to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

10. Tax Consequences. Set forth below is a brief summary as of the date of this Option of some of the federal tax consequences of exercise of this Option and disposition of the Shares. THIS SUMMARY IS NECESSARILY INCOMPLETE, AND THE TAX LAWS AND REGULATIONS ARE SUBJECT TO CHANGE. OPTIONEE SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.

(a) Exercise of Nonstatutory Stock Option. There may be a regular federal income tax liability and a state income tax liability upon the exercise of the Option. The Optionee will be treated as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price and the Company will qualify for a deduction in the same amount, subject to the requirement that the compensation be reasonable. If Optionee is an employee, the Company will be required to withhold from Optionee's compensation or collect from Optionee and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise.

(b) Disposition of Shares. If Shares are held for at least one year, any gain realized on disposition of the Shares will be treated as long-term capital gain for federal income tax purposes.

11. Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Agreement shall be binding upon Optionee and his or her heirs, executors, administrators, successors, transferees and assigns.

12. Interpretation. Any dispute regarding the interpretation of this Agreement shall be submitted by Optionee or by the Company forthwith to the Company's Board of Directors or the Committee that administers the Plan, which shall review such dispute at its next regular meeting. The resolution of such a dispute by the Board or committee shall be final and binding on the Company and on Optionee.

13. Governing Law; Severability. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware excluding that body of law pertaining to conflicts of law. Should any provision of this Agreement be determined by a court of law to be illegal or unenforceable, the other provisions shall nevertheless remain effective and shall remain enforceable.

14. Notices. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon receipt or three (3) days after deposit in the United States mail by certified mail, with postage and fees prepaid, addressed to in the case of the Company at its corporate headquarters and in the case of Optionee at the last address Optionee provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. Option Not a Service Contract.

(a) Your Continuous Service with the Company or a Related Entity is not for any specified term and may be terminated by you or by the Company or a Related Entity at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of your Option pursuant to the schedule set forth in the Notice of Stock Option Grant or the issuance of the shares upon exercise of your option), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or a Related Entity; (ii) constitute any promise or commitment by the Company or a Related Entity regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Option, you acknowledge and agree that the right to continue vesting in the Option pursuant to the schedule set forth in Notice of Stock Option Grant is earned only by continuing as an employee, director or consultant at the will of the Company (not through the act of being hired, being granted this option or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Related Entity at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Related Entity status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the option. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company's right to terminate your Continuous Service at any time, with or without Cause and with or without notice.

16. Further Instruments. The parties agree to execute such further instruments and to take such further action as may be reasonably necessary to carry out the purposes and intent of this Agreement.

17. 2017 Inducement Award Plan. This Option shall be subject to and governed by the terms and conditions of the Plan in all respects, and to the extent of any inconsistency between this Option and the terms of the Plan, the terms of the Plan will control. Optionee acknowledges receipt of a copy of the Plan and represents that he or she is familiar with the terms and provisions thereof, and hereby accepts this Option subject to all of the terms and provisions thereof. Optionee has reviewed the Plan and this Option in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Option and fully understands all provisions of the Option. Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or Committee upon any questions arising under the Plan or this Option.

18. Other Documents. You acknowledge receipt of the Company's insider trading policy and agree to comply with its terms.

EXHIBIT A

ASSEMBLY BIOSCIENCES, INC.

EXERCISE NOTICE

Assembly Biosciences, Inc.

Attention: Secretary

1. **Exercise of Option.** Effective as of today, the undersigned ("Optionee") hereby elects to exercise Optionee's option to purchase _____ shares of the Common Stock (the "Shares") of Assembly Biosciences, Inc. (the "Company") under and pursuant to the Company's 2017 Inducement Award Plan (as amended from time to time, the "Plan") and the Notice of Stock Option Grant dated _____, 20____ with its attached Stock Option Agreement (the "Option Agreement"). The purchase price for the Shares shall be \$ _____ as required by the Option Agreement. Optionee herewith delivers to the Company the full Exercise Price for the Shares.
 2. **Representations of Optionee.** Optionee acknowledges that Optionee has received, read and understood the Plan and the Option Agreement and agrees to abide by and be bound by their terms and conditions. Optionee represents that Optionee is purchasing the Shares for Optionee's own account for investment and not with a view to, or for sale in connection with, a distribution of any of such Shares.
 3. **Rights as Stockholder.** Until the stock certificate evidencing such Shares is issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder shall exist with respect to the optioned Shares, notwithstanding the exercise of the Option. The Company shall issue (or cause to be issued) such stock certificate promptly after the Option is exercised.
 4. **Tax Consultation.** Optionee understands that Optionee may suffer adverse tax consequences as a result of Optionee's purchase or disposition of the Shares. Optionee represents that Optionee has consulted with any tax consultants Optionee deems advisable in connection with the purchase or disposition of the Shares and that Optionee is not relying on the Company for any tax advice.
 5. **Entire Agreement.** The Plan and Option Agreement are incorporated herein by reference. This Exercise Notice, the Plan and the Option Agreement and any Investment Representation statement executed and delivered to Company by Optionee shall constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Optionee with respect to the subject matter hereof, and is governed by Delaware law except for that body of law pertaining to conflict of laws.
-

Submitted by:

Accepted by:

OPTIONEE:

Assembly Biosciences, Inc.

By: _____

Name: _____

Title: _____

Address: _____

Address: _____

ASSEMBLY BIOSCIENCES, INC.
2017 INDUCEMENT AWARD 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: [], 2017

Vesting Commencement Date: [], 2017

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.]

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 option is granted under and governed by the terms and conditions of the Assembly Biosciences, Inc. 2017 Inducement Award 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 2017 INDUCEMENT AWARD 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 2017 Inducement Award 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 become an employee of the Company;

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 Award granted hereby is a material inducement for the Grantee to enter into employment with the Company and to promote the success of the Company's business; 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.

17. 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.

18. 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.

19. 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.

20. 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.

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: August 9, 2017

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

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: August 9, 2017

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

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 June 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: August 9, 2017

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 June 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: August 9, 2017
