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, 2016

OR

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

For the transition period from _____to_____.

Commission file number: 001-35005

ASSEMBLY BIOSCIENCES, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**20-8729264**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
101 Sixth Avenue, Ninth Floor New York, New York	**10013**
(Address of principal executive offices)	(zip code)

(646) 706-5208
(Registrant's telephone number, including area code)

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 x NO ☐

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

Large Accelerated Filer	☐		Accelerated Filer	x
Non-accelerated Filer	☐	(Do not check if smaller reporting company)	Smaller Reporting Company	☐

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

As of August 5, 2016, there were 17,225,554 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, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 20,341,338	$ 27,107,526
Marketable securities, at fair value	43,205,005	40,556,652
Other current assets	556,644	704,287
Total current assets	64,102,987	68,368,465
Long-term assets		
Marketable securities, at fair value	11,167,421	23,392,129
Property, plant and equipment, net	113,679	148,609
Security deposits	183,698	197,158
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	53,102,934	65,376,032
Total assets	**$ 117,205,921**	**$ 133,744,497**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,413,922	$ 1,363,698
Accrued expenses	2,630,946	2,039,204
Total current liabilities	5,044,868	3,402,902
Long-term liabilities		
Deferred tax liabilities	11,600,000	11,600,000
Total long-term liabilities	11,600,000	11,600,000
Total liabilities	**16,644,868**	**15,002,902**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,225,554 and 17,225,662 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	17,226	17,226
Additional paid-in capital	286,489,852	283,511,859
Accumulated other comprehensive loss	(839,362)	(821,585)
Accumulated deficit	(185,106,663)	(163,965,905)
Total stockholders' equity	100,561,053	118,741,595
Total liabilities and stockholders' equity	**$ 117,205,921**	**$ 133,744,497**

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 7,519,031	$ 4,667,754	$ 15,637,607	$ 8,502,188
General and administrative	2,935,099	2,486,151	6,093,675	5,854,935
Total operating expenses	10,454,130	7,153,905	21,731,282	14,357,123
Loss from operations	**(10,454,130)**	**(7,153,905)**	**(21,731,282)**	**(14,357,123)**
Other income (expenses)				
Interest and other income	444,605	211,234	935,026	269,499
Realized loss from marketable securities	(142,675)	-	(344,502)	-
Total other income	301,930	211,234	590,524	269,499
Net loss	**$ (10,152,200)**	**$ (6,942,671)**	**$ (21,140,758)**	**$ (14,087,624)**
Unrealized loss recognized in accumulated other comprehensive loss before reclassification	(232,542)	(134,219)	(362,279)	(134,219)
Reclassification adjustment of unrealized loss included in net loss	142,675	-	344,502	-
Comprehensive loss	**$ (10,242,067)**	**$ (7,076,890)**	**$ (21,158,535)**	**$ (14,221,843)**
Net loss per share, basic and diluted	$ (0.59)	$ (0.41)	$ (1.23)	$ (0.99)
Weighted average common shares outstanding, basic and diluted	17,225,660	17,119,488	17,225,661	14,164,451

See Notes to Condensed Consolidated Financial Statements.

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

	Six Months Ended June 30,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (21,140,758)	$ (14,087,624)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	37,093	30,397
Stock-based compensation	2,977,993	5,206,024
Realized loss from marketable securities	344,503	-
Changes in operating assets and liabilities:		
Other current assets	147,643	(479,878)
Accounts payable	1,050,224	396,694
Accrued expenses	591,742	888,459
Security deposits	13,460	(10,079)
Net cash used in operating activities	(15,978,100)	(8,056,007)
Cash flows from investing activities		
Purchases of fixed assets	(2,163)	(47,991)
Purchases of marketable securities	(7,951,257)	(48,780,784)
Redemptions of marketable securities	17,165,332	-
Net cash provided by (used in) investing activities	9,211,912	(48,828,775)
Cash flows from financing activities		
Proceeds from common stock sold, net of underwriters' discounts and cost	-	81,014,989
Proceeds from exercise of stock options	-	296,825
Net cash provided by financing activities	-	81,311,814
Net (decrease) increase in cash and cash equivalents	(6,766,188)	24,427,032
Cash and cash equivalents at the beginning of the period	27,107,526	29,091,113
Cash and cash equivalents at the end of the period	**$ 20,341,338**	**$ 53,518,145**
Supplemental disclosure of cash flow information:		
Change in unrealized loss on marketable securities available-for-sale	$ (17,777)	$ (134,219)
Cashless exercise of warrants	$ -	$ 88

See Notes to Condensed Consolidated Financial Statements.

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

	Common Stock		Additional	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Comprehensive Loss	Deficit	Equity
Balance as of December 31, 2015	**17,225,662**	**$ 17,226**	**$ 283,511,859**	**$ (821,585)**	**$ (163,965,905)**	**$ 118,741,595**
Stock-based compensation	-	-	2,977,993	-	-	2,977,993
Change in unrealized loss on marketable securities	-	-	-	(17,777)	-	(17,777)
Cancellation of common stock	(108)	-	-	-	-	-
Net loss	-	-	-	-	(21,140,758)	(21,140,758)
Balance as of June 30, 2016	**17,225,554**	**$ 17,226**	**$ 286,489,852**	**$ (839,362)**	**$ (185,106,663)**	**$ 100,561,053**

See Notes to Condensed Consolidated Financial Statements.

Note 1 - Business

Overview

Assembly Biosciences, Inc. ("Assembly" or the "Company") is a biotechnology company advancing two innovative platform programs: (i) HBV-cure program, which is advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and (ii) microbiome program, which is a novel class of oral biological therapeutics, which are designed to restore health to a dysbiotic microbiome.

The Company's HBV-cure program is aimed at increasing the current low cure rates for patients with HBV and is pursuing several drug candidates that inhibit multiple viral targets throughout the HBV lifecycle for possible use alone or in combination therapy. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate a number of HBV core protein (HBc) functions.

The Company's microbiome program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices (cGMP) conditions, and a patent-pending delivery system, GEMICEL ™, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. The lead program from this platform, ABI-M101, is in development for the treatment of C. difficile- infections (CDI). Using its microbiome platform, the Company is developing additional product candidates for multiple indications including metabolic disorders, immunotherapy and autoimmune diseases.

Liquidity

The Company has not derived any revenue from product sales to date as it 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 and issuance of debt. 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.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

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

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 as of June 30, 2016, condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015, condensed consolidated statements of cash flows for the six months ended June 30, 2016 and 2015, and condensed consolidated statement of changes in stockholders' equity for the six months ended June 30, 2016 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which 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, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016 or for any future interim period. The consolidated balance sheet at December 31, 2015 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, 2015, and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed with the SEC on March 11, 2016 (the "2015 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 the disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying financial statements include recoverability and useful lives (indefinite) 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.

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 2015 Annual Report.

Reclassification

Certain reclassifications have been made to previous period amounts to conform to the current period presentation on the condensed consolidated statements of operations and comprehensive loss. The unrealized loss on available-for-sale securities has been included in accumulated other comprehensive income, and the amount of losses reclassified out of accumulated other comprehensive income into realized loss from marketable securities when the securities were sold during the three and six months ended June 30, 2016.

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, 2016 and 2015 are as follows:

	Six Months Ended June 30,	
	2016	**2015**
Warrants to purchase common stock	16,909	56,776
Options to purchase common stock	4,097,952	3,176,519
Total	**4,114,861**	**3,233,295**

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers*, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or U.S. GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also results in enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively and improves guidance for multiple-element arrangements. In July 2015, the FASB voted to approve a one-year deferral of the effective date of ASU 2014-09, which will be effective for the Company in the first quarter of fiscal year 2018 and may be applied on a full retrospective or modified retrospective approach. ASU 2014-09 will have no impact on the Company until it begins to generate revenue.

In June 2014, the FASB issued ASU 2014-12, *Compensation-Stock Compensation (Topic 718)*. ASU 2014-12 clarifies how entities should treat performance targets that can be achieved after the requisite service period of a share-based payment award. The accounting standard is effective for interim and annual periods beginning after December 15, 2015. ASU 2014-12 will have no impact on the Company until it begins to grant performance awards.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 explicitly requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management will assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date. Management will consider relevant conditions that are known, and reasonably knowable, at the issuance date. Substantial doubt exists if it is probable that the entity will be unable to meet its obligations within one year after the issuance date. Disclosures will be required if conditions give rise to substantial doubt. The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its condensed consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. Adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

In January 2016, 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 will be 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, FASB issued ASU 2016-02, *Leases (Topic 842)* which supersedes FASB ASC Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard will be effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the impact that ASU 2016-02 will have on its condensed consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The amendment is to simplify several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public entities, the amendments in ASU 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of ASU 2016-09 on its condensed consolidated financial statements and related disclosures.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customer*. The new guidance is an update to ASC 606 and provides clarity on: identifying performance obligations and licensing implementation. For public companies, ASU 2016-10 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016. The Company is currently evaluating the impact that ASU No. 2016-10 will have on its condensed consolidated financial statements.

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.

Note 3 - Marketable Securities

Marketable securities consist of the following as of June 30, 2016 and December 31, 2015:

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Short-term available-for-sale securities				
Corporate bonds	$ 41,201,117	$ 523	$ (833,051)	$ 40,368,589
Government and agency obligations	1,225,000	3,944	-	1,228,944
Municipal bonds	1,596,160	11,312	-	1,607,472
	44,022,277	15,779	(833,051)	43,205,005
Long-term available-for-sale securities				
Corporate bonds	11,189,511	31,729	(53,819)	11,167,421
	11,189,511	31,729	(53,819)	11,167,421
Total	$ 55,211,788	$ 47,508	$ (886,870)	$ 54,372,426

	December 31, 2015		
	Amortized Cost	Gross Unrealized Loss	Fair Value
Short-term available-for-sale securities			
Corporate bonds	$ 41,126,524	$ (569,872)	$ 40,556,652
	41,126,524	(569,872)	40,556,652
Long-term available-for-sale securities			
Government and agency obligations	1,225,000	(3,834)	1,221,166
Municipal bonds	1,596,160	(4,384)	1,591,776
Corporate bonds	20,822,682	(243,495)	20,579,187
	23,643,842	(251,713)	23,392,129
Total	$ 64,770,366	$ (821,585)	$ 63,948,781

The contractual term to maturity of short-term marketable securities held by the Company as of June 30, 2016 is less than one year. The contractual term to maturity of long-term marketable securities held by the Company as of June 30, 2016 is 1 to 2 years.

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

Quoted prices in active markets for identical assets (Level 1)	$ -
Quoted prices for similar assets observable in the marketplace (Level 2)	54,372,426
Significant unobservable inputs (Level 3)	-
Total	$ 54,372,426

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, 2016 and December 31, 2015.

There were no transfers of marketable securities between Levels 1, 2 and 3 for the six months ended June 30, 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, 2016.

	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate bonds	$ 9,282,011	$ (53,993)	$ 34,182,760	$ (832,877)	$ 43,464,771	$ (886,870)
Total	**$ 9,282,011**	**$ (53,993)**	**$ 34,182,760**	**$ (832,877)**	**$ 43,464,771**	**$ (886,870)**

The Company has determined that the unrealized losses are deemed to be temporary impairments as of June 30, 2016. 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, 2016.

Note 4 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

	Useful life (Years)	June 30, 2016	December 31, 2015
Computer hardware and software	3	$ 86,228	$ 84,065
Lab equipment	3 to 5	177,782	177,782
Office equipment	3 to 5	1,109	1,109
Total property, plant and equipment		265,119	262,956
Less: Accumulated depreciation and amortization		(151,440)	(114,347)
Property, plant and equipment, net		$ 113,679	$ 148,609

Depreciation expense for the three months ended June 30, 2016 and 2015 was approximately $18,000 and $16,000, 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, 2016 and 2015 was approximately $37,000 and $30,000, 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:

	June 30, 2016	December 31, 2015
Accrued expenses:		
Salaries, bonuses and employee benefits	$ 1,619,978	$ 1,628,975
Severance accrued for former CEO	-	106,777
Research and development expenses	624,554	120,700
General and administrative expenses	386,414	-
Other	-	182,752
Total accrued expenses	$ 2,630,946	$ 2,039,204

Note 6 - Stockholders' Equity

Common Stock

On July 10, 2014, the Company's stockholders approved a 1-for-5 reverse stock split of the issued and outstanding shares of the Company's common stock, par value $0.001 per share, effective as of July 11, 2014 at 5:01 p.m. Eastern time (the "Split Effective Time"). At the Split Effective Time, all shares of common stock issued and outstanding immediately prior to the Split Effective Time, including shares issued to the shareholders of Assembly Pharmaceuticals, Inc. in connection with the acquisition of Assembly Pharmaceuticals, Inc., were automatically reclassified into a smaller number of shares such that each five shares of issued common stock immediately prior to the Split Effective Time were reclassified into one share of common stock. Proportional adjustments to outstanding warrants, options and other equity awards and equity compensation were also made. No fractional shares were issued and, in lieu thereof, any person who would otherwise be entitled to a fractional share of common stock as a result of the reverse stock split was entitled to receive a cash payment equal to the fraction to which such holder would otherwise be entitled multiplied by the closing price per share of common stock on the NASDAQ Capital Market on July 11, 2014, which was $1.45. On June 29, 2016, the Company cancelled 108 shares of common stock, which represented the aggregate number of fractional shares that were cashed out as a result of the reverse stock split.

Options

In July 2010, the stockholders approved the 2010 Equity Incentive Plan (the "2010 Plan"), under which, as of June 30, 2016, there were outstanding options to purchase an aggregate of 728,793 shares of common stock. Effective on June 2, 2016, the 2010 Plan was frozen and no further grants will be made under the 2010 Plan. Shares that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the Amended and Restated 2014 Plan (as defined below).

In July 2014, the stockholders approved the 2014 Stock Incentive Plan (the "2014 Plan"). On June 2, 2016, at the 2016 Annual Meeting of Stockholders (the "Annual Meeting"), 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, 2016, there were outstanding options to purchase an aggregate of 2,747,508 shares of common stock and 1,340,403 shares available for grant under the Amended and Restated 2014 Plan. Additionally, 6,667 shares of common stock forfeited under the 2010 Plan since June 2, 2016 are available for issuance under the Amended and Restated 2014 Plan.

A summary of the Company's option activity and related information for the six-month period ended June 30, 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value
Outstanding as of December 31, 2015	3,367,784	$ 7.16	$ 3,971,205
Granted	757,500	6.64	-
Forfeited	(27,332)	8.32	-
Outstanding as of June 30, 2016	4,097,952	$ 7.05	$ 2,070,098
Options vested and exercisable	2,265,890	$ 6.58	$ 1,624,454

The fair value of the options granted for the six months ended June 30, 2016 and 2015, were based on the following assumptions:

	Six Months Ended June 30,	
	2016	2015
Exercise price	$5.84 - $7.03	$9.42 - $16.55
Expected stock price volatility	88.2% - 91.8%	90.7% - 95.6%
Risk-free rate of interest	1.36% - 1.94%	1.49% - 2.08%
Term (years)	5.4 - 7.0	5.1 - 6.6

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

	Future Stock Option Compensation Expenses
Six months ended December 31, 2016	$ 1,959,807
Year ended December 31, 2017	1,959,182
Year ended December 31, 2018	828,835
Year ended December 31, 2019	271,022
Year ended December 31, 2020	14,095
Total	$ 5,032,941

Unamortized stock-based compensation expense amounted to $5.0 million at June 30, 2016, and will be amortized over 3.9 years.

Stock-based compensation expense for the three and six months ended June 30, 2016 and 2015 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$ 850,851	$ 1,419,872	$ 1,569,007	$ 2,475,302
General and administrative	667,287	1,200,372	1,408,986	2,730,722
Total stock-based compensation expense	$ 1,518,138	$ 2,620,244	$ 2,977,993	$ 5,206,024

Warrants

There was no warrant activity for the six months ended June 30, 2016. The weighted average remaining contractual life of 16,909 shares of outstanding warrants at June 30, 2016 is approximately 3.9 years.

Note 7 - Commitments

Real Property Leases

The Company leases office space for corporate and administrative functions in New York, NY under an agreement with a monthly lease payment of $10,130 that expires in August 2016, which will be extended on a month to month basis. The Company also leases office space in Carmel, IN under a lease agreement that expires in June 2021. The leased locations in New York, NY and Carmel, IN are for corporate and administrative functions supporting both the HBV-cure and microbiome programs and are adequate for the Company's current needs.

The Company leases office and laboratory space in San Francisco, California under a sublease that expires in December 2017. Research activities for the HBV-cure program are also being conducted at laboratory space leased from Indiana University at Bloomington, IN that expires in December 2016. Research activities for the microbiome program will also be conducted at office and laboratory space leased from the University of Florida Research Foundation in Alachua, FL. The Company believes these leased facilities are adequate for its current needs and that additional space will be available in the future on commercially reasonable terms as needed.

The total leasing expenses for the three months ended June 30, 2016 and 2015 were approximately $402,637 and $138,000, respectively. The total leasing expenses for the six months ended June 30, 2016 and 2015 were approximately $755,000 and $297,000, 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, 2016 and 2015 amounted to approximately $165,000 and $28,000, respectively. The equipment lease expense for the six months ended June 30, 2016 and 2015 amounted to approximately $256,000 and $47,000, respectively.

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

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2015, 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, 2015 filed with the SEC on March 11, 2016 (the "2015 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 2015 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 biotechnology company advancing two innovative platform programs: (i) HBV-cure program, which is advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and (ii) microbiome program, which is a novel class of oral biological therapeutics, 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 several drug candidates that inhibit multiple viral targets throughout the HBV lifecycle for possible use alone or in combination therapy. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate a number of HBV core protein (HBc) functions.

The Company's microbiome program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices (cGMP) conditions, and a patent pending delivery system, GEMICEL ^{TM}, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. The lead program from this platform, ABI-M101, is in development for the treatment of *C. difficile* infections (CDI). Using its microbiome platform, the Company is developing additional product candidates for multiple indications including metabolic disorders, immunotherapy and autoimmune diseases.

We currently have administrative offices in Carmel, Indiana and New York, New York and research facilities in Bloomington, Indiana, Alachua, Florida and San Francisco, California. Research activities for the HBV-cure program are also being conducted at Indiana University at Bloomington, under the aegis of Adam Zlotnick, PhD, 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.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. 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 2015 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2015 Annual Report.

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and 2015

Research and Development Expense

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third party contract research organizations for preclinical studies, consultants, costs associated with regulatory filings and patents, laboratory costs and other supplies.

Research and development expense, excluding stock-based compensation expense, was approximately $6.7 million for the three months ended June 30, 2016, an increase of approximately $3.5 million or 105.3%, from approximately $3.2 million for the same period in 2015. The increase was primarily due to an increase of approximately $2.2 million in research expenses for our HBV-cure program and an increase of approximately $1.1 million in research expenses for our microbiome program.

Stock-based compensation was approximately $0.9 million for the three months ended June 30, 2016, a decrease of approximately $0.5 million or 40.1%, from approximately $1.4 million for the same period in 2015.

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 administrative employees, consultants, and directors.

General and administrative expense, excluding stock-based compensation expense, was approximately $2.3 million for the three months ended June 30, 2016, an increase of approximately $1.0 million or 76.4%, from approximately $1.3 million for the three months ended June 30, 2015. The increase was primarily due to an increase of approximately $0.5 million of compensation and bonus expenses related to new employees hired in 2016, $0.2 million in professional expenses and $0.2 million in travel and donation expenses classified as operating expense.

Stock-based compensation expense was approximately $0.7 million for the three months ended June 30, 2016, a decrease of approximately $0.5 million or 44.4%, from approximately $1.2 million for the same period in 2015.

Comparison of the Six Months Ended June 30, 2016 and 2015

Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was approximately $14.1 million for the six months ended June 30, 2016, an increase of approximately $8.1 million or 133.4%, from approximately $6.0 million for the same period in 2015. The increase was primarily due to an increase of approximately $5.4 million in research expenses for our HBV-cure program and an increase of approximately $2.6 million in research expenses for our microbiome program.

Stock-based compensation was approximately $1.6 million for the six months ended June 30, 2016, a decrease of approximately $0.9 million or 34.6%, from approximately $2.5 million for the same period in 2015.

General and Administrative Expense

General and administrative expense, excluding stock-based compensation expense, was approximately $4.7 million for the six months ended June 30, 2016, an increase of approximately $1.6 million or 49.9%, from approximately $3.1 million for the six months ended June 30, 2015. The increase was primarily due to an increase of approximately $0.6 million in professional expenses, $0.3 million of compensation and bonus expenses related to new administrative employees hired in 2016 and $0.3 million in capital and other tax expenses classified as operating expense.

Stock-based compensation expense was approximately $1.4 million for the six months ended June 30, 2016, a decrease of approximately $1.3 million or 48.4%, from approximately $2.7 million for the same period in 2015.

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, 2016 principally through equity financing, raising an aggregate of approximately $192.5 million in net proceeds.

Cash Flows for the Six Months Ended June 30, 2016 and 2015

Net Cash from Operating Activities

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 an $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 used in continuing operations for the six months ended June 30, 2015 was $8.1 million and was primarily driven by the loss incurred during the six months ended June 30, 2015 of approximately $14.1 million, partially offset by stock-based compensation expense of approximately $5.2 million and increase in accounts payable and accrued expenses of approximately $1.3 million.

Net Cash from Investing Activities

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 during the year.

Net cash used in investing activities from continuing operations for the six months ended June 30, 2015 was approximately $48.8 million primarily due to the purchase of marketable securities.

Net Cash from Financing Activities

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

Net cash provided by financing activities was approximately $81.3 million for the six months ended June 30, 2015. On March 19, 2015, we received net proceeds of approximately $70.5 million in an underwritten equity offering. On April 6, 2015, we received additional net proceeds of approximately $10.6 million from the exercise of underwriters' options. On April 20, 2015, we paid $0.1 million for accrued offering cost.

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, 2016, 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 scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and future clinical trials for our product candidates;
- the extent to which we acquire or in-license other medicines and technologies;
- 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 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.

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 2015 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 Exchange Act Rules 13a-15(e) and 15d-15(e), which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities Exchange Act of 1934, as amended (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 Rule 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, 2016 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 Securities and Exchange Commission. If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

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

To date, we have no approved product on the market and have generated no product revenues. Our prospects are substantially dependent on our ability to develop and commercialize our HBV and microbiome therapies. Unless and until we receive approval from the FDA and 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 or other strategic arrangements.

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 development programs are derived from either laboratory or pre-clinical 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 and microbiome programs, both of which are in late pre-clinical 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 of our other product candidates we may subsequently identify.

Our lead compounds for HBV and microbiome therapies are our only current product candidates. Both are in preclinical development. None of our current product candidates has advanced into clinical testing, and it may be years before the larger, pivotal trials necessary to support regulatory approval 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;
- 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 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 product. If we are unable to complete development of our HBV or microbiome therapies, or any other product candidates that we may develop, we will be unable to generate revenue or build a sustainable or profitable business.

Preclinical models may not be representative of disease behavior in clinical trials. Results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results and preclinical testing and clinical trials involve a lengthy and expensive process with an uncertain outcome.

The results of preclinical models 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 preclinical 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 from any prior studies or trials, if at all. For example, in late June 2012, we reported that our second Phase III randomized, double-blind, placebo-controlled clinical trial of iferanserin in patients with hemorrhoidal disease did not meet its endpoints, despite favorable Phase II trial results. We also reported in February 2014 that our Phase III clinical trial for diltiazem for the treatment of anal fissures demonstrated no significant improvement compared to placebo despite favorable results in a prior Phase III trial. Based on these unfavorable clinical results, we decided to cease development of these two prior product candidates. These risks apply to our planned development of our current and any other product candidates.

Preclinical 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 preclinical 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 meet the requisite regulatory approvals. 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.

Preclinical 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 preclinical 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 preclinical 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:

- 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;
- modification of clinical trial protocols;
- 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 contract research organizations, or CROs, to conduct our preclinical 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 and good scientific practice. In the event the CROs fail to perform their duties in such a fashion, we may not obtain regulatory approval for any of our product candidates.

The failure of preclinical 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 preclinical studies or clinical trials would delay the filing of our New Drug Applications, or NDAs, 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.

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 and have only a limited operating history. In addition, we have terminated our programs related to our three prior product candidates. 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, 2016, the combined company had an accumulated deficit of $185.1 million. We expect to incur substantial additional losses over the next several years as we continue to pursue our research, development, preclinical studies and clinical trial activities. The amount of future losses and when, if ever, we will achieve profitability are uncertain. 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 therapies 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:

- continue to undertake research and development to identify potential product candidates;
- continue to undertake preclinical studies and clinical trials for our product candidates; and
- seek regulatory approvals for 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, preclinical studies and clinical trials for our product candidates;
- obtaining necessary regulatory approvals from the FDA and international regulatory agencies 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 preclinical studies and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales, marketing and distribution activities.

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, preclinical and clinical testing;
- unplanned expenditures in product development, preclinical 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, or HBc, with core protein Allosteric Modulators, or 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, the technology underlying our microbiome platform is in preclinical development.

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 reduce viral antigens in HBV patients and result in a functional cure is unproven. Thus, even if CpAM technology is successful at reducing antigen levels in HBV patients, it may not be a commercially viable drug if there is not a corresponding medical benefit related to the underlying HBV infection. Similarly, the ability to effectively and reliably deliver bacteria to the GI tract using our microbiome technology 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 candidate 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 into the fourth quarter of 2017. 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 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 raise capital, we could be forced to 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 licensing, sales and/or milestone revenue.

Before we or any commercial partner can obtain the approvals necessary to sell any of our product candidates, we must show through preclinical 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 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 dependent on a license relationship for each of our HBV-cure program and our microbiome program.

Our license agreement with Indiana University Research and Technology Corporation, or IURTC, from whom we have licensed intellectual property rights to 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 total amount of all potential future milestone payments at June 30, 2016 is $825,000. 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, from whom we have licensed intellectual property rights to our microbiome delivery mechanism, 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 delivery mechanism for our microbiome program. If we fail to comply with similar obligations to any other licensor, it 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.

Our collaboration with Adam Zlotnick, the scientific founder of our HBV-cure program, is advantageous. If that collaboration is not maintained, we may not be able to capitalize on the market potential of our HBV-cure program.

Dr. Adam Zlotnick is the founder of our HBV-cure program. We have entered into a three-year consulting agreement with Dr. Zlotnick, the initial term of which expires on July 11, 2017, pursuant to which he serves as the Chairman of our Scientific Advisory Board and provides consulting services as we request. Dr. Zlotnick could refuse to extend the agreement after it expires on July 11, 2017 or we could terminate the consulting agreement for cause or no cause. Although Dr. Zlotnick assigned to us any rights to intellectual property related to our HBV therapy that arise during the term of the consulting agreement, and while the consulting agreement contains a non-compete during the term of the agreement, the loss of Dr. Zlotnick's services could materially impair our ability to further the development of our HBV therapy program.

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, preclinical 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, preclinical 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 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 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 preclinical and clinical testing and expect to rely on third parties to conduct some of our research and preclinical 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 preclinical and clinical testing. As a result, we expect to contract with third parties to conduct most or all preclinical and clinical testing required for regulatory approval for our product candidates. We currently plan to outsource all clinical testing to third parties and will be reliant on the services of these 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 preclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our research, preclinical 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 expect to rely exclusively on third parties to formulate and manufacture our product candidates.

We do not have and presently do not intend to establish our own manufacturing facilities. Consequently, we 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 approval, we expect to rely on one or more third-party contractors to manufacture our products. If, for any reason, we become unable to rely on any future source 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 for preclinical, 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 secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance might be materially affected.

In addition, before 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 contracted 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 any of our future contract manufacturers fails to comply with these requirements, it would be subject to possible regulatory action which 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.

Our reliance on third-party manufacturers exposes us to the following risks:

- We might be unable to identify manufacturers for commercial supply on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any 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.
- Our third-party manufacturers 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.
- Our contract manufacturers 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 our contract manufacturers 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 and foreign regulatory agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. We would not have complete control over third-party manufacturers' compliance with these regulations and requirements.
- 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 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, preclinical 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 preclinical 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 and CDI is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We will compete with organizations that have existing treatments and that are or will be developing treatments for the indications that our product candidates target. If our competitors develop effective treatments for HBV, CDI or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects might be materially harmed, due to intense competition in these markets.

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 preclinical 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 Small, our Chief Medical Officer and Vice President of Research and Development, Dr. Uri Lopatin, our Chief Scientific Officer, Dr. Richard Colonno, our Chief Discovery Officer, Lee D. Arnold, our Chief Development Officer and Head of Microbiome, 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. Arnold, 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 August 1, 2016, we had 61 employees, 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-cure program and our microbiome program 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, preclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. The FDA regulates small molecule chemical entities, whether administered orally, topically or by injection, as drugs, subject to an NDA, under the Federal Food, Drug, and Cosmetic Act. 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 preclinical 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 preclinical 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 worldwide 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 an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research, preclinical 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 that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the drug approval process and might require us to conduct additional preclinical 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. 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.

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 Veteran's 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. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. In addition, 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 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. If the use of one or more of our or our collaborators' 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 insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We expect to obtain clinical trial insurance for our product candidates prior to beginning clinical trials. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we obtain, if any, in the future 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 or our collaborators' 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.

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 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.

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 we went public on December 22, 2010 and through August 1, 2016, the closing price of our common stock has fluctuated between $4.30 and $101.25 (after giving effect to the 1-for-5 reverse stock split effected on July 11, 2014), with significant volatility after we announced on June 25, 2012 that our prior product candidate iferanserin failed to meet the endpoints of our Phase III trial, and after we announced in February 2014 that our prior product candidate diltiazem demonstrated no significant improvement compared to placebo. 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 receipt or loss of required regulatory approvals for our product candidates;
- the timing, costs and results of our preclinical studies and clinical trials and other studies involving our product candidates;
- availability of capital;
- future sales of our common stock;
- any sales 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;
- success or failure of our product candidates;
- 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 August 1, 2016, our executive officers, directors and one of our founders beneficially owned approximately 24.1% of our voting common stock, and this group together with other stockholders holding beneficially 5% of more of our outstanding voting common stock, owned approximately 71.0% 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.

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 Securities Exchange Act of 1934, 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 of 2002, 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. We do not control any industry or financial analysts, and these analysts may not publish an adequate amount of research on our company, or may publish unfavorable or inaccurate research about our business, which could negatively impact our stock price. 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. Amended and Restated 2014 Stock Incentive Plan		8-K	6/6/16	10.1
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			

# Indicates a management compensation plan, contract or arrangement.

* 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 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, 2016

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

Date: August 9, 2016

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

EXHIBIT 31.1

CERTIFICATION

I, Derek 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, 2016

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

EXHIBIT 31.2

CERTIFICATION

I, David J. Barrett, certify that:

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

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

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

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

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

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

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: August 9, 2016

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended June 30, 2016 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Derek 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 Small
Derek Small
President and Chief Executive Officer

August 9, 2016

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended June 30, 2016 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

August 9, 2016