ASSEMBLY BIOSCIENCES, INC.

FORM 10-Q
(Quarterly Report)

Filed 05/08/17 for the Period Ending 03/31/17

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Telephone	(212) 554-4388
CIK	0001426800
Symbol	ASMB
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

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

For the quarterly period ended March 31, 2017

OR

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

For the transition period from _____to_____.

Commission file number: 001-35005

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

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

(317) 210-9311
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of May 4, 2017, there were 17,346,103 shares of registrant's common stock outstanding.

Index

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

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 70,818,011	$ 28,575,085
Marketable securities, at fair value	20,105,000	24,388,403
Prepaid expenses and other current assets	1,298,673	611,176
Total current assets	92,221,684	53,574,664
Long-term assets		
Marketable securities, at fair value	-	2,435,753
Property, plant and equipment, net	182,771	214,687
Security deposits	241,600	255,366
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	42,062,507	44,543,942
Total assets	**$ 134,284,191**	**$ 98,118,606**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,947,183	$ 2,368,131
Accrued expenses	4,013,562	4,752,823
Deferred revenue - short-term	4,995,894	-
Total current liabilities	10,956,639	7,120,954
Long-term liabilities		
Deferred tax liabilities	11,119,651	11,119,651
Deferred revenue - long-term	44,319,737	-
Total long-term liabilities	55,439,388	11,119,651
Total liabilities	**66,396,027**	**18,240,605**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,318,044 and 17,246,754 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively	17,318	17,247
Additional paid-in capital	290,553,583	288,688,990
Accumulated other comprehensive loss	(524,677)	(600,769)
Accumulated deficit	(222,158,060)	(208,227,467)
Total stockholders' equity	67,888,164	79,878,001
Total liabilities and stockholders' equity	**$ 134,284,191**	**$ 98,118,606**

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2017	**2016**
Collaboration revenue	$ 684,369	$ -
Operating expenses:		
Research and development	10,573,739	8,118,576
General and administrative	4,040,459	3,158,576
Total operating expenses	14,614,198	11,277,152
Loss from operations	**(13,929,829)**	**(11,277,152)**
Other income (expenses)		
Interest and other income	136,484	490,421
Realized loss from marketable securities	(137,248)	(201,827)
Total other income	(764)	288,594
Net loss	**$ (13,930,593)**	**$ (10,988,558)**
Other comprehensive (loss) income		
Unrealized loss recognized in accumulated other comprehensive loss before reclassification	(61,156)	(129,737)
Reclassification adjustment of unrealized loss included in net loss	137,248	201,827
Comprehensive loss	**$ (13,854,501)**	**$ (10,916,468)**
Net loss per share, basic and diluted	$ (0.81)	$ (0.64)
Weighted average common shares outstanding, basic and diluted	17,268,280	17,225,662

See Notes to Condensed Consolidated Financial Statements.

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

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (13,930,593)	$ (10,988,558)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	31,916	18,558
Stock-based compensation	1,224,647	1,459,855
Realized loss from marketable securities	137,248	201,827
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(687,497)	(61,394)
Accounts payable	(420,948)	962,450
Accrued expenses	(739,261)	(796,010)
Deferred revenue	49,315,631	-
Security deposits	13,766	(7,121)
Net cash provided by (used in) operating activities	34,944,909	(9,210,393)
Cash flows from investing activities		
Purchases of fixed assets	-	(2,163)
Purchases of marketable securities	-	(7,951,257)
Redemptions of marketable securities	6,658,000	10,451,332
Net cash provided by investing activities	6,658,000	2,497,912
Cash flows from financing activities		
Proceeds from the exercise of stock options	640,017	-
Net cash provided by financing activities	640,017	-
Net increase (decrease) in cash and cash equivalents	42,242,926	(6,712,481)
Cash and cash equivalents at the beginning of the period	28,575,085	27,107,526
Cash and cash equivalents at the end of the period	**$ 70,818,011**	**$ 20,395,045**
Supplemental disclosure of cash flow information:		
Change in unrealized gain on marketable securities available-for-sale	$ 76,092	$ 72,090

See Notes to Condensed Consolidated Financial Statements.

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance as of December 31, 2016	**17,246,754**	**$ 17,247**	**$ 288,688,990**	**$ (600,769)**	**$ (208,227,467)**	**$ 79,878,001**
Proceeds from the exercise of stock options	71,290	71	639,946	-	-	640,017
Change in unrealized gain on marketable securities	-	-	-	76,092	-	76,092
Stock-based compensation	-	-	1,224,647	-	-	1,224,647
Net loss	-	-	-	-	(13,930,593)	(13,930,593)
Balance as of March 31, 2017	**17,318,044**	**$ 17,318**	**$ 290,553,583**	**$ (524,677)**	**$ (222,158,060)**	**$ 67,888,164**

See Notes to Condensed Consolidated Financial Statements.

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc. ("Assembly" or the "Company") is a clinical stage biotechnology company advancing two innovative platform programs: a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and a novel class of oral synthetic live biotherapeutics, which are designed to restore health to a dysbiotic microbiome. The Company's HBV-cure program is aimed at increasing the current low cure rate for patients with HBV and is pursuing multiple drug candidates that inhibit multiple steps of the HBV lifecycle. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate the HBV core (HBc) protein. The lead product candidate from this program, ABI-H0731 has completed a Phase 1a human clinical trial, with the Phase 1b/2a portion of the clinical trial expected to commence in the second quarter of 2017. The Company's Microbiome program consists of a fully integrated platform that includes a disease targeted strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practice, or cGMP, conditions, and a patent pending delivery system, that we call GEMICEL ®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal, or GI tract. The lead product candidate from this platform, ABI-M101, is in development for the treatment of *clostridium difficile* infections (CDI). Using its microbiome platform, the Company is developing additional product candidates.

On January 6, 2017, the Company entered into a Research, Development, Collaboration and License Agreement (the "Collaboration Agreement") with Allergan Pharmaceuticals International Limited ("Allergan") to develop and commercialize select microbiome gastrointestinal programs. Pursuant to the terms of the Collaboration Agreement, in connection with the closing of the transaction on February 10, 2017, Allergan paid the Company an upfront payment of $50 million (see Note 7). Allergan and the Company have agreed to share development costs up to an aggregate of $75 million through proof-of-concept ("POC") studies on a ⅔, ⅓ basis, respectively, and Allergan has agreed to assume all post-POC development costs. Additionally, the Company has an option to co-promote the licensed programs in the United States and China, subject to certain conditions set forth in the Collaboration Agreement.

Liquidity

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

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

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

Basis of Presentation

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

The accompanying condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (the "SEC") and on the same basis as the Company prepares its annual audited consolidated financial statements. The condensed consolidated balance sheet as of March 31, 2017, condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2017 and 2016, condensed consolidated statements of cash flows for the three months ended March 31, 2017 and 2016, and condensed consolidated statement of changes in stockholders' equity for the three months ended March 31, 2017 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 months ended March 31, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017 or for any future interim period. The consolidated balance sheet at December 31, 2016 has been derived from audited financial statements; however, it does not include all of the information and notes required by U.S. GAAP for complete financial statements. The accompanying condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2016, and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 2, 2017 (the "2016 Annual Report").

Use of Estimates

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

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

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

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the 2016 Annual Report.

Revenue Recognition

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

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

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

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit using the relative selling price method. The allocated consideration for each unit of accounting is recognized based on the method most appropriate for that unit of account and in accordance with the revenue recognition criteria detailed above.

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

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

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

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

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

Loss per Share of Common Stock

Basic net loss per share of common stock excludes dilution and is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted net loss per share is the same. Securities that could potentially result in diluted loss per share in the future that were not included in the computation of diluted loss per share at March 31, 2017 and 2016 are as follows:

	Three Months Ended March 31,	
	2017	**2016**
Warrants to purchase common stock	16,909	16,909
Options to purchase common stock	4,816,126	3,851,688
Total	**4,833,035**	**3,868,597**

Adoption of Recent Accounting Pronouncements

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

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* , which requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The FASB has subsequently issued ASU No. 2016-10, *Revenue from Contracts with Customer: (Topic 606) Identifying Performance Obligations and Licensing* to address issues arising from implementation of the new revenue recognition standard. ASU 2014-09 and ASU 2016-10 are effective for interim and annual periods beginning January 1, 2018, and may be adopted earlier, but not before January 1, 2017. The revenue standards are required to be adopted by taking either a full retrospective or a modified retrospective approach. The Company is currently evaluating the impact that ASU 2014-09 and 2016-10 will have on the Company's financial statements and determining the transition method, including the period of adoption, that it will apply. The Company is currently evaluating which transition approach it will utilize and the impact of adopting this accounting standard on the Company's condensed consolidated financial statements.

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

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* , which supersedes FASB Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for 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 June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* . ASU 2016-13 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective on January 1, 2020. Early adoption will be available on January 1, 2019. The Company is currently evaluating the effect that the updated standard will have on its condensed consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments,* which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its condensed consolidated statements of cash flows and related disclosures.

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

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

Note 3 - Marketable Securities

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

	March 31, 2017			
	Amortized Cost	Gross Unrealized Gain [1]	Gross Unrealized Loss [1]	Fair Value
Short-term available-for-sale securities				
Corporate bonds	$ 17,671,194	$ 8,161	$ (401,257)	$ 17,278,098
Government and agency obligations	1,225,000	98	-	1,225,098
Municipal bonds	1,596,160	5,644	-	1,601,804
Total	$ 20,492,354	$ 13,903	$ (401,257)	$ 20,105,000

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

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

The contractual term to maturity of short-term marketable securities held by the Company as of March 31, 2017 is less than one year. There were no long-term marketable securities held by the Company as of March 31, 2017.

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

	March 31, 2017	December 31, 2016
Quoted prices in active markets for identical assets (Level 1)	$ -	$ -
Quoted prices for similar assets observable in the marketplace (Level 2)	20,105,000	26,824,156
Significant unobservable inputs (Level 3)	-	-
Total	$ 20,105,000	$ 26,824,156

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

There were no transfers of marketable securities between Levels 1, 2 or 3 for the three months ended March 31, 2017 and 2016.

The following table shows the Company's investments' gross unrealized losses and fair value, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at March 31, 2017.

	Less than 12 Months		12 Months or More		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate bonds	$ 4,901,519	$ (18,559)	$ 8,939,618	$ (382,698)	$ 13,841,137	$ (401,257)
Total	**$ 4,901,519**	**$ (18,559)**	**$ 8,939,618**	**$ (382,698)**	**$ 13,841,137**	**$ (401,257)**

The Company has determined that the unrealized losses are deemed to be temporary impairments as of March 31, 2017. The Company believes that the unrealized losses generally are caused by increases in the risk premiums required by market participants rather than an adverse change in cash flows or a fundamental weakness in the credit quality of the issuer or underlying assets. Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, it does not consider the investment in corporate bonds to be other-than-temporarily impaired at March 31, 2017.

Note 4 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

	Useful life (Years)	March 31, 2017	December 31, 2016
Computer hardware and software	3	$ 86,228	$ 86,228
Lab equipment	3 to 5	253,735	253,735
Office equipment	3 to 5	1,109	1,109
Leasehold improvement	1	68,213	68,213
Total property, plant and equipment		409,285	409,285
Less: Accumulated depreciation and amortization		(226,514)	(194,598)
Property, plant and equipment, net		$ 182,771	$ 214,687

Depreciation expense for the three months ended March 31, 2017 and 2016 was approximately $32,000 and $19,000, 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:

	March 31, 2017	December 31, 2016
Accrued expenses:		
Salaries, bonuses and employee benefits	$ 1,726,245	$ 2,884,000
Accrued severance expenses	245,028	241,737
Research and development expenses	980,436	916,674
General and administrative expenses	1,061,853	710,412
Total accrued expenses	$ 4,013,562	$ 4,752,823

Note 6 - Stockholders' Equity

Common Stock

For the three months ended March 31, 2017, the Company issued an aggregate of 71,290 shares of common stock and received gross proceeds of approximately $0.6 million from the exercise of options.

Options

In July 2010, the stockholders approved the 2010 Equity Incentive Plan (the "2010 Plan"). As of March 31, 2017, there were outstanding options to purchase an aggregate of 654,834 shares of common stock under the 2010 Plan. Effective on June 2, 2016, the 2010 Plan was frozen and no further grants will be made under the 2010 Plan. Shares that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the Amended and Restated 2014 Plan (as defined below).

In July 2014, the stockholders approved the 2014 Stock Incentive Plan (the "2014 Plan"). On June 2, 2016, at the 2016 Annual Meeting of Stockholders, the stockholders of the Company approved the amendment and restatement of the Company's 2014 Plan (the "Amended and Restated 2014 Plan"). Pursuant to the terms of the Amended and Restated 2014 Plan, the maximum number of shares reserved for issuance thereunder is 4,160,000 (representing an increase of 1,600,000). As of March 31, 2017, there were outstanding options to purchase an aggregate of 3,539,641 shares of common stock and 498,905 shares available for grant under the Amended and Restated 2014 Plan. Additionally, 37,501 shares of common stock forfeited under the 2010 Plan are available for issuance under the Amended and Restated 2014 Plan.

Pursuant to the terms of the merger of Assembly Pharmaceuticals, Inc. with a wholly-owned subsidiary of the Company in 2014, the options to purchase shares of Assembly Pharmaceuticals' common stock issued and outstanding immediately prior to the merger were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company's common stock. As of March 31, 2017, assumed options to purchase an aggregate of 621,651 shares of common stock were outstanding.

A summary of the Company's option activity and related information for the three-month period ended March 31, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value
Outstanding as of December 31, 2016	4,457,251	$ 7.14	$ 23,258,604
Granted	436,500	22.04	1,505,435
Exercised	(71,290)	8.98	-
Forfeited	(6,335)	9.77	-
Outstanding as of March 31, 2017	4,816,126	$ 8.46	$ 82,006,913
Options vested and exercisable	3,087,647	$ 6.56	$ 58,451,683

The fair value of the options granted for the three months ended March 31, 2017 and 2016, were based on the following assumptions:

	Three Months Ended March 31,	
	2017	2016
Exercise price	12.81 - 25.34	6.36 - 7.03
Expected stock price volatility	85.4% - 87.0%	88.7% - 91.8%
Risk-free rate of interest	2.19% - 2.23%	1.53% - 1.94%
Term (years)	5.5 - 7.0	5.4 - 7.0

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

	Future Stock Option Compensation Expenses
Nine Months Ended December 31, 2017	$ 5,902,782
Year Ended December 31, 2018	3,811,811
Year Ended December 31, 2019	1,112,946
Year Ended December 31, 2020	331,969
Year Ended December 31, 2021	5,138
Total	$ 11,164,646

Unamortized stock-based compensation expense amounted to approximately $11.2 million at March 31, 2017. The weighted average remaining amortization period is approximately 1.6 years at March 31, 2017. Effective on January 1, 2017, the Company began accounting for forfeitures as they occur. Ultimately, the actual expenses recognized over the vesting period will be for those shares that vested. Prior to making this election under ASU 2016-09, the Company estimated their forfeiture rate at 0%, or they did not have a significant history of forfeitures.

Stock-based compensation expense for the three months ended March 31, 2017 and 2016 is as follows:

	Three Months Ended March 31,	
	2017	2016
Research and development	$ 951,926	$ 718,156
General and administrative	272,721	741,699
Total stock-based compensation expense	$ 1,224,647	$ 1,459,855

Warrants

There was no warrant activity for the three months ended March 31, 2017. The weighted average remaining contractual life of 16,909 shares of outstanding warrants at March 31, 2017 is approximately 3.2 years.

Note 7 – Collaboration Agreement

On January 6, 2017, the Company entered into the Collaboration Agreement with Allergan to develop and commercialize select microbiome gastrointestinal programs. Pursuant to the Collaboration Agreement, the Company granted Allergan an exclusive worldwide license to certain of its intellectual property, including its intellectual property arising under the Collaboration Agreement, to develop and commercialize licensed compounds for irritable bowel disease (IBD), such as ulcerative colitis (UC) and Crohn's disease, and irritable bowel syndrome (IBS).

Under the Collaboration Agreement, Allergan and the Company will collaborate on research and development activities with respect to the licensed compounds in accordance with a mutually agreed upon research and development plan.

Pursuant to the terms of the Collaboration Agreement, in connection with the closing of the transaction on February 10, 2017, Allergan paid the Company an upfront payment of $50 million. Additionally, the Company is eligible to receive up to approximately $630 million in payments related to 7 development milestones and up to approximately $2.15 billion in payments related to 12 commercial development and sales milestones in connection with the successful development and commercialization of licensed compounds for up to six different indications. At the time of execution of the Collaboration Agreement, there was significant uncertainty as to whether the stated milestones would be achieved. In conjunction with this uncertainty, the Company has determined that the milestones are substantive in nature as they are commensurate with the enhancement of value of the delivered license as they relate to clinical success and advancement within the FDA drug development platform. In addition, the Company is eligible to receive tiered royalties at rates ranging from the mid-single digits to the mid-teens based on net sales. Allergan and the Company have agreed to share development costs up to an aggregate of $75 million through proof-of-concept ("POC") studies on a ⅔, ⅓ basis, respectively, and Allergan has agreed to assume all post-POC development costs. In the event any pre-POC development costs exceed $75 million in the aggregate, the Company may elect either (a) to fund ⅓ of such costs in excess of $75 million or (b) to allow Allergan to deduct from future development milestone payments ⅓ of the development costs funded by Allergan in excess of $75 million plus a premium of 25%. The Company has an option to co-promote the licensed programs in the United States and China, subject to certain conditions set forth in the Collaboration Agreement.

Allergan may terminate the Collaboration Agreement for convenience at any time upon either 90 days' (prior to the initiation of the first POC trial of a licensed product) or 120 days' (after the initiation of the first POC trial of a licensed product), as applicable, advance written notice to the Company. The Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the Collaboration Agreement, subject to cure.

The Collaboration Agreement meets the definition of a collaborative arrangement and a multiple-element arrangement. The Company concluded that there were two significant deliverables under the Collaboration Agreement – the license and the research and development services – but that the license does not have stand-alone value as Allergan cannot obtain value from the license without the research and development services, which the Company is uniquely able to perform. As such, the Company recognized the upfront payment received of $50.0 million as approximately $5.0 million in short-term deferred revenue and $45.0 million in long-term deferred revenue as of the closing date. The deferred revenue will be amortized over a 10-year service period. For the three months ended March 31, 2017, the Company recorded approximately $0.7 million in revenue related to the amortization of deferred revenue. Expense reimbursements will be recognized as collaboration revenue when the related expenses are incurred. There were no reimbursable expenses incurred in connection with the Collaboration Agreement during the three months ended March 31, 2017.

Note 8 – Commitments and Contingencies

Real Property Leases

The Company leases office space for corporate functions in Carmel, Indiana under a lease agreement that expires in June 2021. The leased location in Carmel, Indiana supports both the HBV-cure and microbiome programs. The Company leases office and laboratory space in San Francisco, California under a sublease that expires in December 2017. The Company also conducts research activities for the HBV-cure program at laboratory space leased from Indiana University at Bloomington, Indiana. The related activities performed at Indiana University are being transferred to the Company's Indiana and California locations such that the Company's use of this leased facility will cease by the end of May 2017. Research activities for the Microbiome program are also conducted at office and laboratory space in Groton, Connecticut under a lease that expires in March 2018 and office and laboratory space leased from the University of Florida Research Foundation in Alachua, Florida under a lease that expires in May 2017.

The total leasing expenses for the three months ended March 31, 2017 and 2016 were approximately $0.3 million and $0.3 million, respectively.

Equipment Lease

Pursuant to a Master Lease agreement dated November 25, 2014, the Company leases certain equipment. The equipment lease expense for the three months ended March 31, 2017 and 2016 amounted to approximately $182,000 and $57,000, respectively. These equipment leases begin to expire in 2017, with the final lease expiring in 2020. The sum of all future payments through termination is approximately $1.5 million.

Litigation

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

Note 9 - Subsequent Event

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

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

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 2, 2017 (the "2016 Annual Report"). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our 2016 Annual Report, "Part II. Item 1A. Risk Factors" in this report, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a clinical stage biotechnology company advancing two innovative platform programs: a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and novel class of oral synthetic live biotherapeutics, which are designed to restore health to a dysbiotic microbiome. The company's HBV-cure program is aimed at increasing the current low cure rate for patients with HBV and is pursuing multiple drug candidates that inhibit multiple steps of the HBV lifecycle. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate the HBV core (HBc) protein. The lead product candidate from this program, ABI-H0731 has completed a Phase 1a human clinical trial, with the Phase 1b/2a portion of the clinical trial expected to commence in the second quarter of 2017. The company's Microbiome program consists of a fully integrated platform that includes a disease targeted strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practice, or cGMP, conditions, and a patent pending delivery system, that we call GEMICEL ® , which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal, or GI tract. The lead product candidate from this platform, ABI-M101, is in development for the treatment of *clostridium difficile* infections (CDI). Using its microbiome platform, the company is developing additional product candidates.

On January 6, 2017, we entered into the Collaboration Agreement with Allergan to develop and commercialize select microbiome gastrointestinal programs. Pursuant to the terms of the Collaboration Agreement, in connection with the closing of the transaction on February 10, 2017, Allergan paid us an upfront payment of $50 million. We have agreed with Allergan to share development costs up to an aggregate of $75 million through proof-of-concept ("POC") studies on a ⅔, ⅓ basis, respectively, and Allergan has agreed to assume all post-POC development costs. Additionally, we have an option to co-promote the licensed programs in the United States and China, subject to certain conditions set forth in the Collaboration Agreement.

We currently have corporate and administrative offices in Carmel, Indiana and research facilities in Bloomington, Indiana, Alachua, Florida, Groton, Connecticut and San Francisco, California. We expect to close our research facilities in Alachua, Florida and Bloomington, Indiana by the end of May 2017. Research activities for the HBV-cure program are also being conducted at Indiana University at Bloomington, under the aegis of Adam Zlotnick, Ph.D., co-founder of Assembly Pharmaceuticals, Inc. and head of our HBV Scientific Advisory Board.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

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

Results of Operations

Comparison of the Three Months Ended March 31, 2017 and 2016

For the three months ended March 31, 2017, collaboration revenue was approximately $0.7 million, which is the amortization of deferred revenue related to Allergan Collaboration Agreements. There was no revenue during the same period in 2016.

Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was approximately $9.6 million for the three months ended March 31, 2017, an increase of approximately $2.3 million from approximately $7.4 million for the same period in 2016. The increase was primarily due to an increase of approximately $1.0 million in research expenses for our Microbiome program, an increase of approximately $1.2 million in research expenses for our HBV-cure program, and an increase of approximately $0.1 million in research expenses for outsourced chemistry.

Stock-based compensation expense was approximately $1.0 million for the three months ended March 31, 2017, an increase of approximately $0.3 million from approximately $0.7 million for the same period in 2016.

General and Administrative Expense

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

General and administrative expense, excluding stock-based compensation expense, was approximately $3.8 million for the three months ended March 31, 2017, an increase of approximately $1.4 million from approximately $2.4 million for same period in 2016. The increase was primarily due to an increase of approximately $0.8 million in professional expenses and $0.6 million in legal expenses.

Stock-based compensation was approximately $0.3 million for the three months ended March 31, 2017, a decrease of approximately $0.4 million from approximately $0.7 million for the same period in 2016.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through March 31, 2017 principally through equity financing, raising an aggregate of approximately $192.5 million in net proceeds, and strategic partnerships raising an aggregate of $50 million in upfront payments.

Cash Flows for the Three Months Ended March 31, 2017 and 2016

Net Cash from Operating Activities

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

Net cash used in operating activities was $9.2 million for the three months ended March 31, 2016 and funded our research and development program build out and general and administrative expenses. Net cash used in continuing operations for the three months ended March 31, 2016 was primarily driven by an $11.0 million net loss and offset by a $1.5 million non-cash expense recorded for the stock-based compensation.

Net Cash from Investing Activities

Net cash provided by investing activities from continuing operations for the three months ended March 31, 2017 was $6.7 million due to the redemption of marketable securities.

Net cash provided by investing activities from continuing operations for the three months ended March 31, 2016 was $2.5 million and primarily due to a purchase of $8.0 million of marketable securities and offset by the redemption of $10.5 million of marketable securities during the year.

Net Cash from Financing Activities

Net cash provided by financing activities from continuing operations for the three months ended March 31, 2017 was $0.6 million, resulting from the exercise of stock options to purchase 71,290 shares of common stock.

There was no net cash flow provided by financing activities for the three months ended March 31, 2016.

Funding Requirements

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

We monitor our cash needs and the status of the capital markets on a continuous basis. From time to time, we opportunistically raise capital and have done so multiple times since our initial public offering by issuing equity securities, most recently in March and April 2015. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

Based upon our cash position as of March 31, 2017, we expect that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

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

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

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

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

There were no material changes in our commitments under contractual obligations, as disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our 2016 Annual Report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Exchange Act, is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in the quarter ended March 31, 2017 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are not a party to any material legal proceedings, and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors.

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

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

Risks Related to Our Business

We have no approved products and currently are dependent on the future success of our HBV 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 or other regulatory authorities for our product candidates, we cannot sell our product candidates and will not have product revenues. We will have to fund all of our operations and capital expenditures from cash on hand, any future securities offerings or debt financings and any fees we may generate from out-licensing, collaborations or other strategic arrangements. If we are unable to develop and commercialize any product candidates from our HBV-Cure and Microbiome programs, we will be unable to generate revenues or build a sustainable or profitable business.

In addition, all of our product candidates are in an early stage of development and their risk of failure is high. The data supporting our drug discovery and pre-clinical and clinical 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 program, which has one product candidate in early clinical development, and our Microbiome program, which has one product candidate 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 other product candidates we may subsequently identify.

ABI-H0731 and ABI-M101 are our lead product candidates for our HBV-cure and Microbiome program, respectively. We have completed the Phase 1a portion of a Phase 1a/1b clinical trial for ABI-H0731, our novel oral agent for the treatment of chronic HBV. We anticipate initiating the Phase 1b portion of the trial in the second quarter of 2017. Our lead microbiome biotherapeutic product candidate, ABI-M101, is in late nonclinical development and we plan to initiate a Phase 1b clinical trial of ABI-M101 in CDI patients who have relapsed after two or three standard antibiotic regimens in the second half of 2017. It may be years before the larger, pivotal trials necessary to support regulatory approval of our product candidates are initiated, if ever. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must successfully meet a number of critical developmental milestones, including:

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

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

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

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

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

Nonclinical and clinical testing required for our product candidates is expensive and time-consuming and may result in delays or may fail to demonstrate safety and efficacy for desired indications.

In order to obtain FDA approval to market a new drug product, we must demonstrate safety and effectiveness in humans. To meet these requirements, we must conduct extensive nonclinical testing and sufficient adequate and well-controlled clinical trials. Conducting clinical trials is a lengthy, time consuming, and expensive process. The length of time might vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with product candidates for which we are directly conducting nonclinical studies or clinical trials might cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials might be delayed by many factors, including, for example:

- delays in reaching agreement with regulatory authorities on final trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- the lack of effectiveness during clinical trials;
- the emergence of unforeseen safety issues;
- inability to manufacture sufficient quantities of qualified materials under cGMP for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects, disease progression or other reasons;
- clinical sites dropping out of a trial to the detriment of enrollment;
- modification of clinical trial protocols;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements for clinical trials;

- delays, suspension, or termination of clinical trials by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government, institutional review board, ethics committee, or other regulatory delays or clinical holds requiring suspension or termination of the trials.

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

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

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

Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development. Undesirable side effects caused by any product candidates that we may discover or develop, or safety, tolerability or toxicity issues that may occur in our nonclinical studies, clinical trials or in the future, could cause us or regulatory authorities to interrupt, restrict, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, prospects, financial condition and results of operations.

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

We were established in October 2005, began active operations in the spring of 2007, terminated programs related to three prior product candidates, then merged with Assembly Pharmaceuticals, Inc. (“Assembly Pharmaceuticals”), a private company, in July 2014. We have only a limited operating history since the merger. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We, and Assembly Pharmaceuticals prior to our merger, have generated losses since we began operations and, as of March 31, 2017, the combined company had an accumulated deficit of approximately $222.2 million, and net losses of approximately $13.9 million and $11.0 million for the three months ended March 31, 2017 and 2016, respectively. These net losses have had, and will continue to have, an adverse effect on our stockholders’ equity and working capital. We expect to incur substantial additional losses over the next several years as we continue to pursue our research, development, nonclinical studies and clinical trial activities. Further, since our initial public offering, we have incurred and will continue to incur as a public company significant additional legal, accounting and other expenses to which we were not subject to as a private company, including expenses related to our efforts in complying with the requirements of Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and other public company disclosure and corporate governance requirements and responding to requests of government regulators. The amount of future losses and when, if ever, we will achieve profitability are uncertain and will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products unless and until our HBV or microbiome therapies or any other product candidate is approved by the FDA for sale, and we might never generate revenues from the sale of products.

We are not currently profitable and might never become profitable.

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

- advance ABI-H0731 through clinical development for HBV and initiate and conduct clinical trials of our microbiome product candidate;
- continue to undertake research and development to identify potential additional product candidates;
- seek regulatory approvals for our product candidates; and
- pursue our intellectual property strategy.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins with Core Protein Allosteric Modulators, 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 for our microbiome therapy is in nonclinical development and our GEMICEL®, dual targeted release drug formulation, is novel and not yet shown to successfully deliver live bacteria in patients.

Scientific research and development requires significant amounts of capital and takes a long time to reach commercial viability, if it can be achieved at all. To date, our research and development projects have not produced commercially viable drugs and may never do so. During the research and development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs are not fully proven. More specifically, the theory that CpAMs can selectively lower cccDNA and viral antigen levels in HBV patients and achieve a functional cure is unproven. Thus, even if CpAM technology is successful at targeting the HBV core protein and reducing cccDNA levels in HBV patients, it may not result in a commercially viable drug if there is not a corresponding medical benefit related to the underlying HBV infection. Similarly, with respect to our microbiome program, the ability to effectively and reliably deliver bacteria to the GI tract is unproven, and, even if it can be proven, it may be difficult or impossible to provide the treatment economically. Because of these uncertainties, it is possible that no commercial products will be successfully developed. If we are unable to successfully develop commercial products, we will be unable to generate revenue or build a sustainable or profitable business.

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

We anticipate that we will incur operating losses for the next several years as we continue to develop our HBV therapy and our microbiome platform as well as initiate any development of any other product candidates and will require substantial funds during that time to support our operations. We expect that our current resources will provide us with sufficient capital to fund our operations for at least the next twelve months. However, we might consume our available capital before that time if, for example, we are not efficient in managing our resources or if we encounter unforeseen costs, delays or other issues or if regulatory requirements change. If that happens, we may need additional financing to continue the development of our HBV therapy and our Microbiome program. Thereafter, we will need additional capital to fund our operations in the future. However, there is no assurance that we will be able to generate sufficient revenue from our Collaboration Agreement with Allergan when needed to or that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If such event or other unforeseen circumstances occurred and we were unable to generate revenue or raise capital, we could be forced to delay, scale back or discontinue product development, sacrifice attractive business opportunities, cease operations entirely and sell or otherwise transfer all or substantially all of our remaining assets.

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

Before we or any commercial partners obtain the approvals necessary to sell any of our product candidates, we must show through nonclinical studies and human testing in clinical trials that each potential product is safe and effective. The rates at which we complete our scientific studies and clinical trials depend on many factors, including, but are not limited to, our ability to obtain adequate supplies of the products to be tested and patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial and other potential drug candidates being studied. Delays in patient enrollment for our trials may result in increased costs and longer development times. In addition, we will need additional financing to develop our product candidates, which we might seek and receive from third party commercial partners. Further, we currently do not have the infrastructure to manufacture, market and sell our product candidates. If we partner with one or more third party entities, those commercial partners may demand and receive rights to control product development and commercialization. As a result, these commercial partners may conduct these programs and activities more slowly or in a different manner than expected. If any of these events were to occur, the development of any product candidate could be significantly delayed, more expensive or less lucrative to us than anticipated, any of which would have a significant adverse effect on our business.

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

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

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

Our license agreement with Indiana University Research and Technology Corporation, or IURTC, from whom we have licensed our HBV therapy, requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to our HBV therapy. The aggregate amount of all performance milestone payments under the IURTC License Agreement, should all performance milestones through development be met, is $825,000. As of March 31, 2017, no performance milestone payments have been made. We also are obligated to pay IURTC royalty payments based on net sales of the licensed technology. We are also obligated to pay diligence maintenance fees ($25,000-$100,000) each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year. Our license with Therabiome, LLC ("Therabiome"), from whom we have licensed our Microbiome program, also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to the targeted delivery mechanism of our Microbiome program. If we fail to comply with similar obligations to any other licensor, 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.

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

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

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

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

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

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

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

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

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

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

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

Our reliance on these third parties for research and development activities also reduces our control over these activities but will not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our research, nonclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. As a result, our results of operations and business prospects would be harmed, our costs could increase and our ability to generate revenues could be delayed.

We will need to either establish our own clinical and commercial manufacturing capabilities or rely on third parties to formulate and manufacture our product candidates.

We currently do not have our own manufacturing facilities and rely on third-party manufacturers to supply the quantities of ABI-H0731 used in our Phase 1 clinical trials and drug substance and drug product for ABI-M101. Although we intend to establish our own manufacturing capabilities for our microbiome drug substance and drug products, we currently lack the physical plant to formulate and manufacture our own product candidates for use in our planned clinical trials. In addition, if any product candidate we might develop or acquire in the future receives FDA or other regulatory approval, we will need to either manufacture commercial quantities of the product on our own or rely on one or more third-party contractors to manufacture our products. The establishment of internal manufacturing capabilities is difficult and costly, and we may not be successful in doing so. If, for any reason, we are unable to establish our own manufacturing capabilities and we are unable to rely on any third-party sources we have identified to manufacture our product candidates, either for clinical trials or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds, drug substance and drug products for nonclinical, clinical and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity either on our own or through third parties, the development and sales of our products and our financial performance will be materially and adversely affected.

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

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

- If we are unable to establish our own manufacturing capabilities, we will need to identify manufacturers for commercial supply on acceptable terms, which we may not be able to do because the number of potential manufacturers is limited and the FDA must approve any new or replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- We or any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and, if approved, commercial needs.
- Any third-party manufacturers with whom we contract might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. Any internal manufacturing facilities we establish may fail to comply, and we would not have complete control over any third-party manufacturers' compliance, with these regulations and requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of March 31, 2017, we had 73 employees, 11 temporary contractors and various consultants and multiple contract research organizations with whom we have contracted. We will need to hire or contract with additional qualified personnel with expertise in clinical research and testing, formulation and manufacturing and sales and marketing to commercialize our HBV drug candidates and our microbiome biotherapeutics or any other product candidate we may seek to develop. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

We might not successfully manage our growth.

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

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

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

- assimilating the purchased technologies, products or business operations;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory requirements; and
- adverse effects on existing business operations.

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

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

Risks Related to Our Regulatory and Legal Environment

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, nonclinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical and biological products. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation might be equally or more demanding than corresponding U.S. regulation.

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

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

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

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

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

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

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

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

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

Even if approved, our product candidates will be subject to extensive post-approval regulation.

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

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

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

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

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

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

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

In the U.S. and in other countries, there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the Patient Protection and Affordable Care Act and its amendment, the Health Care and Education Reconciliation Act, or the ACA. 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. The current administration supports a repeal of the ACA and an Executive Order has been signed commanding federal agencies to try to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. The Executive Order also declares that the administration will seek the "prompt repeal" of the law and that the government should prepare to "afford the States more flexibility and control to create a more free and open healthcare market." At this time, the immediate impact of the Executive Order is not clear. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding. 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.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the listing standards of NASDAQ, the exchange on which our common stock is listed. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly and place significant strain on our personnel, systems and resources.

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

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

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

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs and biotherapeutics. If the use of one or more of our 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.

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

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

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with United States Foreign Corrupt Practices Act, or FCPA, the U.K. anti-bribery laws and other anti-bribery laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, delays in clinical trials, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees (the "Code of Conduct"), but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

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

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

We are establishing international operations and conducting clinical trials outside of the U.S. and a number of risks associated with international operations could materially and adversely affect our business.

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

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

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

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

We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and chemical and biological compositions that are important to our business. To date, although our licensors have filed patent applications, we do not own or have any rights to any issued patents that cover any of our product candidates, and we cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary product candidates and technologies. The patent prosecution process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

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

- Any patent rights, if obtained, might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the U.S. or in international markets;

- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful; and
- Countries other than the U.S. might have patent laws that provide less protection than those governing U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

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

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

Risks Related to Our Common Stock

We might not be able to maintain the listing of our common stock on The NASDAQ Capital Market.

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

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

Since we went public on December 22, 2010 and through March 31, 2017, the closing price of our common stock has fluctuated between $4.30 and $105.30 (after giving effect to the 1-for-5 reverse stock split effected on July 11, 2014). Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock might be volatile and subject to wide price fluctuations in response to various factors, including:

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

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

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

At March 31, 2017, our executive officers, directors and one of our founders beneficially owned approximately 17.1% of our outstanding voting common stock, and this group together with other stockholders holding beneficially 5% of more of our outstanding voting common stock, owned approximately 60.0% of our outstanding voting common stock. Therefore, these stockholders, if acting together, have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of certain significant matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

At December 31, 2016, the Company had potentially utilizable gross Federal net operating loss carryforwards of approximately $146.5 million, State net operating loss carry-forwards of approximately $174.0 million and research and development credit carry forward of approximately $4.0 million, all of which expire between 2027 and 2036. Our ability to utilize our net operating loss and credit carryforwards is dependent upon our ability to generate taxable income in future periods and may be limited due to restrictions imposed on utilization of net operating loss and credit carryforwards under federal and state laws upon a change in ownership.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change," is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three year period (calculate on a rolling basis). We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, some of which are outside the Company's control. These ownership changes may subject our existing net operating losses or credits to substantial limitations under Sections 382 and 383. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits. Limitations on our ability to utilize our net operating losses to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of net operating lossess is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

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

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

As a public company, we face increased legal, accounting, administrative and other costs and expenses not faced by private companies. We are subject to the reporting requirements of the Exchange Act, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act, and The NASDAQ Capital Market, each of which imposes additional reporting and other obligations on public companies. These rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. Complying with these requirements might divert management's attention from other business concerns, which could have a material adverse effect on our prospects, business, and financial condition.

Additionally, the expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. These increased costs will require us to divert a significant amount of money that we could otherwise use to develop our product candidates or otherwise expand our business. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Several provisions of the Delaware General Corporation Law and our Amended and Restated Certificate of Incorporation and Bylaws could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our securities.

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

- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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

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

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

Exhibit Number	Description of Document	Filed Herewith	Incorporated by Reference from	Date	Number
10.1†	Research, Development, Collaboration and License Agreement dated January 6, 2017 between Assembly Biosciences, Inc. and Allergan Pharmaceuticals International Limited.	X			
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2*	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	Financials in XBRL format.	X			

† Certain portions of this exhibit have been omitted and filed separately with the SEC under a confidential treatment request pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

* 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: May 8, 2017

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

Date: May 8, 2017

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

EXHIBIT 10.1

EXECUTION COPY

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

ASSEMBLY BIOSCIENCES, INC.

and

ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED

RESEARCH, DEVELOPMENT, COLLABORATION AND LICENSE AGREEMENT

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

TABLE OF CONTENTS

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

RESEARCH, DEVELOPMENT, COLLABORATION AND LICENSE AGREEMENT

THIS RESEARCH, DEVELOPMENT, COLLABORATION AND LICENSE AGREEMENT (the " **Agreement** ") is entered into as of January 6, 2017 (the " **Execution Date** ").

PARTIES:

1. **ASSEMBLY BIOSCIENCES, INC.** , a company organized under the laws of Delaware whose registered address is 11711 N. Meridian Street, Suite 310, Carmel, Indiana 46032 (" **Assembly** "); and

2. **ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED (formerly known as Aptalis Pharma Ltd.)** , a company organized under the laws of Ireland with a place of business at Clonshaugh Industrial Estate, Coolock, Dublin 17, Ireland (" **Allergan** ").

In this Agreement, Allergan and Assembly are collectively referred to as the " **Parties** " and each individually a " **Party** ".

BACKGROUND:

A. Assembly has developed or is developing and owns or controls certain Microbiome-Based Compounds, technology and other intellectual property intended to treat the indications set forth on Exhibit A hereto, as such list of indications may be expanded from time to time as described herein.

B. Allergan has expertise in the Exploitation of pharmaceutical products.

C. The Parties desire to enter into a research, development, collaboration and license agreement with the purpose of further Exploiting certain compounds in development that are owned or controlled by Assembly and to discover additional new Microbiome-Based Compounds directed to certain indications as described herein.

NOW, THEREFORE , in consideration of the respective covenants set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth below:

1.1. " **201 Compound Candidate** " shall mean a composition that [* * *] pursuant to the R&D Plan under this Agreement.

1.2. " **301 Compound Candidate** " shall mean a composition that [* * *] pursuant to the R&D Plan under this Agreement.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.3. " **[* * *] IND** " shall mean any IND for a Product Candidate filed by Assembly pursuant to this Agreement (a) for which within thirty (30) days of such filing, no clinical hold has been placed by a Regulatory Authority and no Regulatory Authority has otherwise prevented initiation of a Clinical Trial for such Product Candidate and (b) [* * *], during the course of at least one (1) Clinical Trial of such Product Candidate.

1.4. " **Affiliate** " shall mean any individual, corporation, company, partnership, trust, limited liability company, association or other business entity (" **Person** ") that directly or indirectly controls, is controlled by or is under common control with the Party in question at any time for so long as such Party controls, is controlled by or is under common control with such first Person. As used in this definition of "Affiliate," the term "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean, as to any Person, (a) direct or indirect ownership of at least fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction, provided , that such Party has the ability, directly or indirectly, to direct or cause the direction of management or policies of such Person) of the voting interests or other ownership interests in the Person in question; (b) direct or indirect ownership of at least fifty percent (50%) of the interest in the income of the Person in question; or (c) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the Person in question (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.5. " **Agreement** " shall have the meaning set forth in the preamble hereto.

1.6. " **Allergan** " shall have the meaning set forth in the preamble hereto.

1.7. " **Allergan Collaboration IP** " shall mean all Patents or Know-How that are Controlled by Allergan or its Affiliates during the Term that arise out of Allergan's activities under the R&D Plan. For clarity, the Allergan Collaboration IP includes Allergan's interest in the Joint Intellectual Property Rights that are necessary or useful for Assembly to carry out Assembly's activities under the R&D Plan.

1.8. " **Allergan Indemnitees** " shall have the meaning set forth in Section 12.1.

1.9. " **Alliance Manager** " shall have the meaning set forth in Section 3.9.

1.10. " **Assembly** " shall have the meaning set forth in the preamble hereto.

1.11. " **Assembly Indemnitees** " shall have the meaning set forth in Section 12.2.

1.12. " **Assigned Regulatory Documentation** " shall have the meaning set forth in Section 6.2.

1.13. " **Audited Party** " shall have the meaning set forth in Section 7.10.2.

1.14. " **Auditing Party** " shall have the meaning set forth in Section 7.10.2.

1.15. " **Backup Compound** " shall mean (a) any Backup Compound Candidate incorporated in a product administered to subjects in a first-in-human Clinical Trial or any Clinical Trial conducted under the R&D Plan, in each case for a Permitted Indication or (b) any other composition [* * *] (and no [* * *]) as a Backup Compound Candidate described in clause (a) of this Section 1.14 (including, for example, a composition [* * *] (and no [* * *]) as a composition described in (a) but differing [* * *]). A Backup Compound Candidate shall be a "Backup Compound" and no longer a "Backup Compound Candidate" at the time that such Backup Compound Candidate is administered to a subject in a first-in-human Clinical Trial or other Clinical Trial conducted under the R&D Plan. For clarity, [* * *] IND.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.16. " **Backup Compound Candidate** " shall mean any composition, other than an Initial Compound Candidate or New Compound Candidate, comprising [* * *] and that is selected for further Development by Allergan pursuant to the procedures set forth in Section 4.5, as [* * *] pursuant to the R&D Plan under this Agreement.

1.17. " **Bankruptcy Code** " shall have the meaning set forth in Section 10.6.2.

1.18. " **Biosimilar Application** " shall have the meaning set forth in Section 9.1.9(a).

1.19. " **Biosimilar Product** " shall mean a biologic product (a) whose Regulatory Approval relies in whole or in part on a prior Regulatory Approval granted to a Licensed Product, (b) whose Regulatory Approval relies in whole or in part on any pivotal safety or efficacy data generated in support of a prior Regulatory Approval granted to a Licensed Product; or (c) otherwise meets the criteria for constituting a "biosimilar" or "interchangeable" product pursuant to Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) or a "similar biological medicinal product" pursuant to the EU Directive 2001/83/EC or any successors thereto or any other equivalent provision that comes into effect during the Term, or is the subject of an analogous determination or has otherwise achieved analogous regulatory approval from another applicable Regulatory Authority. For clarity, a product may be a Biosimilar Product regardless of whether it is subject to regulation as a biologic or drug product and regardless of the route used to obtain approval (for example, whether by Abbreviated New Drug Application, BLA, or under 42 U.S.C. § 262).

1.20. " **BLA** " means (a) in the United States, a Biologics License Application, as defined in the United States Public Health Service Act (42 U.S.C. § 262), and applicable regulations promulgated thereunder by the FDA, or any equivalent application that replaces such application, (b) in the EU, a marketing authorization application, as defined in applicable regulations of the EMA, and (c) in any other country, the relevant equivalent to the foregoing.

1.21. " **Blocking Third Party IP** " shall mean, with respect to any country, any Patent or Know-How in such country controlled by a Third Party that is necessary or useful to Develop, manufacture, Commercialize or otherwise Exploit a Licensed Compound in the Field in or for such country.

1.22. " **Business Day** " shall mean any Monday, Tuesday, Wednesday, Thursday or Friday that is not a public holiday in New York, New York.

1.23. " **Calendar Quarter** " shall mean a period of three (3) consecutive months corresponding to the calendar quarters commencing on the first day of January, April, July or October, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.24. " **Calendar Year** " shall mean a period of twelve (12) consecutive months corresponding to the calendar year commencing on the first day of January, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.25. " **Change of Control** ", with respect to a Party, shall mean (a) the closing of a sale of all or substantially all of the assets of such Party to which this Agreement relates to a Third Party in one transaction or series of transactions, (b) the closing of a merger or other business combination or transaction that results in a Third Party owning, directly or indirectly, of more than 50% of the voting securities of such Party or of its ultimate parent entity, or (c) the closing of a transaction, following which a Third Party acquires direct or indirect ability or power to direct or cause the direction of the management and policies of such Party or of its ultimate parent entity or otherwise direct the affairs of such Party or of its ultimate parent entity, whether through ownership of equity, voting securities, beneficial interest, by contract or otherwise.

1.26. " **China Co-Promotion Option Right** " shall have the meaning set forth in Section 5.2.1.

1.27. " **Clinical Quality Agreement** " shall have the meaning set forth in Section 6.4.2.

1.28. " **Clinical Trial** " shall mean any of a Phase I Clinical Trial, Phase Ib Clinical Trial, Phase IIa Clinical Trial, Phase IIb Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial or a clinical trial conducted after obtaining Regulatory Approval.

1.29. " **CMO** " shall have the meaning set forth in Section 6.4.1.

1.30. " **Combination Product** " shall mean a Licensed Product that is comprised of or contains a Licensed Compound as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units in a single package.

1.31. " **Combination Sale** " shall have the meaning set forth in the definition of Net Sales.

1.32. " **Commercialize** " shall mean any and all activities directed to the promotion, marketing, distribution or sale (and offer for sale or import or export for sale) for a product. " **Commercializing** " and " **Commercialization** " shall have corresponding meanings.

1.33. " **Commercially Reasonable Efforts** " shall mean efforts that are not less than those discovery, research, development or commercialization efforts a Party makes with respect to other compounds or products in its portfolio at a similar stage of development or in a similar stage of product life, with similar developmental risk profiles and of similar market and commercial potential, based on conditions then-prevailing and taking into account all other relevant factors including issues of safety and efficacy, the nature and extent of market exclusivity (including regulatory exclusivity and the patent and other proprietary position of the product), product labeling or anticipated labeling, performance of other products that are of similar market potential and the likely timing of other product's entry into the market, costs, timing, and the likelihood of success of technology transfer, process development and manufacturing validation and scale-up, the likelihood and cost of obtaining regulatory approval and of the anticipated or actual approved labeling, financial return, medical and clinical considerations, regulatory environment, the regulatory structure involved, and other relevant scientific, technical and commercial factors.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.34. " **Committee Deadlock** " shall have the meaning set forth in Section 3.7.

1.35. " **Competing Compound** " shall mean any microbiome modulating product that is actually sold for the same Permitted Indication as any Licensed Product.

1.36. " **Completion** " shall mean, with respect to a POC Trial, that top-line results for such POC Trial that have been generated in accordance with industry standards and provided to Allergan in accordance with the R&D Plan.

1.37. " **Compound Candidate** " shall mean any Initial Compound Candidate, New Compound Candidate or Backup Compound Candidate.

1.38. " **Compound R&D Term** " shall have the meaning set forth in Section 4.2.

1.39. " **Confidential Information** " shall mean all secret, confidential or proprietary information, Know-How or data, whether provided in written, oral, graphic, video, computer or other form, that (a) is provided by one Party (the " **Disclosing Party** ") to the other Party (the " **Receiving Party** ") that is marked or otherwise identified as confidential or that by its nature a reasonable person would understand to be confidential in connection with this Agreement, or (b) constitutes Licensed Compound Know-How, in each case ((a) and (b)), including information, Know-How or data relating to the Disclosing Party's existing or proposed research, development efforts, Patent applications, business, Licensed Compounds or Licensed Products, other compounds or products and any other materials that have not been made available by the Disclosing Party to Third Parties (other than under an obligation of confidentiality). Notwithstanding the foregoing sentences, Confidential Information shall not include any information or materials that:

(i) were already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party to the extent such Receiving Party has contemporaneous documentation or other competent evidence to that effect; provided , that the foregoing exception shall not apply with respect to Joint Know-How or Licensed Compound Know-How;

(ii) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

(iv) were subsequently lawfully disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(v) were independently discovered or developed by or on behalf of the Receiving Party without the use of, reliance on or reference to the Confidential Information belonging to the other Party and the Receiving Party has contemporaneous documentation or other competent evidence to that effect; provided , that the foregoing exception shall not apply with respect to Joint Know-How or Licensed Compound Know-How.

Notwithstanding anything contained herein to the contrary, Confidential Information constituting (x) Licensed Compound Know-How that is material to the Exploitation of Licensed Compound or Licensed Product and (y) the terms of this Agreement shall each be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto).

1.40. " **Control** " and its correlative terms, " **Controlled** " or " **Controls** ", shall mean, with respect to any intellectual property right or other intangible property, that a Party owns or has a license or sublicense to such item or right, and has the ability to assign, grant access, license or sublicense, as applicable, in or to such right without violating the terms of any agreement or other arrangement with any Third Party. For the avoidance of doubt, Third Party intellectual property shall only be considered "Controlled" by a Party, if the Party has the right to disclose, assign, or grant a license, sublicense or other right to the other Party as provided for in this Agreement.

1.41. " **Controlling Party** " shall have the meaning set forth in Section 9.2.2.

1.42. " **Co-Promotion Agreement** " shall have the meaning set forth in Section 5.4.1.

1.43. " **Co-Promotion Option Rights** " shall have the meaning set forth in Section 5.2.1.

1.44. " **Cover** ," " **Covering** " or " **Covers** " means, as to a compound or product and Patent, that, in the absence of a license granted under, or ownership of, such Patent, the making, using, selling, offering for sale or importation of such compound or product would infringe such Patent or, as to a pending claim included in such Patent, the making, using, selling, offering for sale or importation of such compound or product would infringe such Patent if such pending claim were to issue in an issued patent without modification.

1.45. " **CPI** " shall mean the Consumer Price Index – Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, published by the US Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the US.

1.46. " **Defending Party** " shall have the meaning set forth in Section 9.3.2.

1.47. " **Development** " shall mean any and all activities, including research, discovery, compound identification and generation, non-clinical, pre-clinical and clinical trials, post approval studies, supporting manufacturing, production process development and formulation and related regulatory activities directed to obtaining and maintaining Regulatory Approval for a product for an indication. Development shall include, with respect to any Licensed Compound or Licensed Product, the Optimization of a Compound Candidate or Product Candidate with the goal of further Developing such resultant Licensed Compound or Licensed Product. " **Develop** " and " **Developing** " shall have corresponding meanings.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.48. " **Development Costs** " shall mean the costs and expenses incurred by or on behalf of a Party or its Affiliates in connection with the Development of Licensed Compounds or Licensed Products in the Field, including without limitation (a) costs of each Party's or its Affiliates' employees supporting such efforts (calculated as the FTE Costs), (b) all out-of-pocket costs of procuring services, products or materials used in the Development of Licensed Compounds or Licensed Products in the Field, (c) any amounts paid to clinical research organizations or other Third Parties engaged to conduct Development activities and (d) amounts paid to Third Party contractors to supply Licensed Compounds or Licensed Products for Development. "Development Costs" shall include without limitation all costs of toxicological, pharmacokinetic, metabolical studies, Clinical Trials, the preparation, collation and/or validation of data from such studies and the preparation of medical writing and publishing, which include expenses for data management, statistical designs and studies, document preparation, and other administrative expenses associated with the clinical testing program or post-marketing studies required or necessary to maintain product approvals, development of quality assurance and quality control procedures and protocols, formulation development and other nonclinical and preclinical studies for Licensed Compounds or Licensed Products. For the avoidance of doubt, "Development Costs" shall not include any costs of procuring capital equipment used in Development.

1.49. " **Development Milestone Events** " shall have the meaning set forth in Section 7.2.1.

1.50. " **Development Milestone Payments** " shall have the meaning set forth in Section 7.2.1.

1.51. " **Disclosing Party** " shall have the meaning set forth in Section 1.39.

1.52. " **Distributor** " shall mean any Third Party that purchases its requirements for Licensed Product in final packaged form from Allergan or its Affiliates or Sublicensees and is appointed as a distributor to distribute, market and resell such Licensed Product in a country, regardless of whether such Third Party is granted ancillary rights to further develop, package or obtain regulatory approvals of Licensed Product in order to distribute, market or sell Licensed Product; provided that a Third Party that pays Allergan, or an Affiliate or Sublicensee of Allergan, a royalty or similar payment based on the sale or transfer by such Third Party of Licensed Product shall be a Sublicensee, and not a Distributor, for purposes of this Agreement.

1.53. " **DOJ** " shall have the meaning set forth in Section 1.81.

1.54. " **Effective Date** " shall mean (a) if Assembly delivers to Allergan representations and warranties that are identical to the representations and warranties delivered as of the Execution Date in accordance with clause (a) of Section 11.6, the second (2nd) Business Day following the date on which HSR Clearance occurs, (b) if Assembly is deemed to have delivered representations and warranties that are identical to the representations and warranties as of the Execution Date pursuant to Section 11.6, the third (3rd) Business Day following the date on which HSR Clearance occurs, or (c) if Assembly makes any supplement or amendment to its representations and warranties in accordance with clause (b) of Section 11.6 and Allergan does not exercise its right pursuant to Section 10.10 to cause the Agreement not to come into effect, the sixth (6th) Business Day following Assembly making such amendment or supplement.

1.55. " **EMA** " shall mean the European Medicines Agency and any successor or replacement agency.

1.56. " **Establishment of POC** " shall mean, as to a specific Licensed Product, the generation of data from the first POC Trial of such Licensed Product that demonstrates to Allergan's satisfaction that such Licensed Product has efficacy for treatment of a particular indication using a specific dosing regimen with no adverse events that would reasonably warrant discontinuation of Development of such Licensed Product for such indication.

1.57. " **EU** " shall mean the European Union as of the Effective Date.

1.58. " **EU Major Markets** " shall mean the United Kingdom, Germany, France, Spain and Italy.

1.59. " **Exclusivity Term** " shall have the meaning set forth in Section 2.4.1.

1.60. " **Execution Date** " shall have the meaning set forth in the preamble hereto.

1.61. " **Existing In-License Agreements** " shall have the meaning set forth in Section 11.2.10.

1.62. " **Existing Regulatory Documentation** " shall mean the Regulatory Documentation Controlled by Assembly or any of its Affiliates as of the Effective Date.

1.63. " **Exploit** " shall mean to make, have made, import, use, sell or offer for sale, including to Develop, Commercialize, register, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. " **Exploitation** " shall mean the act of Exploiting a compound, product or process.

1.64. " **Facility Deadline** " shall have the meaning set forth in Section 6.4.3(a).

1.65. " **FD&C Act** " means the Federal Food, Drug and Cosmetic Act, as the same may be amended or supplemented from time to time.

1.66. " **FDA** " shall mean the US Food and Drug Administration, and any successor or replacement agency.

1.67. " **Field** " shall mean the treatment, prevention or diagnosis of any human or animal disease or condition.

1.68. " **FTC** " shall have the meaning set forth in the definition of HSR Filing.

1.69. " **FTE** " shall mean the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [* * *] hours per Calendar Year) of work directly related to the Development of a Licensed Compound or a Licensed Product. Any person who works more than [* * *] hours per Calendar Year and any person who devotes less than [* * *] hours per Calendar Year (or such other number as may be agreed by the JDC) shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by eighteen hundred (1800).

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.70. " **FTE Cost** " means, for any period, the FTE Rate multiplied by the number of FTEs in such period.

1.71. " **FTE Rate** " shall mean a rate of USD $[* * *] per FTE per annum (reflecting the fully burdened cost of the FTE), exclusive of VAT and increasing on each January 1 following the first anniversary of the Effective Date during the R&D Term by a percentage increase equal to the percentage increase, if any, in the CPI reported for the immediately preceding Calendar Year. For the avoidance of doubt, such rate includes (a) all salaries, wages, bonuses, benefits, management fees, profit sharing, stock option grants and FICA costs and other similar costs, national insurance and pension contributions, meals and entertainment, training, recruiting, relocation, operating supplies and equipment, materials, consumables and other disposable goods to the extent required for the performance of the applicable services and (b) managerial and other overhead costs associated with such FTE and the performance of his or her activities hereunder.

1.72. " **Force Majeure Event** " shall have the meaning set forth in Section 13.5.

1.73. " **GAAP** " shall mean United States generally accepted accounting principles, consistently applied.

1.74. " **Good Clinical Practice** " or " **GCP** " shall mean the then-current good clinical practice applicable to the clinical Development of a Licensed Product under applicable Law, including the ICH guidelines, U.S. Good Clinical Practice and clause 2 of ARTICLE 1 of European Union directive on the conduct of clinical trials 2001/20/EC.

1.75. " **Good Laboratory Practice** " or " **GLP** " shall mean the then-current Good Laboratory Practice Standards promulgated or endorsed by the FDA or in the case of any other country in the Territory, comparable regulatory standards promulgated or endorsed by the Regulatory Authorities in that country.

1.76. " **Good Manufacturing Practice** " or " **GMP** " shall mean the then-current Good Manufacturing Practices as specified in the United States Code of Federal Regulations, ICH Guideline Q7A, or equivalent Laws of an applicable Governmental Authority of any other relevant country at the time of manufacture.

1.77. " **Governmental Authority** " shall mean any court, tribunal, arbitrator, agency, department, board, division, administration, legislative body, commission, official or other instrumentality of (a) any government of any country, (b) a federal, state, province, county, city or other political subdivision thereof or (c) any international, multinational or supranational body.

1.78. " **Gross Combination Sale Amount** " shall have the meaning set forth in the definition of Net Sales.

1.79. " **HSR Act** " shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.80. " **HSR Clearance** " shall mean, with respect to this Agreement, the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.81. " **HSR Filing** " shall mean filings by Allergan and Assembly with the United States Federal Trade Commission (the " **FTC** ") and the Antitrust Division of the United States Department of Justice (the " **DOJ** ") of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.82. " **ICC** " shall have the meaning set forth in Section 13.4.

1.83. " **ICH** " means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.84. " **IND** " shall mean any Investigational New Drug application, as defined in Title 21 of the Code of Federal Regulations, on file with the FDA before commencement of Clinical Trials, or any comparable filing with any relevant Regulatory Authority in any country or jurisdiction in the Territory including a clinical trial application.

1.85. " **Indemnification Claim Notice** " shall have the meaning set forth in Section 12.3.

1.86. " **Indemnified Party** " shall have the meaning set forth in Section 12.3.

1.87. " **Indemnifying Party** " shall have the meaning set forth in Section 12.3.

1.88. " **Indemnitees** " shall have the meaning set forth in Section 12.3.

1.89. " **Independent Price** " shall have the meaning set forth in Section 1.117.

1.90. " **Initial Compound** " shall mean (a) any Initial Compound Candidate incorporated in a product administered to subjects in a first-in-human Clinical Trial or any Clinical Trial conducted under the R&D Plan, in each case for a Permitted Indication or (b) any other composition [* * *] (and no [* * *]) as an Initial Compound Candidate described in clause (a) of this Section (including, for example, [* * *] (and no [* * *]) as a composition described in (a) but differing [* * *]). An Initial Compound Candidate shall be an "Initial Compound" and no longer an "Initial Compound Candidate" at the time that such Initial Compound Candidate is administered to a subject in a first-in-human Clinical Trial or other Clinical Trial conducted under the R&D Plan. For clarity, multiple [* * *] IND.

1.91. " **Initial Compound Candidate ”** shall mean each and either of the 201 Compound Candidate or the 301 Compound Candidate.

1.92. " **Initial Indication Development Costs** " shall have the meaning set forth in Section 4.8.2(a).

1.93. " **Initial Indications** " shall mean (a) ulcerative colitis, (b) Crohn's disease, (c) irritable bowel syndrome with constipation (IBS-c), (d) irritable bowel syndrome with diarrhea (IBS-d) and (e) and mixed irritable bowel syndrome (IBS-m). It is contemplated as of the Effective Date that the 201 Compound Candidate will initially be Developed for ulcerative colitis and that the 301 Compound Candidate will initially be Developed for Crohn's disease.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.94. " **Initiation** " of a Clinical Trial shall mean the dosing of the first subject in the relevant Clinical Trial of a Licensed Product.

1.95. " **In-License Agreements** " shall mean the Existing In-License Agreements and any other agreements deemed In-License Agreements pursuant to Section 2.3.4.

1.96. " **Invalidity/Unenforceability Action** " shall have the meaning set forth in Section 9.2.1.

1.97. " **Joint Intellectual Property Rights** " shall have the meaning set forth in Section 9.3.

1.98. " **Joint Know-How** " shall have the meaning set forth in Section 9.3.

1.99. " **Joint Patents** " shall have the meaning set forth in Section 9.3.

1.100. " **Joint Co-Promotion Committee** " or " **JCC** " shall have the meaning set forth in Section 5.3.

1.101. " **Joint Development Committee** " or " **JDC** " shall have the meaning set forth in Section 3.1.

1.102. " **Know-How** " shall mean all technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, ideas, concepts, designs, drawings, specifications, data, results and other material (together with all improvements to any of the foregoing).

1.103. " **Knowledge** " shall mean, with respect to each Party, the actual knowledge of any of the individuals listed on Schedule 1.103, in each case after due inquiry of such named individuals' files and records and of outside counsel (including patent counsel, as applicable) and those employees of such Party or its Affiliates who are such named individuals' direct reports or are otherwise responsible for the relevant activity or subject matter.

1.104. " **Launch** " shall mean, with respect to a Licensed Product for a particular Permitted Indication and a country in the Territory, the first invoiced commercial sale by Allergan, its Affiliates or their respective Sublicensees in the Territory for monetary value for use by the end user of such Licensed Product in such country for such Permitted Indication after receipt of all Regulatory Approvals for such Licensed Product for such Permitted Indication in such country, including, if applicable, commercially reasonable pricing and reimbursement approvals; provided that commercially reasonable pricing and reimbursement approvals shall be deemed to have been received with respect to a Licensed Product for a particular Permitted Indication in a country in the Territory in the event Net Sales of such Licensed Product for such Permitted Indication in any Calendar Year in such country exceed [* * *] USD ($[* * *]).

1.105. " **Law** " shall mean all laws, statutes, ordinances, rules, rulings, treaties, procedures, notices, regulations, writs, judgments, decrees, injunctions (whether preliminary or final), orders and other pronouncements having the effect of law of any Governmental Authority that may be in effect from time to time.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.106. " **Licensed Compound** " shall mean any (a) Initial Compound, (b) New Compound and (c) Backup Compound.

1.107. " **Licensed Compound Know-How** " shall mean, subject to Section 2.3.4, all Know-How (a) owned or Controlled by Assembly or any of its Affiliates (including Joint Know-How) as of the Effective Date or during the Term that is necessary or useful for the Development (including activities under any R&D Plan), manufacture, Commercialization or other Exploitation of Licensed Compounds or Licensed Products for the Initial Indications or any other indications set forth on Exhibit A and (b) Controlled by Assembly or any of its Affiliates (including Joint Know-How) upon or following the exercise by Allergan of an option pursuant to Section 2.7.1 that is necessary or useful for the Development (including activities under any R&D Plan), manufacture, Commercialization or other Exploitation of Licensed Compounds or Licensed Products for any Option Indication that becomes a Permitted Indication pursuant to the exercise of such option.

1.108. " **Licensed Compound Patents** " shall mean, subject to Section 2.3.4, (a) the Patent(s) listed on **Schedule 1.108** , and (b) any other Patents that are (i) owned or Controlled by Assembly or any of its Affiliates as of the Effective Date or during the Term (including Joint Patents) that would be infringed, absent a license, by Developing, making, using, selling, offering for sale, importing, or otherwise Exploiting any Licensed Compound or Licensed Product for the Initial Indications or any other indications set forth on Exhibit A and (ii) Controlled by Assembly or any of its Affiliates (including Joint Patents) upon or following the exercise by Allergan of an option pursuant to Section 2.7.1 that would be infringed, absent a license, by Developing, making, using, selling, offering for sale, importing, or otherwise Exploiting any Licensed Compound or Licensed Product for any Option Indication that becomes a Permitted Indication pursuant to the exercise of such option and, in each case (clauses (i) and (ii)), such additional Patents to be included on **Schedule 1.108** as it may be updated from time to time; provided , that, a failure to so include a Patent on **Schedule 1.108** that otherwise meets the definition of a Licensed Compound Patent shall not preclude such Patent from being deemed a Licensed Compound Patent hereunder.

1.109. " **Licensed Product** " shall mean any product incorporating a Licensed Compound, in any form or formulation.

1.110. " **Losses** " shall have the meaning set forth in Section 12.1.

1.111. " **Manufacturing Facility** " shall have the meaning set forth in Section 6.4.3.

1.112. " **Materials** " shall mean any tangible chemical or biological material, including any small molecules, DNA, RNA, clones, cells, and any expression product, progeny, derivative or other improvement thereto, along with any tangible chemical or biological material.

1.113. " **Microbiome-Based Compound** " shall mean a compound [* * *]. For clarity, a compound that comprises [* * *], shall not be considered a Microbiome-Based Compound hereunder.

1.114. " **Milestone Payments** " shall have the meaning set forth in Section 7.2.2.

1.115. " **Milestone Events** " shall have the meaning set forth in Section 7.2.2.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.116. " **Mono Product** " shall have the meaning set forth in Section 1.117.

1.117. " **Net Sales** " shall mean, with respect to a Licensed Product in a country in the Territory, the gross amount invoiced for sale or other disposition of such Licensed Product in such country by Allergan, its Affiliates or Sublicensees to Third Parties (including Distributors, wholesalers and end users), less the following deductions accounted for in accordance with GAAP:

(a) sales returns and allowances actually paid, granted or accrued on the Licensed Product, including trade quantity, prompt pay and cash discounts and any other adjustments, including those granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return or wastage replacement of Licensed Products or for rebates or retroactive price reductions;

(c) price reductions, rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers (including Medicare, Medicaid, managed care and similar types of rebates and chargebacks);

(d) costs of freight, insurance, and other transportation charges, as well as any administration fees or other fees for services provided by wholesalers, distributors, warehousing chains and other Third Parties related to the distribution of such Licensed Product;

(e) taxes, duties or other governmental charges (including any tax such as a value added or similar tax, other than any taxes based on income) relating to the sale of such Licensed Product, as adjusted for rebates and refunds, including pharmaceutical excise taxes;

(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Licensed Product;

(g) any consideration actually paid or payable for any delivery system which is reflected as a separate item in the applicable gross amount invoiced for such Licensed Product; and

(h) any other similar and customary revenue deductions that are consistent with GAAP;

to the extent such deductions: (i) are applicable and in accordance with standard allocation procedures, (ii) have not already been deducted or excluded, (iii) are incurred in the ordinary course of business, and (iv) except with respect to the pharmaceutical excise taxes described in subsection (e) above, are determined in accordance with, and as recorded in revenues under GAAP. Net Sales shall not be imputed to transfers of Licensed Product without consideration or for nominal consideration for use in any clinical trial, or for any bona fide charitable, compassionate use or indigent patient program purpose or as a sample. For the avoidance of doubt, in the case of any transfer of any Licensed Product between or among Allergan and its Affiliates or Sublicensees for resale, Net Sales shall be determined based on the sale made by such Affiliate or Sublicensee to a Third Party. In the case of any sale for value, such as barter or counter-trade, of a Licensed Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be deemed to be the Net Sales at which substantially similar quantities of such Licensed Product are sold for cash in an arm's length transaction in the relevant country.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

In the event that any Licensed Product is sold as a Combination Product (a " **Combination Sale** "), the Net Sales amount for such Licensed Product sold in such a Combination Sale in any period and country shall be calculated by multiplying the gross amount invoiced for the Combination Sale (the " **Gross Combination Sale Amount** "), less all deductions in (a)-(i) above (" **Permitted Deductions** "), by the fraction, the numerator of which is the wholesale acquisition cost charged by Allergan or its Affiliates in such period and country for a Licensed Product containing the Licensed Compound(s) in the Combination Product as its sole active ingredients (the " **Mono Product(s)** "), if such Mono Product is sold separately by Allergan or its Affiliates in such period and country (the " **Independent Price(s)** "), and the denominator is the Independent Price(s) plus the wholesale acquisition cost charged by Allergan or its Affiliates for product(s) containing as their sole active ingredient(s) those active ingredients that are not Licensed Compounds included in the Combination Product (" **Other Product(s)** ") if such Other Product(s) are sold separately by Allergan or its Affiliates in such period and country, in each case for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable; provided that if any of such Other Product(s) are not sold separately by Allergan or its Affiliates, but are independently marketed by one or more Third Parties, in such period and country, then such product(s) shall be deemed to be separately sold by Allergan or its Affiliates at the average wholesale acquisition costs charged by such Third Parties for purposes of the calculations in this paragraph; and provided , further, if the calculation of Net Sales resulting from a Combination Sale cannot be determined by the foregoing method, the calculation of Net Sales for such Combination Sale shall be calculated based upon the relative value of the active components of such Combination Product as reasonably determined by the mutual agreement of the Parties in good faith.

Notwithstanding anything to the contrary contained herein, sales of a Licensed Product (w) that uses a Licensed Product as the reference –listed drug in a so-called 351(k) BLA or other similar filing under applicable Law by any Sublicensee, (x) by any Sublicensee that has received a license from Allergan in settlement of any dispute or pursuant to any judgment, (y) by a Sublicensee pursuant to a compulsory license or (z) as to which Allergan does not receive any monetary consideration tied to sales of such Licensed Product, shall not be considered Net Sales for purposes of this Agreement, in each case of clauses (w) through (z) except to the extent Allergan receives consideration based on such Sublicensee's sales of the Licensed Product in which case such consideration received by Allergan shall be deemed Net Sales.

1.118. " **New Compound Candidate** " shall mean any composition comprising [* * *] based on or discovered using Assembly's microbiome program platform that is intended to treat irritable bowel syndrome with constipation (IBS-c), irritable bowel syndrome with diarrhea (IBS-d) or mixed irritable bowel syndrome (IBS-m) and is selected for further Development by Allergan as a "New Compound Candidate" pursuant to the procedures set forth in Section 4.4, as such composition may be Optimized pursuant to the R&D Plan under this Agreement.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.119. " **New Compound** " shall mean (a) any New Compound Candidate incorporated in a product administered to subjects in a first-in-human Clinical Trial or any Clinical Trial conducted under the R&D Plan, in each case for a Permitted Indication or (b) any other composition [* * *] (and no [* * *]) as a New Compound Candidate described in clause (a) of this Section (including, for example, a composition [* * *] (and no [* * *]) as a composition described in (a) but differing [* * *]). A New Compound Candidate shall be a "New Compound" and no longer a "New Compound Candidate" at the time that such New Compound Candidate is administered to a subject in a first-in-human Clinical Trial or other Clinical Trial conducted under the R&D Plan. For clarity, [* * *] IND.

1.120. " **Optimization** " shall mean, with respect to a Product Candidate and a particular Permitted Indication, Development activities conducted with respect to such Product Candidate under the R&D Plan in order to adjust the composition of such Product Candidate to optimize the safety or efficacy of such Product Candidate for such Permitted Indication prior to the Initiation of a POC Trial. "Optimization" shall include the following activities: (a) [* * *] the Compound Candidate included in such Product Candidate; (b) [* * *] the Compound Candidate included in such Product Candidate, such [* * *] then comprising the Compound Candidate, (c) [* * *] in the Compound Candidate included in such Product Candidate; (d) [* * *] to the Compound Candidate or [* * *] from the Compound Candidate, in each case included in such Product Candidate; or (e) [* * *] the Compound Candidate included in such Product Candidate, including [* * *].

1.121. " **Option Exercise Fee** " shall have the meaning set forth in Section 2.7.1.

1.122. " **Option Indications** " shall have the meaning set forth in Section 2.7.1.

1.123. " **Option Indication Right** " shall have the meaning set forth in Section 2.7.1.

1.124. " **Option Notice** " shall have the meaning set forth in Section 2.7.1.

1.125. " **Other Product(s)** " shall have the meaning set forth in the definition of Net Sales.

1.126. " **Party** " and " **Parties** " shall have the meaning set forth in the preamble hereto.

1.127. " **Patents** " shall mean (a) all patents or patent applications, including any continuations, continuations-in-part, divisions, provisional, converted provisional, continued prosecution or substitute applications, (b) any patent issued with respect to any of the foregoing patent applications, including utility models, petty patents, innovation patents and design patents and certificates of invention, (c) any reissue, reexamination, renewal, restoration or extension (including any supplementary protection certificate and the like) of any of the foregoing patents or patent applications, (d) any confirmation patent or registration patent or patent of addition based on any such patent, (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents, and (f) all foreign counterparts of any of the foregoing, or as applicable portions thereof or individual claims therein.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.128. " **Patent Challenge** " shall have the meaning set forth in Section 10.5.

1.129. " **Permitted Deductions** " shall have the meaning set forth in the definition of Net Sales.

1.130. " **Permitted Indications** " shall mean (a) the Initial Indications (other than any Initial Indication with respect to which Allergan has provided a notice to Assembly pursuant to Section 2.4.2 following the delivery of any such notice), (b) any other indications set forth on Exhibit A hereto and (c) any Option Indications for which Allergan has exercised the Option Indication Right.

1.131. " **Personal Information** " shall have the meaning set forth in Section 11.5.1.

1.132. " **Phase of Development Multiple** " shall have the meaning set forth in Section 2.7.2.

1.133. " **Phase I Clinical Trial** " shall mean, as to a specific Licensed Product, the first clinical study of such Licensed Product conducted in humans but excluding so-called "phase 0 trials" conducted using very small doses in fewer than twenty (20) people.

1.134. " **Phase II Clinical Trial** " shall mean, as to a specific Licensed Product, a well-controlled, closely monitored human clinical trial that is intended to evaluate the safety and effectiveness of such Licensed Product for a particular indication or indications in patients with the disease or indication under study or would otherwise satisfy the requirements of 21 C.F.R. 312.21(b) as amended from time to time, or the corresponding regulation in jurisdictions other than the United States.

1.135. " **Phase IIb Clinical Trial** " shall mean, as to a specific Licensed Product, a Phase II Clinical Trial that is intended to make a further determination of the effectiveness and safety of such Licensed Product for a particular indication or indications in patients with the disease or indication under study, at the intended clinical dose or doses or range of doses, on a sufficient number of subjects and for a sufficient duration to confirm the optimal manner of use of such Licensed Product (dose and dose regimen) prior to Initiation of one or more pivotal Phase III Clinical Trials or filing for a Regulatory Approval without the Initiation of such pivotal Phase III Clinical Trials.

1.136. " **Phase III Clinical Trial** " shall mean, as to a specific Licensed Product, a clinical study in humans, performed to gain evidence of statistical significance of the efficacy of such Licensed Product in a target patient population, and to obtain expanded evidence of safety for such Licensed Product that is needed to evaluate the overall benefit-risk relationship of such Licensed Product and provide an adequate basis for obtaining Regulatory Approval, including physician labeling, as described in 21 C.F.R. 312.21(c) as amended from time to time, or the corresponding regulation in jurisdictions other than the United States.

1.137. " **POC Trial** " shall mean, as to a specific Licensed Compound, the first Clinical Trial of a Licensed Product incorporating such Licensed Compound designed to demonstrate that a Licensed Product incorporating such Licensed Compound has efficacy for treatment of a particular indication using a specific dosing regimen.

1.138. " **PPACA** " shall mean the Patient Protection and Affordable Care Act, as modified by the Health Care and Education Reconciliation Act.

1.139. " **Product Candidate** " shall mean any product incorporating a Compound Candidate, in any form or formulation, prior to Completion of the first POC Trial for such product.

1.140. " **Product Only Claims** " shall have the meaning set forth in Section 9.1.2.

1.141. " **Product Only Patents** " shall mean any Licensed Compound Patent that solely Covers Licensed Compounds and/or Licensed Products, including the composition, method of use, delivery and manufacture of Licensed Compounds and/or Licensed Products. For clarity, whether a Licensed Compound Patent is a Product Only Patent shall be determined without regard [* * *] that the Licensed Compound Patent claims.

1.142. " **Product Related Patents** " shall mean any Licensed Compound Patent that Covers Licensed Compounds and/or Licensed Products that are not Product Only Patents.

1.143. " **Product Trademarks** " shall mean the Trademark(s) used or to be used by Allergan or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory, including any unregistered Trademark rights related to the Licensed Products as may exist through use before, on or after the Effective Date (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates or its or their Sublicensees).

1.144. " **Prosecuting Party** " shall have the meaning set forth in Section 9.2.2.

1.145. " **Regulatory Approval** " shall mean any and all approvals (including applicable pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary to commercially distribute, sell or market a product in a country.

1.146. " **Regulatory Authority** " shall mean any national, supranational, regional, state or local regulatory agency, administration, department, bureau, commission, council or other governmental entity including the FDA and the EMA and any other agencies in any country involved in the granting or receipt of Regulatory Approvals.

1.147. " **Regulatory Documentation** " shall mean all (a) applications (including all INDs), registrations, licenses, authorizations and Regulatory Approvals; (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all documents cited therein, including as applicable, all adverse event files and complaint files; and (c) clinical, chemistry, manufacturing and controls and other data contained or relied upon in any of the foregoing; in each case ((a), (b) and (c)) relating to a Licensed Compound or a Licensed Product.

1.148. " **Regulatory Exclusivity** " shall mean any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority, or otherwise by statute, with respect to a Licensed Product other than Patents, including rights conferred in the US under the Hatch-Waxman Act or rights similar thereto outside the US and including orphan drug designations or approvals.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.149. " **Restricted Party** " shall have the meaning set forth in Section 2.4.4.

1.150. " **R&D Budget** " shall mean the R&D Budget (Initial Indications) and the R&D Budget (New Indications) collectively.

1.151. " **R&D Budget (Initial Indications)** " shall mean the budget prepared by Assembly and mutually agreed upon by the Parties for Assembly's activities with respect to a Compound Candidate, Product Candidate, Licensed Compound or Licensed Product being Developed for an Initial Indication under this Agreement, as such budget may be modified from time to time by mutual agreement of the Parties.

1.152. " **R&D Budget (New Indications)** " shall mean the budget prepared by Assembly and mutually agreed upon by the Parties for Assembly's activities with respect to a Compound Candidate, Product Candidate, Licensed Compound or Licensed Product being Developed for a Permitted Indication other than an Initial Indication under this Agreement, as such budget may be modified from time to time by mutual agreement of the Parties.

1.153. " **R&D Plan** " shall mean the plan of work, a preliminary version of which is set out at **Schedule 1.153** as such plan of work may be finalized and amended in accordance with this Agreement. The R&D Budget shall be a part of the R&D Plan.

1.154. " **R&D Term** " shall mean the period beginning on the Effective Date and ending upon the first day on which there are no Compound R&D Terms in effect for any Compound Candidates or Licensed Compounds.

1.155. " **Receiving Party** " shall have the meaning set forth in Section 1.39.

1.156. " **Restricted Indication "** shall mean (a) in the event that the relevant Restricted Party is Allergan, any Initial Indication (other than any Initial Indication with respect to which Allergan has provided a notice to Assembly pursuant to Section 2.4.2 following the delivery of any such notice) and (b) in the event that the relevant Restricted Party is Assembly, any Permitted Indication that is not an Option Indication.

1.157. " **Retained Regulatory Documentation** " has the meaning set forth in Section 6.2.

1.158. " **Reversion IP** " shall have the meaning set forth in Section 10.8.4(c).

1.159. " **Reversion Product** " shall have the meaning set forth in Section 10.8.4(c).

1.160. " **Royalty Payment** " shall have the meaning set forth in Section 7.3.

1.161. " **Royalty Term** " shall have the meaning set forth in Section 7.3.

1.162. " **Sales Milestone Events** " shall have the meaning set forth in Section 7.2.2.

1.163. " **Sales Milestone Payments** " shall have the meaning set forth in Section 7.2.2.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.164. " **Senior Officer** " shall mean the Chief Executive Officer of Assembly and Chief R&D Officer of Allergan or the functional successor in their respective organizations, or their respective designees at Senior Vice President level or above.

1.165. " **Specifications** " shall have the meaning set forth in Section 6.4.2.

1.166. " **[* * *]** " shall mean [* * *].

1.167. " **Sublicensee** " shall mean a Third Party to whom Allergan has granted a right to Exploit a Licensed Product, excluding (a) Distributors and (b) wholesalers of biopharmaceutical products, including, for example, McKesson Corporation, AmerisourceBergen and Cardinal Health.

1.168. " **Supply Agreement** " shall have the meaning set forth in Section 6.4.5.

1.169. " **Term** " shall have the meaning set forth in Section 10.1.

1.170. " **Termination Date** " shall mean the effective date of termination of this Agreement in accordance with its terms.

1.171. " **Territory** " shall mean worldwide.

1.172. " **[* * *]** " shall mean [* * *] and its successors and assigns under the [* * *] Agreement.

1.173. " **[* * *] Agreement** " shall mean that certain License and Collaboration Agreement effective as of [* * *], by and between [* * *] and [* * *].

1.174. " **[* * *] Letter** " shall mean the letter between [* * *] and Assembly dated as December 23, 2016.

1.175. " **Third Party** " shall mean any Person who is not a Party or an Affiliate of a Party.

1.176. " **Third Party Infringement Claim** " shall have the meaning set forth in Section 9.3.1.

1.177. " **Third Party Claim** " shall have the meaning set forth in Section 12.1(a).

1.178. " **Third Party Patents** " shall mean [* * *].

1.179. " **Third Party Payments** " shall have the meaning set forth in Section 7.4.3.

1.180. " **Trademark** " shall mean any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.181. " **US** " and " **USA** " shall mean the United States of America, including all of its territories and possessions.

1.182. " **USA Co-Promotion Option Right** " shall have the meaning set forth in Section 5.1.1.

1.183. " **USD** " shall mean United States Dollars.

1.184. " **Valid Claim** " shall mean:

(a) a claim of an issued and unexpired patent included within the Licensed Compound Patents that has not been abandoned, cancelled or held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction unappealed within the time allowed for appeal, or that has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or

(b) a claim of a pending patent application included within the Licensed Compound Patents, which patent application was filed and is being prosecuted in good faith and has not been cancelled, withdrawn from consideration, abandoned or finally disallowed without the possibility of appeal or refiling of the application and that has not been pending for more than seven (7) years from the earliest date from which the patent application claims priority. If the patent application is a continuation, divisional or other continuing application, the seven (7) year period mentioned above shall be calculated from the first application filed in the series of applications.

(c) If a claim of a pending patent application included within the Licensed Compound Patents that claims a Licensed Compound is pending in a country for more than seven (7) years from the earliest date from which the patent application claims priority but is subsequently issued, then such issued patent claim shall not be reinstated as a Valid Claim, unless such patent issues (i) prior to the Launch of a Licensed Product containing such Licensed Compound in such country, or (ii) following the Launch of a Licensed Product containing such Licensed Compound in such country, if during the entire time between Launch and such issuance, (A) the Royalty Term with respect to such Licensed Product in such country has been in effect due to events described in clause (a) or clause (b)(i) of Section 7.3 and (B) no reduction in the royalties due hereunder has occurred pursuant to Section 7.4.1 in such country.

1.185. " **Value Added Tax** " or " **VAT** " shall mean any value added tax, ad valorem, goods and services or similar tax chargeable on the supply or deemed supply of goods or services, sales and use taxes, transaction taxes, consumption taxes and other similar taxes required by applicable Law including any interest, penalties or other additions to tax thereon, required under applicable Law.

1.186. " **Year 5 Forecast** " shall mean either or both of the Year 5 Forecast of Option Indication and the Year 5 Forecast of IBS-d.

1.187. " **Year 5 Forecast of Option Indication** " shall have the meaning set forth in Section 2.7.2.

1.188. " **Year 5 Forecast of IBS-d** " shall have the meaning set forth in Section 2.7.2.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.189. " **Withholding Taxes** " shall have the meaning set forth in Section 7.5.

1.190. Interpretation . Unless the context of this Agreement otherwise requires: (a) words of one gender include the other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms "hereof," "herein," "hereby," and other similar words refer to this entire Agreement; (d) the words "include", "includes", and "including" when used in this Agreement shall be deemed to be followed by the words "without limitation", unless otherwise specified; (e) the terms "Article" and "Section" refer to the specified Article and Section of this Agreement (unless clear from the context that it refers to an Article or Section of some other document); (f) references to any "person" include individuals, sole proprietorships, partnerships, limited partnerships, limited liability partnerships, corporations, limited liability companies, business trusts, joint stock companies, trusts, incorporated associations, joint ventures or similar entities or organisations, and the successors and permitted assigns of that person, (g) "or" has the inclusive meaning represented by the phrase "and/or"; (h) the words "will" and "shall" shall have the same meaning; (i) The letter "M" used in connection with the USD figures in this Agreement denotes "million" and the letter "B" used in connection with the USD figures in this Agreement denotes "billion"; and (j) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules or regulations occurs, before or, only with respect to events or developments occurring or actions taken or conditions existing after the date of such amendment, modification or issuance, after the date of this Agreement, but only to the extent such amendment or modification, to the extent it occurs after the date hereof, does not have a retroactive effect. Whenever this Agreement refers to a number of days, unless otherwise specified, such number shall refer to calendar days.

ARTICLE 2
LICENSE

2.1. Licenses Granted by Assembly .

2.1.1. Subject to the terms and conditions of this Agreement, as of the Effective Date, Assembly, on behalf of itself and its Affiliates, hereby grants to Allergan, and Allergan hereby accepts, a non-transferable (except as provided in Section 13.1), sublicensable (subject to Section 2.1.4), exclusive (including with regard to Assembly and its Affiliates), royalty-bearing, license under Assembly's right, title and interest in and to the Licensed Compound Patents and the Licensed Compound Know-How solely to Develop, have Developed, use, Commercialize, have Commercialized, import into and export out of any country, have imported into and exported out of any country and otherwise Exploit (except to make or have made) the Licensed Compounds and Licensed Products in the Field in the Territory.

2.1.2. Subject to the terms and conditions of this Agreement, as of the Effective Date, Assembly, on behalf of itself and its Affiliates, hereby grants to Allergan, and Allergan hereby accepts, a non-transferable (except as provided in Section 13.1), exclusive (including with regard to Assembly and its Affiliates), license and right of reference, with the right to grant further rights of reference solely to a Sublicensee in connection with the grant of a sublicense granted in accordance with Section 2.1.4, in and to the Retained Regulatory Documentation solely to Develop, have Developed, use, Commercialize, have Commercialized, import into and export out of any country, have imported into and exported out of any country and otherwise Exploit (except to make or have made) the Licensed Compounds and Licensed Products as permitted by Section 2.1.1.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.1.3. Subject to the terms and conditions of this Agreement, as of the Effective Date, Assembly, on behalf of itself and its Affiliates, hereby grants to Allergan, and Allergan hereby accepts, a non-transferable (except as provided in Section 13.1), sublicensable (subject to Section 2.1.4), worldwide, non-exclusive license under Assembly's interest in and to the Licensed Compound Patents and the Licensed Compound Know-How to make or have made the Licensed Compounds and Licensed Products solely to Develop, have Developed, use, Commercialize, have Commercialized, import into and export out of any country, have imported into and exported out of any country and otherwise Exploit the Licensed Compounds and Licensed Products in the Field in the Territory.

2.1.4. Allergan shall have the right to sublicense any of its rights under Section 2.1 to any Third Party (which sublicensed rights may be further sublicensable through multiple tiers) without the prior consent of Assembly, subject to the requirements of this Section 2.1.4. Each sublicense granted by Allergan pursuant to this Section 2.1.4 shall be subject and subordinate to the terms of this Agreement and shall contain provisions consistent with those in this Agreement. Except with respect to standard commercial vendor agreements that include a sublicense of any of Allergan's rights under Sections 2.1.1 through 2.1.3, Allergan shall promptly provide Assembly with a copy of the fully executed sublicense agreement covering any sublicense granted hereunder (which copy may be redacted to remove provisions which are not necessary to monitor compliance with this Section 2.1.4). Each sublicense agreement shall contain the following provisions: (i) a requirement that the Sublicensee comply with the confidentiality and non-use provisions of ARTICLE 8 with respect to Assembly's Confidential Information and (ii) a requirement that the Sublicensee submit applicable sales or other reports to Allergan to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement. Notwithstanding any sublicense, Allergan shall remain primarily liable to Assembly for the performance of all of Allergan's obligations under, and Allergan's compliance with all provisions of, this Agreement.

2.2. Licenses Granted by Allergan .

2.2.1. Subject to the terms and conditions of this Agreement, as of the Effective Date, Allergan, on behalf of itself and its Affiliates, hereby grants to Assembly, and Assembly hereby accepts, a non-exclusive, royalty-free, sublicensable (solely to permitted subcontractors under this Agreement) license and right of reference under Allergan's right, title and interest in and to the Allergan Collaboration IP and the Assigned Regulatory Documentation solely to carry out Assembly's activities under the R&D Plan.

2.2.2. Subject to the terms and conditions of this Agreement, as of the Effective Date, Allergan, on behalf of itself and its Affiliates, hereby grants to Assembly, and Assembly hereby accepts, a non-transferable (except as provided in Section 13.1), exclusive (including with regard to Allergan and its Affiliates), license and right of reference, with the right to grant further rights of reference, in and to the Assigned Regulatory Documentation solely to Develop, have Developed, use, Commercialize, have Commercialized, import into and export out of any country, have imported into and exported out of any country and otherwise Exploit (except to make or have made) products comprising Microbiome-Based Compounds, including Reversion Products, subject to the limitations imposed by Section 2.4.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.2.3. Notwithstanding anything in this Agreement to the contrary, the licenses granted by Allergan pursuant to this Section 2.2 do not include any intellectual property rights relating to compounds that are not Licensed Compounds.

2.3. Additional In-Licensed Intellectual Property .

2.3.1. Assembly will use Commercially Reasonable Efforts to ensure that it or its Affiliate Controls any Patent or Know-How to which it is granted rights by a Third Party to the extent such Patent or Know-How would be deemed a Licensed Compound Patent or Licensed Compound Know-How, as applicable, if Controlled by Assembly or its Affiliate at the time of such grant of rights.

2.3.2. If Assembly intends to secure rights pursuant to a license or similar agreement to any such Patent or Know-How, and the terms of the initial draft of the definitive agreement exchanged between Assembly and such Third Party would, if Allergan accepted a sublicense of such rights on such terms pursuant to Section 2.3.4, impose obligations or restrictions on Allergan in addition to Allergan's existing obligations and restrictions hereunder, then [* * *].

2.3.3. Without limiting any other obligation under this Section 2.3, Assembly shall promptly notify Allergan in the event (a) [* * *], (b) [* * *] or (c) [* * *], which notice, in the case of clause (b) or (c) shall be provided prior to entering into any such license or other agreement, and Assembly shall not enter into such license or other agreement prior to the Parties engaging in the discussions described in the next sentence. In the event of clause (b) or (c) under this Section 2.3.3, (y) the Parties shall discuss in good faith the underlying issues causing such inability on the part of Assembly and, [* * *] and (z) unless otherwise mutually agreed by the Parties, Assembly shall only be permitted to obtain a non-exclusive license (or an exclusive license of a scope that will not prevent Allergan from obtaining a license directly from such Third Party to exploit Licensed Compounds and Licensed Products under this Agreement) to such relevant Patent or Know-How with respect to the Licensed Compounds and Licensed Products in the Field in the Territory so that Allergan may, [* * *]. For the purposes of this Section 2.3.3 only, the Licensed Compounds and Licensed Products under this Agreement at any given time will include solely Compound Candidates and Product Candidates included in or contemplated by the then-current R&D Plan and then-current Licensed Compounds and Licensed Products and the Field shall be the then-current Permitted Indications.

2.3.4. Notwithstanding anything to the contrary in this Agreement, in the event that Assembly enters into an agreement or arrangement under which Assembly or its Affiliate is granted rights to any Patent or Know-How that would be a Licensed Compound Patent or Licensed Compound Know-How hereunder, such Patent or Know-How is hereby deemed not to be a Licensed Compound Patent or Licensed Compound Know-How hereunder, as applicable, unless and until (a) Assembly provides Allergan with a written notice of all obligations, limitations and conditions to which Allergan would be subject pursuant to the terms of such agreement or arrangement if such Patent or Know-How were deemed, as applicable, a Licensed Compound Patent or Licensed Compound Know-How hereunder and (b) Allergan, at any time after receipt of such notice, provides written notice to Assembly that it agrees to such obligations, limitations and conditions (upon delivery of such notice, such relevant agreement or arrangement shall be deemed an "In-License Agreement" hereunder). Assembly shall be required to provide the notice described in clause (a) of this Section 2.3.4 within five (5) Business Days of its execution of an agreement or arrangement under which Assembly or its Affiliate is granted rights to any Patent or Know-How that would be a Licensed Compound Patent or Licensed Compound Know-How hereunder if accepted by Allergan. If Allergan does not provide the notice described in clause (b) of this Section 2.3.4 or indicates in such written notice that it does not wish to obtain a sublicense under the relevant Patent or Know-How, such Patent or Know-How is hereby deemed not to be a Licensed Compound Patent or Licensed Compound Know-How hereunder. In no event shall Allergan be responsible or liable for any obligation, limitation or condition under an agreement or arrangement under which Assembly or its Affiliate is granted rights to any Patent or Know-How unless Allergan has expressly agreed to such obligation, limitation or condition pursuant to this Section 2.3.4.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.4. Exclusivity .

2.4.1. Except as otherwise expressly provided herein (including as provided in Section 2.7.4 and under the R&D Plan), Assembly shall not, and shall cause its Affiliates not to, either itself, or together with or through enabling (including through the grant of rights) any Third Party, [* * *] in the Territory prior to [* * *] (such period, the " **Exclusivity Term** "); provided that the restrictions in this Section 2.4.1 shall not apply during any time period during the Exclusivity Term that [* * *].

2.4.2. Except with respect to activities under this Agreement and as otherwise expressly provided herein, [* * *], Allergan shall not, and shall cause its Affiliates not to, either itself, or together with or through enabling (including through the grant of rights) any Third Party, [* * *] in the Territory prior to [* * *]; provided that the restrictions in this Section 2.4.2 shall not apply with respect to [* * *].

2.4.3. Except as expressly provided in Section 2.7, Allergan shall not, and shall cause its Affiliates not to, either itself, or together with or through enabling (including through the grant of rights) any Third Party, Exploit any Licensed Compound or Licensed Product outside of the Permitted Indications; provided , that, Allergan shall not be in breach of this Section 2.4.3 merely as a result of off-label use of a Licensed Product outside of a Permitted Indication for a Licensed Product that has only received Regulatory Approvals for, and has only been promoted by Allergan or its Affiliates for, one or more Permitted Indications.

2.4.4. Notwithstanding anything to the contrary in this Agreement, the restrictions placed on a Party and its Affiliates in Sections 2.4.1 through 2.4.2, respectively (the relevant restricted Party, the " **Restricted Party** "), will not apply to any product Developed or Commercialized by any Third Party that becomes an Affiliate of the Restricted Party after the Effective Date (a) as a result of [* * *] or (b) if such product (i) is sold or marketed by such Third Party or its licensee and such sales (whether by such Third Party or a licensee of such Third Party) represents less than fifty percent (50%) of the worldwide sales of the acquired business at the time such Third Party becomes an Affiliate of such Restricted Party by direct or indirect acquisition of such Third Party by such Restricted Party or (ii) is not sold or marketed by such Third Party and represents less than fifty percent (50%) of the enterprise value of the acquired business at the time such Third Party becomes an Affiliate of such Restricted Party by direct or indirect acquisition of such Third Party by such Restricted Party, in each case solely (x) if a "firewall" of reasonable safeguards is put in place by the Restricted Party between individuals with access to Licensed Compound Know-How or Licensed Compound Patents (to the extent unpublished), on the one hand, and the personnel responsible for the Development or Commercialization of such product, on the other hand and (y) if such Development or Commercialization (i) was initiated prior to such Third Party becoming an Affiliate of such Restricted Party and without any access to Licensed Compound Know-How or Licensed Compound Patents (to the extent unpublished), and (ii) continues without the use of any Licensed Compound Know-How (to the extent not in the public domain) or Licensed Compound Patents after such Third Party becomes an Affiliate of the Restricted Party.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.4.5. Notwithstanding anything to the contrary in this Section 2.4, if a Third Party becomes an Affiliate of a Restricted Party by direct or indirect acquisition of such Third Party by such Restricted Party and such Third Party is, at the time of such acquisition, Developing or Commercializing a Microbiome-Based Compound for, with respect to such Party, a Restricted Indication, that (a) if sold or marketed, represents fifty percent (50%) or more of the worldwide sales of the acquired Third Party at the time of such acquisition or (b) if not sold or marketed, represents fifty percent (50%) or more of the enterprise value of the acquired Third Party at the time of such acquisition, then, within six (6) months after the closing of such acquisition, such Restricted Party shall divest all rights (other than the right to merely receive payments based on the Development or Commercialization of such Microbiome-Based Compound) or cease to Develop and Commercialize such Microbiome-Based Compound for the duration of the relevant restriction on such Restricted Party as set forth in Section 2.4.1 or 2.4.2, as applicable; provided that such Restricted Party shall ensure that: (x) no personnel of such Restricted Party or its Affiliates that is involved in the Development, manufacture or Commercialization of such Microbiome-Based Compound prior to such divestment or cessation obtains any rights or access to the Confidential Information of the other Party until completion of such divestment or cessation; and (y) all of such Party's or its Affiliates' Development and Commercialization activities related to any such Microbiome-Based Compound prior to such divestment or cessation are kept separate from the Development and Commercialization activities for the Licensed Compound and Licensed Products under this Agreement.

2.5. Retention of Rights .

2.5.1. Assembly retains the right under the Licensed Compound Patents, the Licensed Compound Know-How and the Retained Regulatory Documentation solely to perform its obligations as set forth in, and subject to, the R&D Plan. Except as expressly provided herein, Assembly grants no other right or license, including any rights or licenses to the Licensed Compound Patents, the Licensed Compound Know-How or any other Patent or intellectual property rights not otherwise expressly granted herein.

2.5.2. Except as expressly provided herein, Allergan grants no other right or license, including any rights or licenses to the Allergan Collaboration IP, the Assigned Regulatory Documentation, Allergan's interest in the Joint Patents and the Joint Know-How or any other Patent or intellectual property rights not otherwise expressly granted herein.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.6. Disclosure of Know-How and Regulatory Documentation .

2.6.1. Assembly shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Allergan, in electronic or hardcopy form, as Allergan may reasonably request, copies of all physical embodiments of Regulatory Documentation, Licensed Compound Know-How and Joint Know-How Controlled by Assembly or its Affiliates, including (a) all clinical and non-clinical data, (b) summaries of such data, research, analyses and other information relating to the Licensed Compounds or the Licensed Products (including the results achieved in the performance of the R&D Plan and the Development of a Compound Candidate, Product Candidate, Licensed Compound or Licensed Product), and (c) any other information claimed or covered by any Licensed Compound Patent or Joint Patent or otherwise relating to any Licensed Compound, any Licensed Product or the Exploitation of any Licensed Compound or Licensed Product requested by Allergan, in each case (x) that is in existence as of the Effective Date, promptly after (but in any case within thirty (30) calendar days following) the Effective Date and (y) that comes into existence after the Effective Date, promptly after the earlier of the development, making, conception or reduction to practice of such Regulatory Documentation, Licensed Compound Know-How or Joint Know-How.

2.6.2. Assembly, at its sole cost and expense, shall provide Allergan with all reasonable assistance required in order to transfer to Allergan the Regulatory Documentation, Licensed Compound Know-How, Joint Know-How, and other information required to be produced pursuant to Section 2.6.1 above, in each case, in a timely manner. Without limiting the foregoing, Assembly shall make available to Allergan, those of Assembly's representatives as Allergan may reasonably request for purposes of transferring the Regulatory Documentation, Licensed Compound Know-How, Joint Know-How, or other information to Allergan or for purposes of Allergan acquiring expertise on the practical application of such information or assisting on issues arising during such Exploitation, including through site visits to Allergan's facility as reasonably required or useful.

2.6.3. In connection with the foregoing disclosure obligation, Assembly will disclose to Allergan information relating to [* * *] by Assembly for use [* * *] by Assembly hereunder for selection by Allergan as a Compound Candidate, including Assembly's [* * *], but, anything to the contrary in this Agreement notwithstanding, neither Assembly nor any of its Affiliates shall be required to disclose or make available to Allergan or any Third Party any [* * *] a compound.

2.7. Option to Expand the Permitted Indications .

2.7.1. Allergan shall have the right, at Allergan's sole discretion at any time during the Term, to expand the Permitted Indications (the " **Option Indication Right** ") on an Option Indication-by-Option Indication basis by (i) providing written notice (an " **Option Notice** ") to Assembly specifying an additional indication or indications (each, an " **Option Indication** " and collectively, " **Option Indications** ") with respect to which Allergan desires to exercise the Option Indication Right and the identity of the Licensed Compound or Compound Candidate that Allergan initially intends to Develop for the relevant Option Indication(s) and (ii) paying the fee (the " **Option Exercise Fee** ") and committing to pay the development milestones (" **Option Indication Development Milestones** ") as described in Section 2.7.2. There shall be no limit to the number of times Allergan may exercise the Option Indication Right. Within ten (10) Business Days of receipt of an Option Notice, Assembly shall notify Allergan (a) if a proposed Option Indication is available, such Option Indication to only be deemed unavailable if [* * *] and (b) if such proposed Option Indication is available, whether any Licensed Compound Know-How described in clause (a) of Section 1.107 or any Licensed Compound Patents described in clause (b)(i) of Section 1.108 would not be Licensed Compound Know-How or Licensed Compound Patents with respect to such proposed Option Indication, assuming solely for the purposes of this Section 2.7.1 that any Compound Candidate subject to the Option Notice is a Licensed Compound. If Assembly does not provide notice to Allergan within such ten (10) Business Day period or otherwise notifies Allergan that such Option Indication is available under this Agreement (provided that, unless Assembly notifies Allergan that such Option Indication is not available, it shall provide to Allergan the information described in clause (b) of the preceding sentence), such Option Indication shall become a Permitted Indication upon payment by Allergan of the Option Exercise Fee.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.7.2. Option Exercise Fee .

(a) The Option Exercise Fee shall be determined as follows:

Option Exercise Fee = [* * *]

[* * *]

[* * *]

[* * *]

[* * *]

[* * *]

The Option Exercise Fee for any Option Indication shall not be any greater than $[* * *], regardless of its calculated amount. If the Option Exercise Fee as calculated above results in an amount (a) that is less than $[* * *], then the Option Exercise Fee shall be adjusted to be equal to $[* * *] and (b) that is greater than $[* * *], then the Option Exercise Fee shall be payable as follows: (i) $[* * *] shall be payable at the time of exercise of the Option Indication Rights in accordance with this paragraph and (ii) the remainder (up to $[* * *]) shall be [* * *] payable for the relevant Option Indication. The Option Exercise Fee shall be payable within [* * *] days after receipt by Allergan of an invoice therefor from Assembly, which invoice shall be delivered promptly following the determination of the Option Exercise Fee in accordance with this Section 2.7.2; provided that, Allergan may revoke its Option Notice within thirty (30) days after such determination is made and, in such case, the relevant Option Indication will not be deemed a Permitted Indication hereunder, Allergan shall have no obligation to pay the relevant Option Exercise Fee and Allergan shall maintain its Option Indication Right with respect to such Option Indication.

(b) The Option Indication Development Milestones shall become due and payable upon the achievement of the Development Milestones set forth in Section 7.2.1 by the first Licensed Product in an Option Indication on and subject to the same terms as are applicable to Licensed Products that are in Development for use to treat IBS; provided that the amount of such Development Milestones (a) shall be determined by [* * *] and (b) with respect to the first two (2) Development Milestones owed, [* * *]; provided further that, with respect to immediately foregoing clause (a), [* * *].

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.7.3. In the event the Parties are unable to agree on the calculation of a Year 5 Forecast under Section 2.7.2 within thirty (30) days of delivery of an Option Notice, either Party may provide written notice to the other Party (an " **Expert Resolution Notice** "), and such matter shall be resolved by a final, binding determination by an independent Third Party expert mutually acceptable to the Parties (the " **Expert** "). Once the Expert has been selected, each Party shall, within ten (10) Business Days following selection of the Expert, provide the Expert and the other Party with a written statement setting forth its proposed calculation with respect to the applicable Year 5 Forecast with any such supporting documentation as such Party may determine to provide. The Expert shall, no later than ten (10) Business Days (or such other period as the Parties may agree) after the submission of the Parties' written statements, determine the appropriate amount for the Year 5 Forecast for the purposes of Section 2.7.2; provided , that, the Expert may only choose one of the relevant Year 5 Forecast proposals submitted by the Parties without modification as the relevant Year 5 Forecast. The decision of the Expert shall be the sole, exclusive and binding remedy between the Parties with respect to any dispute with respect to the calculation of any Year 5 Forecast under Section 2.7. The costs of the Expert shall be shared by the Parties.

2.7.4. Notwithstanding anything to the contrary set forth herein, Assembly shall not be prevented from directly or indirectly Developing or Commercializing a Microbiome-Based Compound in any Option Indication.

ARTICLE 3
GOVERNANCE

3.1. Establishment of Joint Development Committee . Within thirty (30) days of the Effective Date, the Parties shall establish a Joint Development Committee (the " **Joint Development Committee** " or " **JDC** ") consisting of an appropriate number of representatives as may be agreed upon by the Parties, with an equal number of representatives designated by each Party. The initial members of the JDC will be nominated by the Parties promptly following the Effective Date. Such representatives shall be individuals suitable in seniority and experience and having delegated authority to make decisions of the JDC with respect to matters within the scope of the JDC's responsibilities. The JDC shall operate in accordance with the provisions of Sections 3.2 to 3.8, and shall have no authority to alter, amend or waive the terms and conditions of this Agreement, including any payment conditions or terms, periods for performance, or obligations of the Parties. A Party may change one or more of its representatives serving on the JDC at any time upon written notice to the other Party; provided that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. At its meetings, the JDC shall discuss the matters described below and such other matters as are reasonably requested by either Party's Alliance Manager. The JDC shall remain in effect until the Launch of all Licensed Products.

3.2. Responsibilities of JDC . Subject to the limitations set forth in Section 3.6, the JDC shall perform the following functions:

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.2.1. oversee and direct the conduct of the R&D Plan, including (a) selection, prioritization, and Optimization of Compound Candidates and Product Candidates and (b) on a Licensed Compound-by-Licensed Compound basis, conduct of Clinical Trials with respect to any Licensed Product containing a Licensed Compound until the Completion of the first POC Trial for a Licensed Product containing such Licensed Compound;

3.2.2. allocate (and reallocate from time to time) activities between the Parties under the R&D Plan;

3.2.3. review and comment on any development plan produced by Allergan in respect of a Licensed Compound pursuant to Section 4.1.2;

3.2.4. facilitate communication between the Parties regarding all material activities performed by such Party under the R&D Plan, including preclinical and clinical Development of Compound Candidates and Product Candidates, under or in connection with the R&D Plan;

3.2.5. review, and provide a forum for the Parties to discuss, any subcontractors through which Assembly intends to conduct any Development or manufacturing activities hereunder, together with the subcontracts related thereto;

3.2.6. provide a forum for the Parties to discuss Allergan's Development of any Licensed Compound or Licensed Product containing such Licensed Compound; and

3.2.7. perform such other functions as are specifically designated for the JDC in this Agreement.

3.3. Co-Chairs . Each Party shall designate one of its representatives on the JDC to co-chair the meetings for the JDC (each, a " **Co-Chair** "). The Co-Chairs shall, through and with the assistance of the Alliance Managers, coordinate and prepare the agenda for, and ensure the orderly conduct of, the meetings of the JDC. The Co-Chairs shall, through and with the assistance of the Alliance Managers, solicit agenda items from the JDC members and provide an agenda, along with appropriate information for such agenda, reasonably in advance of any meeting. Such agenda shall include all items requested by either Co-Chair for inclusion therein. In the event the Co-Chairs or another JDC member from either Party is unable to attend or participate in a meeting of the JDC, the Party whose Co-Chair or member is unable to attend may designate a substitute co-chair or other representative for the meeting.

3.4. Meetings . The JDC shall meet at least quarterly, or more or less frequently if determined by the JDC, during the R&D Term and JDC meetings can be called at other times by agreement between the Parties for any reason. JDC meetings may be conducted by telephone, videoconference or in person. Any in-person JDC meetings shall be held on an alternating basis between Assembly's and Allergan's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for the cost of such Party's own personnel and for its own expenses in attending such meetings and carrying out the other activities contemplated under this ARTICLE 3. As appropriate, the JDC may invite a reasonable number of non-voting employees, consultants and scientific advisors to attend its meetings as non-voting observers; provided , that such invitees are bound by confidentiality obligations at least as stringent as the provisions set forth herein. Each Party may also call for special meetings of the JDC to discuss particular matters requested by such Party. The Alliance Managers shall provide the members of the JDC with no less than ten (10) Business Days' notice of each regularly scheduled meeting and, to the extent reasonably practicable under the circumstances, no less than five (5) Business Days' notice of any special meetings called by either Party.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.5. Minutes . Minutes will be kept of all JDC meetings by one of the Co-Chairs of the JDC (or his or her designees) on a rotating basis and sent to all members of the JDC by e-mail for review and approval within thirty (30) days after each such meeting. The JDC shall formally accept the minutes of the previous meeting at or before the next meeting of the JDC. Minutes will be deemed approved unless any member of the JDC objects to the accuracy of such minutes by providing written notice to the other members of the JDC prior to the next meeting of the JDC. Minutes shall list action items and shall designate any issues that need to be resolved by the JDC or applicable resolution process. In the event of any objection to the minutes that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

3.6. Decision Making within JDC .

3.6.1. During the R&D Term, decisions of the JDC pursuant to Sections 3.2.1 to 3.2.2 shall be made by unanimous vote, with each Party having one (1) vote. In order to make any decision, the JDC must have present (in person or via telephone or videoconference) and voting at least one (1) representative of each Party.

3.6.2. On a Licensed Compound-by-Licensed Compound basis, following the end of the Compound R&D Term for such Licensed Compound, (a) the JDC shall cease to have any decision-making authority with respect to such Licensed Compound and any Licensed Product incorporating such Licensed Compound, (b) Allergan shall make all decisions, including Development decisions, regarding such Licensed Compound and any Licensed Products incorporating such Licensed Compound and (c) the JDC shall serve solely as a forum for the Parties to discuss Allergan's Development with respect to such Licensed Compound and any Licensed Products incorporating such Licensed Compound.

3.6.3. In the event there is a [* * *] during the R&D Term, immediately upon [* * *], the JDC shall thereafter serve solely as a forum for the Parties to discuss, on a Compound Candidate-by-Compound Candidate basis, the Development of a Compound Candidate prior to such Compound Candidate becoming a "Licensed Compound" hereunder, and Allergan shall have the right to make all decisions previously subject to Assembly's final decision making authority under Section 3.7 with respect to the Development of each of the Compound Candidates following completion of [* * *] activities with respect thereto.

3.7. Committee Deadlocks . Subject to the limitations set forth in Section 3.6 and the terms of this Agreement, if during the R&D Term, the JDC cannot resolve a matter described in Section 3.6.1 within thirty (30) days, or such shorter time as may be determined by the Parties, after it begins discussing any such delegated matter (a " **Committee Deadlock** "), then the JDC shall escalate such Committee Deadlock to the Senior Officers for resolution by consensus. If following consideration by the Senior Officers for a period of up to ten (10) Business Days there is still no consensus, then, [* * *].

3.8. Joint Patent Committee .

3.8.1. Formation; Composition . Within thirty (30) days of the Effective Date, the Parties will establish a joint patent committee (the " **Joint Patent Committee** ") comprised of an equal number of representatives from each Party (or appointed representatives of an Affiliate of such Party) with sufficient seniority within the applicable Party to make decisions arising within the scope of the Joint Patent Committee's responsibilities.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

3.8.2. Specific Responsibilities . The Joint Patent Committee will:

(a) provide a forum for discussing the preparation, filing, prosecution, and maintenance of Product Only Patents, Product Related Patents, and other Licensed Compound Patents, as set forth in Sections 9.1.1 to 9.1.3;

(b) comply with the procedures set forth in Section 9.1.6(c); and

(c) perform such other functions regarding Patents included in the Licensed Compound Patents as appropriate, to further the purposes of this Agreement, in each case as agreed in writing by the Parties.

3.8.3. Meetings . The Joint Patent Committee shall meet at least one (1) time per Calendar Year, or more or less frequently if determined by the Joint Patent Committee.

3.9. Alliance Managers .

Each Party shall designate an individual to serve as the main point of contact for such Party to exchange information, facilitate communication and coordinate the Parties' activities under this Agreement (each, an " **Alliance Manager** "). The Alliance Managers shall attend meetings (or designate an appropriate representative to attend meetings on the Alliance Manager's behalf) between the Parties, including JDC meetings. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.

ARTICLE 4
R&D PLAN, DEVELOPMENT AND DILIGENCE REQUIREMENTS

4.1. R&D Plan .

4.1.1. General . As at the Execution Date, the Parties have agreed to a preliminary version of the R&D Plan attached as **Schedule 1.153** . Assembly will prepare, and the Parties will review and mutually agree to, a final R&D Plan within forty-five (45) days after the Effective Date. The R&D Plan, among other things as further specified in this Section 4.1, will specify the scientific direction and activities of, and allocate responsibilities and resources between, the Parties in a manner consistent with this Agreement. The R&D Plan will be updated from time-to-time during the Term to ensure that it reflects the then-current scope of activities planned by the Parties, with more detail being provided for activities that are to be conducted in the near-term and that are less contingent on the achievement of anticipated results of Development. The R&D Plan will include the information referenced in the outline attached to the R&D Plan attached as **Schedule 1.153** , and will include information relevant to the following topics and events, as and when such information is determinable:

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(a) activities conducted in connection with the Optimization (including the goals of and strain selection methodology and gene sequence analysis protocols used to select and validate Initial Candidate Compounds in such Optimization) of each Initial Compound Candidate for its proposed Permitted Indication and the conduct of a POC Trial for the Licensed Product containing the Initial Compound resulting from such Optimization activities for such Permitted Indication and delivery to Allergan of top-line results for such POC Trial;

(b) the delivery of, and timing of such delivery of, potential New Compound Candidates by Assembly to Allergan as further described in Section 4.4, the Optimization (including the goals of and strain selection methodology and gene sequence analysis protocols used to select and validate New Candidate Compounds in such Optimization) of each New Compound Candidate for its proposed Permitted Indication and the conduct of a POC Trial for the Licensed Product containing the New Compound resulting from such Optimization activities for such Permitted Indication and delivery to Allergan of top-line results for such POC Trial;

(c) the delivery of potential Backup Compound Candidates by Assembly to Allergan following Allergan's request as described in Section 4.5, the Optimization (including the goals of and strain selection methodology and gene sequence analysis protocols used to select and validate Backup Candidate Compounds in such Optimization) of each Backup Compound Candidate for its proposed Permitted Indication and the conduct of a POC Trial for the Licensed Product containing the Backup Compound resulting from such Optimization activities for such Permitted Indication and delivery to Allergan of top-line results for such POC Trial.

In the event that Allergan desires to Develop a Compound Candidate or Licensed Compound for a Permitted Indication other than an Initial Indication, the R&D Plan shall also contain a R&D Budget (New Indications) as further described in Section 4.8.3 for the Development activities required to conduct such Development until completion of all activities related to the first POC Trial of a Licensed Product incorporating such Licensed Compound, including Completion of such POC Trial and completion of the final clinical study report for such POC Trial for a Licensed Product incorporating such Licensed Compound. The terms of, and activities set forth in, the R&D Plan shall at all times be designed to be in compliance with all applicable Laws and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, and, where applicable, each Party's respective health care compliance policies and applicable standard operating procedures.

4.1.2. Responsibilities . Each Party shall only be obliged to perform activities under the R&D Plan if, and solely to the extent, expressly set forth and allocated to such Party in the R&D Plan or this Agreement. On a Permitted Indication-by-Permitted Indication basis, neither Party will undertake any material, ongoing Development activities in connection with any Compound Candidate or Licensed Compound prior to the Completion of the first POC Trial for such Licensed Compound, in such Permitted Indication, that are not provided for or consistent with the then-current R&D Plan. The JDC shall be responsible for reviewing and making recommendations in respect of any updates or amendments to the R&D Plan. Any amendments or modifications to the R&D Plan shall require the mutual agreement of the Parties. For the sake of clarity, from and after the Completion of a POC Trial for a Licensed Product, the R&D Plan shall not apply to, or govern in any way, Allergan's Development efforts for such Licensed Product or the Licensed Compound incorporated into such Licensed Product. Following the Completion of a POC Trial for a Licensed Product, Allergan's Development efforts, if any, in respect of such Licensed Product or the Licensed Compound incorporated in such Licensed Product for any Permitted Indication shall be set forth in a high-level development plan and biannual updates thereto produced by Allergan and presented to the JDC solely for review and comment.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.2. Compound R&D Term . On a Licensed Compound-by-Licensed Compound and Permitted Indication-by-Permitted Indication basis, the period starting on the Effective Date and ending on the earliest of (a) the Completion of the first POC Trial for a Licensed Product incorporating such Licensed Compound for such Permitted Indication, or earlier termination, of the Development activities for such Licensed Compound under the R&D Plan for such Permitted Indication pursuant to this Agreement and (b) early termination of this Agreement in accordance with ARTICLE 10 shall be the " **Compound R&D Term** " for such Licensed Compound for such Permitted Indication. For clarity, any Development activities conducted under the R&D Plan with respect to a Compound Candidate or Product Candidate shall be deemed to have occurred during the Compound R&D Term for the resultant Licensed Compound stemming from such Development.

4.3. Development Efforts During the R&D Term .

4.3.1. During the R&D Term, each Party shall devote the FTEs as designated pursuant to the R&D Plan, which FTEs shall be appropriately qualified research and development personnel possessing at least the level of skill and experience that such Party's personnel engaged in discovery, research and other Development activities for such Party's other programs possess. [* * *]. Each Party will conduct its activities under the R&D Plan in accordance with good scientific standards and practices and in compliance in all material respects with the requirements of GLP, GCP and all applicable Laws, including those regarding environmental, safety and industrial hygiene, quality assurance and quality control (including data integrity), standards for pharmacovigilance practice, and all requirements relating to the protection of human subjects. Each Party shall maintain laboratories, offices and all other facilities reasonably necessary to carry out the activities to be performed by it pursuant to the R&D Plan. In conformity with standard pharmaceutical and biotechnology industry practices and the terms and conditions of this Agreement, each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate laboratory notebooks and other written records, accounts, notes, reports and data with respect to activities conducted pursuant to the R&D Plan and, upon such other Party's written request and at its expense, will send legible copies of relevant portions of the aforesaid to such Party in such form(s) as such Party may reasonably request.

4.3.2. When conducting Development under the R&D Plan to identify proposed Compound Candidates for a particular Permitted Indication, for clarity, in addition to any other potential compounds that Assembly may identify under the R&D Plan, Assembly will provide to Allergan, as proposed Compound Candidates, [* * *] that Assembly or its Affiliates have found to demonstrate, in the aggregate, characteristics that [* * *] most likely to have a favorable safety and efficacy profile for the treatment or maintenance of remission of such Permitted Indication. After selection of a proposed Compound Candidate, Assembly shall work to Optimize such Compound Candidates in accordance with the R&D Plan.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.3.3. During the applicable Compound R&D Term, subject to Allergan's final decision-making authority set forth in Section 3.6 if applicable, Assembly shall be responsible for [* * *] and preclinical research of such Compound Candidate and Development of such Compound Candidate and resultant Licensed Compound through the completion of all activities related to the first POC Trial of a Licensed Product incorporating such Licensed Compound, including Completion of such POC Trial and completion of the final clinical study report for such POC Trial for such Licensed Product; provided that, notwithstanding anything to the contrary in this Agreement, an IND for a Product Candidate in a Permitted Indication may only be filed with a Regulatory Authority with the mutual consent of the Parties, such consent to be given or withheld in good faith.

4.4. Development of New Compounds .

4.4.1. Assembly shall use Commercially Reasonable Efforts to provide proposed New Compound Candidate(s) for selection by Allergan, including summaries of data, research, analyses, rationale for such selection and any other information relating to such proposed New Compound Candidate(s) required by the R&D Plan.

4.4.2. Allergan shall have the right to select, in its sole discretion, up to two (2) candidates as New Compound Candidates for Optimization, one for the Initial Indication of irritable bowel syndrome with constipation (IBS-c) or mixed irritable bowel syndrome (IBS-m) and one for the Initial Indication of irritable bowel syndrome with diarrhea (IBS-d) or mixed irritable bowel syndrome (IBS-m) and, upon such selection, each such candidate will be deemed a New Compound Candidate hereunder. If Allergan, in its sole discretion, does not select two (2) candidates proposed by Assembly as New Compound Candidates for an Initial Indication, Assembly shall use Commercially Reasonable Efforts to provide other candidates for such New Compound for such Initial Indication reasonably thereafter. For clarity, the Development Costs incurred by Assembly in providing additional candidates to Allergan shall be included within and subject to the limitation on total Development Costs to be incurred by Assembly as set forth in Section 4.8.2(a). In the event Allergan does select a candidate to be a New Compound Candidate, Assembly shall submit to the JDC (which shall be re-established if disbanded pursuant to this Agreement at the time of such candidate selection), for approval by mutual agreement of the Parties, a proposed amendment to the R&D Plan providing for the activities for the Development (including Optimization) of such New Compound Candidate and resultant New Compound (and products incorporating each of such) for the applicable Initial Indication through the Completion of the first POC Trial for a Licensed Product incorporating such New Compound.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.5. Development of Backup Compounds; [* * *] .

4.5.1. Subject to the terms of this Section 4.5, Allergan shall have the right, upon written notice to Assembly, to request that Assembly provide potential Backup Compound Candidate(s) (such Backup Compound Candidate(s) to be backups to the Initial Compounds or New Compounds initially for the same Permitted Indications as the such Initial Compound or New Compound but subject to Development for additional indications thereafter as provided in Section 4.8.3) for evaluation and possible selection by Allergan, such written request to include selection criteria for such potential Backup Compound Candidate(s). Upon receipt of Allergan's written request, Assembly shall use Commercially Reasonable Efforts to identify potential Backup Compound Candidate(s) in accordance with the selection criteria provided by Allergan in such written request; provided that unless otherwise agreed by Allergan, Assembly shall not propose any potential Backup Compound Candidate that has [* * *] (without regard to [* * *]) as a Compound Candidate. Allergan shall provide the written request contemplated by this Section 4.5.1 in sufficient reasonable time for Assembly to provide potential Backup Compound Candidate(s) for evaluation by Allergan no later than the conclusion of the Phase III Clinical Trial for the Licensed Product incorporating the Licensed Compound for which such potential Backup Compound Candidate(s) are intended to be backup(s). Assembly shall provide Allergan with access to such data, research, analyses, rationale for selection and any other information relating to such potential Backup Compound Candidate(s) as is requested by Allergan and that is possessed and controlled by Assembly, as soon as practicable following the date of Allergan's written request.

4.5.2. Allergan shall have the right to select, in its sole discretion, up to a total of [* * *] Backup Compound Candidates as backups to the Initial Compounds and New Compounds for Development for Permitted Indications from the compound candidates provided by Assembly pursuant to Section 4.5.1, and, upon such selection, such candidates will be deemed Backup Compound Candidates hereunder. In the event Allergan does select a candidate to be a Backup Compound Candidate, it may submit to the JDC (which shall be re-established if disbanded at the time of such candidate selection), for approval by mutual agreement of the Parties, a proposed amendment to the R&D Plan providing for the activities for the Optimization and Development of such Backup Compound Candidate and resultant Backup Compound through the Completion of the first POC Trial for a Licensed Product incorporating such Backup Compound, such proposed amendment to be the R&D Plan once such amendment is mutually agreed upon by the Parties. If Allergan, in its sole discretion, does not select [* * *] proposed candidates as Backup Compound Candidates, Assembly shall, at Allergan's request, use Commercially Reasonable Efforts to provide other proposed Backup Compound Candidate(s) pursuant to the procedure set forth in Section 4.5.1.

4.5.3. For the sake of clarity, (i) the composition of Backup Compounds shall not be limited to [* * *] as the relevant Licensed Compound to which it is a backup, and (ii) subject to the terms of this Agreement, [* * *] included in a Licensed Compound may be used by Assembly in its development of compounds for itself or Third Parties.

4.6. Development Efforts Following the End of the Compound R&D Term . Following the end of a Compound R&D Term with respect to any Licensed Compound being Developed for any Permitted Indication in the Field, subject to Assembly's performance of its obligations set forth in Section 6.4, Allergan shall be responsible for all Development and Commercialization activities regarding such Licensed Compound and any Licensed Products incorporating such Licensed Compound; provided , that, if Assembly has, at the time of the Completion of the first POC Trial for a Licensed Product incorporating such Licensed Compound, established an Affiliate in China with sufficient capabilities to manage Development of such Licensed Product in China, as determined by Allergan in its reasonable discretion, then Assembly shall conduct Development of such Licensed Product in China through such Affiliate under Allergan's oversight and direction, and Allergan shall reimburse Assembly for all Development Costs reasonably incurred by Assembly in connection with such activities, pursuant to the processes set forth in Section 4.9.2.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.7. Diligence Obligations .

4.7.1. Each Party shall use Commercially Reasonable Efforts to perform its obligations under the R&D Plan with respect to the Development of each Licensed Compound and each Licensed Product.

4.7.2. On an Initial Indication-by-Initial Indication basis, from and after [* * *] of a Licensed Product for an Initial Indication, Allergan shall use Commercially Reasonable Efforts to (a) Develop and seek Regulatory Approval of such Licensed Product for such Initial Indication in [* * *] and (b) Commercialize such Licensed Product in each of [* * *] following receipt of Regulatory Approval (including, for clarity, in [* * *], pricing approval) in such country in such Initial Indication.

4.8. Development Costs .

4.8.1. General . In incurring Development Costs under this Agreement while conducting activities under the R&D Plan, Assembly will incur Development Costs that are reasonable for the activity conducted and will work in good faith to avoid or minimize any Development Cost overages to the R&D Budget.

4.8.2. Initial Indications .

(a) Subject to the terms of this Agreement, Allergan and Assembly shall be jointly responsible for all Development Costs incurred in the conduct of activities under the R&D Plan for Development of a Licensed Compound (other than a Backup Compound) and a Licensed Product incorporating such Licensed Compound for an Initial Indication. On a Licensed Compound-by-Licensed Compound basis, Allergan shall be obligated to fund up to Fifty Million USD ($50M) and Assembly shall be obligated to fund up to Twenty Five Million USD ($25M) of such Development Costs through the completion of all activities related to the first POC Trial of a Licensed Product incorporating such Licensed Compound for the Initial Indications, including Completion of such POC Trial and completion of the final clinical study report for such POC Trial (the " **Initial Indication Development Costs** "). The Parties shall fund up to such aggregate of Seventy-Five Million USD ($75M) of Initial Indication Development Costs on a pro-rata basis in the manner of two-thirds (2/3) borne by Allergan and one-third (1/3) borne by Assembly.

(b) To the extent the Initial Indication Development Costs exceed Seventy Five Million USD ($75M), Assembly may elect, prior to the first day of the Calendar Quarter in which the Initial Indication Development Costs are expected to exceed Seventy Five Million USD ($75M), to either (a) continue to bear one-third (1/3) of any such Development Costs or (b) cease to bear any additional Initial Indication Development Costs in excess of its $25M share. If Assembly elects, pursuant to this Section 4.8.2(b), to cease bearing its portion of the Initial Indication Development Costs, Allergan shall be entitled to deduct from any Development Milestone Payments payable to Assembly as set forth in Section 7.4.5(a) one-third (1/3) of the Initial Indication Development Costs actually paid by Allergan in excess of the first Seventy-Five Million USD ($75M) of Initial Indication Development Costs incurred by the Parties pursuant to Section 4.8.2(a) plus a premium of 25% ([* * *]).

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(c) Anything herein to the contrary notwithstanding, (i) on a Licensed Compound-by-Licensed Compound basis, Allergan shall be solely responsible for all Development Costs incurred pursuant to this Agreement in connection with the Development of a Licensed Compound and Licensed Products incorporating such Licensed Compound from and after the completion of the final clinical study report for such POC Trial for such Licensed Product, including Completion of such POC Trial and completion of the final clinical study report for such POC Trial and (ii) all Development Costs incurred in respect of the Development of a Backup Compound pursuant to this Agreement shall be borne solely by Allergan.

4.8.3. Other Indications .

(a) In the event that Allergan desires to Develop a Licensed Compound for a Permitted Indication other than an Initial Indication, Allergan shall so notify Assembly. Assembly shall prepare and provide to Allergan a proposed amendment to the R&D Plan describing the activities for such Development, containing a proposed R&D Budget (New Indications) for such activities. Such proposed amendment to the R&D Plan and proposed R&D Budget (New Indications) shall be given effect once mutually agreed upon by the Parties. Allergan shall be solely responsible for all Development Costs incurred pursuant to this Section 4.8.3(a) for such Development; provided that, at its option, Assembly may elect to bear one-third (1/3) of such Development Costs for Development of a Licensed Compound and Licensed Products incorporating such Licensed Compound in a Permitted Indication other than an Initial Indication by giving written notice to Allergan within ten (10) Business Days after approval by the Parties of the relevant proposed amendment to the R&D Plan. Upon Assembly's delivery of such written notice to participate in the payment of such Development Costs, it shall be obligated to do so under the terms of this Agreement.

(b) If Assembly does not elect to bear one-third (1/3) of any such Development Costs pursuant to Section 4.8.3(a), then (i) Allergan shall be entitled to deduct from any Development Milestone Payments payable to Assembly in respect of a Licensed Product that incorporates such Licensed Compound for such Permitted Indication an amount equal to one-third (1/3) of the Development Costs actually incurred by Allergan for Development activities for such Licensed Compound and Licensed Product incorporating such Licensed Compound, in each case for such Permitted Indication plus a premium of 25% ([* * *]).

4.9. Invoicing; Payment of Development Costs .

4.9.1. With respect to Development Costs incurred in connection with Development activities for which the Parties are sharing Development Costs in accordance with this Agreement, within ten (10) days following the last day of each Calendar Quarter during the R&D Term, each Party shall provide the other Party with a report of all Development Costs that were incurred by such Party performing activities under the R&D Plan in the prior Calendar Quarter and reasonable supporting documentation with respect thereto. Based on such reports, the Parties shall determine which Party has incurred more than its allocable share of the aggregate Development Costs incurred by both Parties during such Calendar Quarter as set forth in this Agreement, and the Party that has incurred more than its allocable share of such Development Costs shall provide to the other Party an invoice for such excess amount of Development Costs incurred by such Party for such Calendar Quarter within thirty (30) days of the receipt by both Parties of the reports of Development Costs pursuant to this Section 4.9.

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4.9.2. With respect to Development Costs incurred by Assembly in connection with Development activities for which Allergan is solely responsible for Development Costs in accordance with this Agreement, Assembly shall provide Allergan an invoice for the amount of Development Costs incurred by Assembly in connection with such activities and reasonable supporting documentation with respect thereto within forty-five (45) days of the end of each Calendar Quarter.

4.9.3. Each Party shall pay the undisputed amount of invoices provided pursuant to this Section 4.9 within forty-five (45) days of receipt of such invoice and supporting documentation, as applicable. If a Party disputes in good faith any charge contained in an invoice, it will pay any undisputed amounts in accordance with the preceding sentence and provide written notice of the nature of the dispute to the other Party, and the disputed amount will be addressed under the dispute resolution provisions of Section 13.4.

4.10. Subcontracts. Either Party may perform appropriate Development activities under the R&D Plan pursuant to this Agreement through one or more Third Party subcontractors; provided, that such Party engages each such Third Party subcontractor through a written agreement consistent with the terms and conditions of this Agreement, and further provided, that, such Party shall provide prior written notice to the other Party of such Party's intent to engage such subcontractor, such notice to include the relevant contact information of the subcontractor and a description of the work to be performed by such subcontractor. Notwithstanding anything to the contrary in this Agreement, a Party may only engage a Third Party subcontractor to perform Development activities under the R&D Plan if: (a) no rights of either Party under this Agreement would be diminished or otherwise adversely affected as a result of such subcontracting, (b) the subcontractor undertakes the obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to ARTICLE 8 hereof, and (c) the subcontractor agrees that any intellectual property developed in the course of the work hereunder shall be assigned to the Party engaging the subcontractor or such Party's designee, so as to permit licensing or re-assignment as required by the terms and conditions of this Agreement. The Party engaging any such Third Party subcontractor shall be responsible for all inventive contributions of the subcontractor's employees or agents with respect to any intellectual property. Subcontracting shall not relieve either Party of its obligations or liability under this Agreement.

4.11. Materials. Each Party will, during the R&D Term, as a matter of course as described in the R&D Plan or on the other Party's reasonable written request, furnish to the other Party samples of Materials that it Controls and that are necessary for the other Party to carry out its responsibilities under the R&D Plan. Each Party will use such Materials only in accordance with the R&D Plan and otherwise in accordance with the terms and conditions of this Agreement. Except with the prior written consent of the supplying Party, the Party receiving any Materials will not distribute or otherwise allow the release of Materials to any Third Party, except for subcontracting (subject to the provisions of Section 4.10) or sublicensing as permitted hereunder. All Materials will remain the sole property of the supplying Party, will be used in compliance with all applicable Laws, and will be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.12. Reports . Each Party shall promptly provide the other Party with written reports of all Know-How, results, discoveries, inventions and technical developments made or generated in the course of performing activities under or in connection with the R&D Plan with respect to a Licensed Compound or Licensed Product by such reporting Party. Without limitation to the foregoing, during the R&D Term, each Party shall prepare and provide to the other Party (a) a written report every Calendar Quarter that (i) details the Development activities performed by the reporting Party, including all results achieved, (ii) sets forth the expected activities to be undertaken by the reporting Party during the next Calendar Quarter and the prioritization thereof, and (iii) identifies any issues or circumstances of which the reporting Party is aware that may prevent or adversely affect in a material manner its future performance of activities assigned to it under the R&D Plan and (b) such other reports or updates as may be required under the R&D Plan. The Parties may agree, on a case by case basis, that minutes or presentations from JDC meetings may be used to satisfy certain of the foregoing reporting requirements.

ARTICLE 5
CO-PROMOTION

5.1. Co-Promotion in the USA .

5.1.1. Assembly shall have the right, subject and pursuant to the terms set forth in this Agreement, to co-promote one or more Licensed Products in the USA (the " **USA Co-Promotion Option Right** "). The USA Co-Promotion Option Right shall be exercisable by Assembly on a Licensed Product-by-Licensed Product basis.

5.1.2. Assembly may exercise its USA Co-Promotion Option Right with respect to a Licensed Product by providing [* * *] prior written notice to Allergan; provided , that Assembly may only exercise the USA Co-Promotion Option Right following the commencement of the respective Calendar Years specified below, provided the related criteria have been achieved: (i) the third Calendar Year following Launch in the USA of the applicable Licensed Product, if annualized Net Sales of such Licensed Product in the USA in the second Calendar Year following Launch of such Licensed Product are at least [* * *] USD ($[* * *]) and trending upwards such that annualized Net Sales of [* * *] USD ($[* * *]) may reasonably be expected by the end of the fourth Calendar Year following Launch of such Licensed Product; (ii) the fourth Calendar Year following Launch of the applicable Licensed Product, if annualized Net Sales of such Licensed Product in the USA in the third Calendar Year following Launch of such Licensed Product are at least [* * *] USD ($[* * *]) and trending upwards such that annualized Net Sales of [* * *] USD ($[* * *]) may reasonably be expected by the end of the fourth Calendar Year following Launch of such Licensed Product; or (iii) the fifth Calendar Year following Launch of the applicable Licensed Product, if annualized Net Sales of such Licensed Product in the USA in the fourth Calendar Year following Launch of such Licensed Product are at least [* * *] USD ($[* * *]).

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.1.3. On a Licensed Product-by-Licensed Product basis and subject to Section 5.4, following exercise by Assembly of the USA Co-Promotion Option Right with respect to a Licensed Product, Assembly shall have the right to co-promote such Licensed Product in the USA in accordance with this Agreement until (A) Assembly terminates its co-promotion right with respect to such Licensed Product by providing [* * *] months' prior written notice to Allergan, which notice may be given at any time after Assembly has been co-promoting such Licensed Product in the USA for at least [* * *] months; or (B) Allergan terminates Assembly's co-promotion right with respect to such Licensed Product upon [* * *] written notice to Assembly if (I) Assembly fails to provide at least [* * *] ([* * *]%) of its share of the detailing efforts (i.e. [* * *]% of the total detailing efforts) in the US in the manner described in Section 5.4 and the Co-Promotion Agreement in [* * *] or (II) [* * *]. A failure of Assembly to provide its share of the detailing efforts in the United States shall not, for purposes of Section 10.3, constitute a material breach of this Agreement by Assembly.

5.2. Co-Promotion in China .

5.2.1. Assembly shall have the right, subject and pursuant to the terms set forth in this Agreement, to co-promote one or more Licensed Products in China (the " **China Co-Promotion Option Right** ," together with the USA Co-Promotion Option Right, the " **Co-Promotion Option Rights** "). The China Co-Promotion Option Right shall be exercisable by Assembly on a Licensed Product-by-Licensed Product basis.

5.2.2. Assembly may exercise its China Co-Promotion Option Right by providing [* * *] prior written notice to Allergan prior to the anticipated Launch of the applicable Licensed Product in China, which date Allergan shall communicate to Assembly no later than [* * *] prior to such Launch date.

5.2.3. On a Licensed Product-by-Licensed Product basis and subject to Section 5.4, following exercise of the China Co-Promotion Option with respect to a Licensed Product, Assembly shall have the right to co-promote such Licensed Product in China in accordance with this Agreement until (A) Assembly terminates such right by providing [* * *] prior written notice to Allergan, which notice may be given at any time after Assembly has been co-promoting such Licensed Product in China for at least [* * *]; or (B) Allergan terminates Assembly's co-promotion right with respect to such Licensed Product upon [* * *] written notice to Assembly if (I) Assembly fails to conduct its detailing efforts as set forth in Section 5.4 and the Co-Promotion Agreement in [* * *] or (II) [* * *]. A failure of Assembly to provide its share of the detailing efforts in China shall not, for purposes of Section 10.3, constitute a material breach of this Agreement by Assembly.

5.3. Joint Co-Promotion Committee . Following Assembly's exercise of the USA Co-Promotion Option Right or the China Co-Promotion Option Right with respect to any Licensed Product, the Parties shall establish a Joint Co-Promotion Committee (the " **Joint Co-Promotion Committee** " or " **JCC** ") consisting of three (3) representatives, or such other number, as may be agreed upon by the Parties, designated by each Party of appropriate authority and scope of functional responsibility within that Party's organization. The JCC shall operate in accordance with the provisions of Sections 3.3 to 3.5, and shall have no authority to alter, amend or waive the terms and conditions of this Agreement, including any payment conditions or terms, periods for performance, or obligations of the Parties. A Party may change one or more of its representatives serving on the JCC at any time upon written notice to the other Party; provided , that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. The JCC shall serve solely as a forum for discussion regarding the Parties' co-promotion activities for the applicable Licensed Product(s) pursuant to a marketing plan developed by Allergan for the applicable Licensed Product(s). Allergan shall have final decision-making authority for all matters regarding Commercialization of the Licensed Products. The JCC shall remain in effect until either Party's termination of the applicable Co-Promotion Option Right pursuant to this ARTICLE 5, or for such longer period as the Parties may mutually agree.

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5.4. Co-Promotion Agreement; Detailing Efforts .

5.4.1. No later than one-hundred twenty (120) days following Assembly's exercise of a Co-Promotion Option Right, the Parties shall negotiate in good faith and enter into the terms of a co-promotion agreement, the terms of which shall be consistent with this ARTICLE 5 and such additional customary terms and conditions (including terms regarding training, marketing materials, responsibility for recalls and adverse event reporting, and maintenance of records relating to detailing activities) as may be appropriate to provide for such co-promotion activities (the " **Co-Promotion Agreement** "). Notwithstanding anything to the contrary in this Agreement, Assembly shall not have the right to co-promote a Licensed Product in a country prior to the effective date of the Co-Promotion Agreement for such Licensed Product in such country.

5.4.2. Upon execution of a Co-Promotion Agreement with respect to a country, Assembly shall be responsible for [* * *] ([* * *]%) of the detailing efforts to physicians who are not general practitioners in the applicable country for the applicable Licensed Product. In addition, Assembly may not engage a contract sales organization in respect of any co-promotion activities of a Licensed Product in the United States or China. Assembly shall comply, and shall cause the Assembly sales force and all other employees, agents and representatives of Assembly to comply, with all applicable Laws, regulations and guidelines in connection with its promotion, marketing and sale activities in respect of a Licensed Product, including without limitation the Prescription Drug Marketing Act and the Federal Anti-Kickback Statute. Assembly shall design and implement incentive compensation programs for its internal sales force responsible for detailing efforts under the Co-Promotion Agreement, that are comparable to Allergan's incentive compensation programs for Allergan's internal sales force.

5.4.3. Notwithstanding anything to the contrary in this Agreement, Assembly's right to co-promote Licensed Products in either the United States or China is subject to Assembly possessing a fully trained and qualified sales force consisting of Assembly FTEs in the applicable jurisdiction, as determined by Allergan based on the same criteria applied by Allergan to the qualification and training of its own sales representatives, at least ninety (90) days prior to the commencement of detailing for the applicable Licensed Product in the applicable jurisdiction.

5.5. Co-Promotion Expenses . Allergan, or its Sublicensees and Distributors on behalf of Allergan, shall promote, detail and book sales, and be solely responsible for expenses associated with Commercialization of the Licensed Products. In the event Assembly exercises either or both of its Co-Promotion Option Rights with respect to a Licensed Product, as to be set forth more fully in the Co-Promotion Agreement, Allergan shall reimburse Assembly [* * *] for Assembly's detailing efforts in the applicable country based on [* * *] as mutually determined by the Parties; provided that, in the event Assembly does not provide [* * *] ([* * *]%) of the detailing efforts in a country in any full Calendar Quarter pursuant to Section 5.4 following execution of the Co-Promotion Agreement with respect to such country, Allergan may [* * *].

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE 6
REGULATORY AFFAIRS ; MANUFACTURING

6.1. During Compound R&D Term . On a Licensed Compound-by-Licensed Compound basis, Assembly shall own all Regulatory Documentation relating to a Licensed Compound or Licensed Products incorporating such Licensed Compound for a Permitted Indication during the Compound R&D Term of such Licensed Compound. During the Compound R&D Term of a Licensed Compound for a Permitted Indication:

6.1.1. Assembly shall conduct interactions or communications with (including preparing communications or submissions to) such Governmental Authority relating to such Licensed Compound or a Licensed Product incorporating such Licensed Compound;

6.1.2. Assembly shall promptly provide Allergan with (i) copies of all material written or electronic communications received by it or its Affiliates from, or forwarded by it or its Affiliates to, any Governmental Authority related to such Licensed Compound or a Licensed Product incorporating such Licensed Compound, including copies of all minutes and summaries of all meetings and discussions with any Governmental Authority concerning the R&D Plan or such Licensed Compound or Licensed Product, and (ii) written notice of all meetings and discussions scheduled with any Governmental Authority concerning such Licensed Compound or Licensed Product in sufficient time to give Allergan a reasonable opportunity to attend such meetings and discussions;

6.1.3. Allergan shall have the right to review and comment on any proposed substantive communication or submission to any Governmental Authority related to such Licensed Compound or Licensed Product, and Assembly shall incorporate all reasonable comments of Allergan;

6.1.4. Allergan shall also be entitled to have at least one (1) representative of Allergan (or its Affiliates) present at any meetings or discussions with any Governmental Authority related to such Licensed Compound or Licensed Product if permitted by applicable Law and consistent with the practices of the relevant Governmental Authority;

6.1.5. Without limitation to the foregoing, no substantive changes or amendments, whether mandated by an institutional review board or otherwise, shall be made to any Clinical Trial protocol or investigator-related materials relating to such Licensed Compound or Licensed Product without Allergan's prior written approval; and

6.1.6. Where Allergan receives from Assembly any document or proposed communication or submission for review, Allergan shall carry out such review promptly and shall provide its feedback to Assembly within five (5) Business Days after receiving the same or such shorter period as may be required in order to allow Assembly to comply with its obligations under applicable Law or the reasonable requirements of the relevant Governmental Authority, if applicable.

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6.2. Following Compound R&D Term . On a Licensed Compound-by-Licensed Compound basis, following the Compound R&D Term for such Licensed Compound, Allergan shall own, and be responsible for preparing, seeking, submitting and maintaining, all regulatory filings and Regulatory Approvals for such Licensed Compound and Licensed Products incorporating such Licensed Compound, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Except to the extent prohibited by applicable Law, following the Compound R&D Term for such Licensed Compound, all Regulatory Documentation (including all Regulatory Approvals) relating solely to the relevant Licensed Compound or Licensed Products shall be owned by and shall be the sole property and held in the name of Allergan or its designated Affiliate, Sublicensee or designee, and Assembly hereby assigns to Allergan all of its right, title, and interest in and to all such Regulatory Documentation (including such Regulatory Approvals) and all Existing Regulatory Documentation (including any existing Regulatory Approvals), in each case to the extent such solely relates to such Licensed Compound or a Licensed Product incorporating such Licensed Compound (collectively, the " **Assigned Regulatory Documentation** ", with any such Regulatory Documentation retained by Assembly pursuant to this sentence being " **Retained Regulatory Documentation** "); provided that any IND or other Regulatory Approval filed with respect to a Licensed Product shall be deemed Assigned Regulatory Documentation. Assembly shall duly execute and deliver or cause to be duly executed and delivered such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary under, or as Allergan may reasonably request in connection with or to carry out more effectively the purpose of or to assure and confirm unto Allergan its rights under, this ARTICLE 6. On a Licensed Compound-by-Licensed Compound basis, following the Compound R&D Term for a Licensed Compound, Allergan shall have the [* * *] to conduct and control all interactions and communications with any Governmental Authority relating to such Licensed Compound or Licensed Product incorporating such Licensed Compound, or the Exploitation thereof.

6.3. Inspection or Audit . If any Governmental Authority conducts, or gives notice to Assembly of its intent to conduct, an inspection or audit at any investigational site or any Assembly office or facility or to take any other regulatory action, or otherwise makes an inquiry, in each case with respect to or involving or that would otherwise reasonably be expected to affect the Licensed Compounds or Licensed Products or the conduct of the R&D Plan, Assembly shall, unless prohibited from doing so by applicable Law, notify Allergan within three (3) Business Days after Assembly first learns of such governmental inspection or audit and, where reasonably practicable, consult with Allergan in advance of implementing, and permit Allergan to comment on, any proposed plan of action for responding to or complying with any associated demand or request of such Governmental Authority. Wherever possible, and to the extent permitted under applicable Law, Assembly shall provide Allergan with the opportunity (a) to have a representative present at any such governmental inspection or audit and (b) to review in advance and comment on any communications or submissions proposed to be made by Assembly to any Regulatory Authority in relation to any such inquiry, inspection or audit. Assembly shall not unreasonably reject any comments provided by Allergan under this ARTICLE 6.

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6.4. Manufacturing of Licensed Compounds and Licensed Products .

6.4.1. Responsibility . Subject to the provisions of this Section 6.4, Assembly (either directly or through the use of a Third Party as a contract manufacturing organization (a " **CMO** ")) shall be solely responsible for the manufacture and supply of Compound Candidates, Product Candidates, Licensed Compounds and Licensed Products, in bulk or finished form as determined by Allergan in its sole discretion, for Development and Commercialization in the Field in the Territory. For clarity, "bulk" forms of Product Candidates or Licensed Products for the purposes of this Section 6.4.1 will have been subject to the encapsulation and coating process.

6.4.2. Specifications and Quality . Specifications for the release of Compound Candidates, Product Candidates, Licensed Compounds and Licensed Products in bulk or finished form will be set forth in the R&D Plan (such specifications, as amended by mutual agreement of the Parties from time to time, the " **Specifications** "). The Parties will use good faith reasonable efforts to enter into a clinical pharmaceutical product quality agreement within sixty (60) days of the Effective Date (as amended from time to time, the " **Clinical Quality Agreement** "). Assembly shall be responsible for ensuring that Compound Candidates, Product Candidates, Licensed Compounds and Licensed Products it or any CMO supplies hereunder to Allergan or its designee are manufactured and stored in accordance with their applicable Specifications, this Agreement and the Clinical Quality Agreement. The Clinical Quality Agreement will be updated by mutual agreement of the Parties to reflect additional relevant information resulting from ongoing Development activities under this Agreement.

6.4.3. Manufacturing Facility .

(a) Assembly shall use good faith efforts to establish a manufacturing facility to support manufacturing of each Licensed Product and Licensed Compound contained therein (the " **Manufacturing Facility** ") in a timely fashion, but in no event later than, on a Licensed Product-by-Licensed Product basis, [* * *] of such Licensed Product (the " **Facility Deadline** ") unless and until Assembly provides written notice to Allergan that it will abandon those efforts, which notice must be given, if at all, no less than [* * *] prior to the applicable Facility Deadline. Assembly shall update Allergan every Calendar Quarter (or more often at Allergan's reasonable request) as to the progress of the Manufacturing Facility and the estimated timeline for the completion of such Manufacturing Facility. In addition, Assembly shall promptly notify Allergan if and as soon as it reasonably believes in good faith that the Manufacturing Facility will not be ready by or before the Facility Deadline for a Licensed Product or that the Manufacturing Facility will not be able to manufacture a Licensed Product (and the Licensed Compound contained therein) using the final manufacturing process for such Licensed Product in order to undergo inspection by a Regulatory Authority to include such Manufacturing Facility in the application for Regulatory Approval of such Licensed Product. Upon Assembly's notice to Allergan as described in the preceding sentence, the Parties shall meet to discuss the timing for the Manufacturing Facility's completion.

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(b) If (i) Assembly notifies Allergan no less than [* * *] prior to the Facility Deadline for a Licensed Product that Assembly elects not to establish a Manufacturing Facility for such Licensed Product, (ii) Allergan, at any time with respect to a Licensed Product, reasonably believes in good faith that the Manufacturing Facility will not be established by the Facility Deadline and Assembly will otherwise not be able to itself manufacture commercial supplies of such Licensed Product or Licensed Compound or (iii) the Manufacturing Facility has not been established and become operational by the Facility Deadline with respect to such Licensed Product and Licensed Compound, Allergan shall have the right, at its option and in its sole discretion, to establish, itself or via an Affiliate, a manufacturing facility for such Licensed Product and the Licensed Compound therein, as applicable, for which the Facility Deadline has not been met, or to directly engage any CMOs (including one or more CMOs used by Assembly) to act as Allergan's primary and/or secondary suppliers of such Licensed Product and the Licensed Compound therein, as applicable, for which the Facility Deadline has not been met. If, in the process of engaging or establishing a CMO for any aspect of the manufacture of one or more Licensed Products or Licensed Compounds, Allergan makes any capital expenditure investment with respect to such CMO (including any investment in facility expansion or upgrades or in the purchase of new or updated equipment or tooling), Assembly and its Affiliates, licensees and sublicensees shall not, directly or indirectly, use, access or otherwise benefit from any such capital expenditure investment by Allergan with respect to such CMO, including ensuring that such CMO does not manufacture for Assembly, its Affiliates, licensees or sublicensees any Microbiome-Based Compounds or products containing Microbiome-Based Compounds using any facilities, equipment or other tools that have been purchased or additional capacity that has been realized, in each case as a result of such investment by Allergan; provided that Assembly shall not be so restricted if it makes payment to Allergan that constitutes [* * *] ([* * *]%) of the aggregate costs of such capital expenditure investment by Allergan (including, for the avoidance of doubt, any such investment previously made by Allergan and any such investment to be made at future time(s) by Allergan) as disclosed by Allergan to Assembly upon request by Assembly. Allergan will, at Assembly's request, provide any documentation in Allergan's possession not subject to a confidentiality obligation that corroborates the amount of the relevant capital expenditure investment. If Assembly has provided timely notice under Section 6.4.3(a), or met its obligation to use good faith efforts to establish the Manufacturing Facility under Section 6.4.3(a), a failure to establish the Manufacturing Facility shall not constitute a breach of this Agreement by Assembly.

(c) If the Manufacturing Facility has been established and becomes operational by the Facility Deadline for a Licensed Product and Licensed Compound, then, unless Allergan has, pursuant to Section 6.4.3(b), (i) entered into any agreement with a CMO or (ii) otherwise made any investment in (A) its or its Affiliate's manufacturing facility or (B) a CMO's equipment, facility or other tools, in each case of clause (i) and (ii) for any aspect of the manufacture of such Licensed Product and Licensed Compound, Assembly shall serve as Allergan's primary manufacturer for such Licensed Product and Licensed Compound at the Manufacturing Facility, and Allergan shall, at its option, have the right to have itself or an Affiliate, or to directly engage the CMO(s) used by Assembly or other CMOs to act as Allergan's secondary manufacturers for such Licensed Product and Licensed Compound, and Allergan shall be able to purchase a reasonable quantity of Licensed Product and Licensed Compound from such secondary manufacturer in order to satisfy such manufacturer's requirements; provided that in the event Allergan has made any investment described in clause (ii) of this Section 6.4.3(c) for any aspect of the manufacture of any Licensed Product or Licensed Compound, Allergan shall have the option of electing, by written notice to Assembly, to have (X) the manufacturer in which the relevant investment was made (or its assignee) be the primary manufacturer for any Licensed Product(s) and Licensed Compound(s) for which Assembly has not previously been designated as a primary manufacturer pursuant to this Section 6.4.3(c) and (Y) Assembly as the secondary manufacturer for such Licensed Product(s) or Licensed Compound(s).

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(d) Assembly shall provide reasonable assistance, including transferring such Know-How, Materials and other technology to Allergan, its Affiliate or any CMO, and facilitating interaction between Allergan and any CMO, as reasonably requested by Allergan and/or its CMO(s) to enable Allergan or its Affiliate to establish a manufacturing facility to manufacture such Licensed Product and Licensed Compound, or to enable any CMO(s) engaged by Allergan to manufacture such Licensed Product and Licensed Compound, in each case, as permitted in this Section 6.4.3. In the event that Allergan directly engages a CMO(s) of Assembly to manufacture any Licensed Product or Licensed Compound pursuant to this Section 6.4.3 and is unable to expeditiously enter into an agreement with such CMO on substantially similar terms as such CMO's agreement with Assembly or its Affiliates, Assembly shall use Commercially Reasonable Efforts, upon Allergan's request, to assign (in whole or in part, if applicable) its agreement with such CMO to Allergan or its designated Affiliate with respect to such Licensed Product or Licensed Compound.

(e) Notwithstanding anything to the contrary in this Agreement, prior to release of any Licensed Product or Licensed Compound from the Manufacturing Facility for any Clinical Trial, Allergan will be permitted to conduct a quality assurance audit of the Manufacturing Facility confirming quality assurance compliance compatible with entry of the Manufacturing Facility inside Allergan's manufacturing network.

6.4.4. Clinical Supply . On a Licensed Compound-by-Licensed Compound basis, until the Completion of the first POC Trial for a Licensed Product incorporating such Licensed Compound, Assembly shall supply such Licensed Compounds and Licensed Products for Development under the R&D Plan at [* * *]. On a Licensed Compound-by-Licensed Compound basis, following the Completion of first POC Trial for a Licensed Product incorporating such Licensed Compound, Assembly shall supply such Licensed Compounds and Licensed Products for Development by Allergan (a) [* * *] if such Licensed Compounds and Licensed Products are manufactured by Assembly; provided that in no event [* * *] or (b) [* * *] as determined by Assembly's [* * *] of such supply from Assembly's CMO(s), if such Licensed Compounds and Licensed Products are manufactured by a CMO. Supply of Licensed Compounds and Licensed Products for Development or Clinical Trials shall be ordered by Allergan on a purchase order basis, with the Parties [* * *] on reasonable lead times required for manufacture and delivery of such Licensed Compounds or Licensed Products, or as otherwise required to comply with the terms of an agreement with a CMO, if such Licensed Compounds and Licensed Products are manufactured by a CMO.

6.4.5. Commercial Supply . Subject to Section 6.4.3, no later than [* * *] prior to the anticipated receipt of Regulatory Approval for the first Licensed Product, the Parties will negotiate and enter into a supply agreement consistent with this Agreement (the " **Supply Agreement** ") for Assembly to supply Licensed Products to Allergan in bulk or finished form for Commercialization of Licensed Products. Under the Supply Agreement, Licensed Product shall be supplied (a) on [* * *] if such Licensed Compounds and Licensed Products are manufactured by Assembly; provided that in no event [* * *], or (b) on [* * *] as determined by Assembly's [* * *] of such supply from Assembly's CMO(s), if such Licensed Compounds and Licensed Products are manufactured by a CMO. Each Party or its CMO shall use manufacturing systems, processes and procedures consistent with GMP.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

6.4.6. Unless otherwise agreed by the Parties and notwithstanding anything to the contrary in this Agreement, any agreement with any CMO or other service provider entered into by Assembly on or after the Effective Date that relates to any Licensed Compound or Licensed Product shall be assignable to Allergan without the consent of the counterparty thereto to the extent related to such Licensed Compound or Licensed Product. With respect to any CMO appointed prior to the Execution Date that is set forth on Schedule 11.2.23, Assembly shall be permitted to continue to perform manufacturing activities through any such manufacturer.

ARTICLE 7
FINANCIAL PROVISIONS

7.1. Upfront Cash Payment . In partial consideration of the rights granted under Section 2.1, within five (5) Business Days of the Effective Date, Allergan shall pay Assembly a one-time lump sum payment of Fifty Million USD ($50M) in upfront cash, which payment shall be non-refundable and non-creditable against other payments due hereunder.

7.2. Milestone Payments .

7.2.1. Development Milestone Payments . As additional consideration for the grant of rights under this Agreement, and on the terms and subject to the conditions set forth herein, Allergan shall make the following payments to Assembly (the " **Development Milestone Payments** ") after the achievement following the Effective Date by or on behalf of Allergan of the applicable event set forth below (collectively, the " **Development Milestone Events** "). Each of the Development Milestone Payments are payable only once per Permitted Indication as set forth in the table below upon the first achievement of each Development Milestone Event regardless of the number of Licensed Products that are developed for such Permitted Indication or subsequent achievement of such Development Milestone Events for such Permitted Indication with a different Licensed Product; provided , that, the Development Milestone Events for [* * *] Permitted Indications in addition to the Initial Indications shall be payable subject to the credit provided in Section 4.8.3. Allergan or Assembly, as applicable, will notify the other Party in writing as soon as reasonably possible following the achievement of a Development Milestone Event. Allergan shall pay to Assembly the corresponding Milestone Payment within [* * *] days after achievement of the applicable Development Milestone Event. The Development Milestone Payments shall be non-refundable.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Development Milestones	Milestone Payment			
	Ulcerative Colitis	Crohn's Disease	Each IBS program up to two (2)	Each Additional Permitted Indication [* * *](excluding [* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]	[* * *]

7.2.2. Sales Milestone Payments . As additional consideration for the grant of rights under this Agreement, and on the terms and subject to the conditions set forth herein, Allergan shall make the following payments to Assembly (the " **Sales Milestone Payments** ," together with the Development Milestone Payments, the " **Milestone Payments** ") after the achievement following the Effective Date by or on behalf of Allergan of the applicable event set forth below (collectively, the " **Sales Milestone Events** ," together with the Development Milestone Events, the " **Milestone Events** "). Each of the Sales Milestone Payments are payable only once upon achievement in the first Calendar Year in which aggregate annual Net Sales of [* * *] for that Calendar Year in the Territory surpass the respective Net Sales threshold set forth in the table below. Allergan will notify Assembly in writing of the achievement of a Sales Milestone Event within forty-five (45) days of the end of the applicable Calendar Year. Allergan shall pay to Assembly such Milestone Payment within [* * *] days after the end of the Calendar Year in which the applicable Sales Milestone Event occurs. The Sales Milestone Payments shall be non-refundable.

Sales Milestones	Milestone Payment
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]
Net Sales of [* * *] in the Territory in a Calendar Year of greater than $[* * *]	$[* * *]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

In the event that more than one Sales Milestone Event is achieved in the same Calendar Year, all applicable Sales Milestone Payments shall become due in respect of such Calendar Year.

7.3. Royalty Payments . Subject to the terms of this Agreement (including Section 7.4), on a Licensed Product-by-Licensed Product basis, Allergan or its Affiliates shall pay Assembly a royalty on annual Net Sales of each Licensed Product in the Territory as set forth in this Section 7.3 (" **Royalty Payment** "). The Royalty Payment shall be payable to Assembly on a Licensed Product-by-Licensed Product and country-by-country basis until the later to occur of (a) the last to expire Valid Claim of a Licensed Compound Patent that Covers the manufacture or sale of such Licensed Product by Allergan, its Affiliates or Sublicensees in such country and (b) (i) for such countries where there is [* * *] or more of Regulatory Exclusivity, the expiry of Regulatory Exclusivity granted by the applicable Governmental Authority for such Licensed Product in such country and (ii) for such countries in which there is less than [* * *] of Regulatory Exclusivity, [* * *] after the expiration of such Regulatory Exclusivity (the " **Royalty Term** "). The Royalty Payments for Licensed Products during the Royalty Term shall be as follows:

Net Sales Tranche	US Royalty Rate for such portion of such Net Sales from the United States	Royalty Rate for such portion of such Net Sales from outside of the United States
For that portion of aggregate global Net Sales of the applicable Licensed Product in any given Calendar Year of less than or equal to $[* * *]	[* * *]%	[* * *]%
For that portion of aggregate global Net Sales of the applicable Licensed Product in any given Calendar Year of greater than $[* * *] but less than or equal to $[* * *	[* * *]%	[* * *]%
For that portion of aggregate global Net Sales of the applicable Licensed Product in any given Calendar Year of greater than $[* * * but less than or equal to $[* * *]	[* * *]%	[* * *]%
For that portion of aggregate global Net Sales of the applicable Licensed Product in any given Calendar Year of greater than $[* * *] but less than or equal to $[* * *]	[* * *]%	[* * *]%
For that portion of aggregate global Net Sales of the applicable Licensed Product in any given Calendar Year of greater than $[* * *]	[* * *]%	[* * *]%

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

7.4. Reductions .

7.4.1. Biosimilar Competition . On a Licensed Product-by-Licensed Product and country-by-country basis, if a Licensed Product is sold in a country in the Territory and at any time a product that is a Biosimilar Product with respect to such Licensed Product is sold or marketed by a Third Party in such country and the aggregate sales of all Biosimilar Products reach [* * *] percent ([* * *]%) of the market share held by the Licensed Product in such country in the last full Calendar Quarter prior to the Biosimilar Product's commercial sale in such country (calculated on a unit month over month basis) in any Calendar Quarter, then the Net Sales of such Licensed Product in such country shall be reduced by [* * *] percent ([* * *]%) for the remainder of the applicable Royalty Term.

7.4.2. Expiry of Regulatory Exclusivity . Solely in the event that, pursuant to clause (b)(ii) of the Royalty Term set forth in Section 7.3, on a Licensed Product-by-Licensed Product and country-by-country basis, the Royalty Term extends beyond the expiration of both (a) the last to expire Valid Claim of a Licensed Compound Patent that Covers the manufacture or sale of a Licensed Product in such country by Allergan, its Affiliates or Sublicensees and (b) the expiration of Regulatory Exclusivity in such country, Net Sales in any such country shall be reduced by [* * *] percent ([* * *]%) for the remainder of the applicable Royalty Term.

7.4.3. Blocking Third Party IP . Subject to Section 11.2.3, if, during the Term and on a Licensed Product-by-Licensed Product and country-by-country basis, Allergan obtains rights under any Blocking Third Party IP in order to Develop, manufacture, or Commercialize a Licensed Product in the Field in a country in the Territory, then, in the event Allergan obtains a license or acquisition of such Blocking Third Party IP, and any amounts, including without limitation upfront payments, milestones or royalties, are paid by Allergan to any Third Party to license or acquire such Blocking Third Party IP (" **Third Party Payments** "), Allergan shall have the right to reduce any amount otherwise payable to Assembly pursuant to the terms of this Agreement that relate to such Licensed Product, as such payments may be adjusted by Sections 7.4 or 10.9(c) in a given period, by up to [* * *] percent ([* * *]%) of the Third Party Payments; provided , that, in no event may any amounts payable to Assembly hereunder be reduced as a result of the application of this Section 7.4.3 by more than [* * *] percent ([* * *]%) of the amount that would otherwise be owed to Assembly hereunder (after all other Permitted Deductions are taken). If the amount equal to [* * *] percent ([* * *]%) of any Third Party Payments is not fully offset against amounts otherwise payable to Assembly under Section 7.2 and Section 7.3 in the applicable period as a result of the proviso of the preceding sentence, such amount may be carried forward and applied to future periods until fully exhausted, subject to the other provisions of this Section 7.4.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

7.4.4. Backup Compounds . On a Licensed Product-by-Licensed Product basis, Allergan shall be entitled to deduct from any Royalty Payments and Development Milestone Payments payable to Assembly in respect of a Licensed Product that incorporates a Backup Compound an amount equal to [* * *] incurred by Allergan for the POC Trial for such Licensed Product [* * *] of such Development Costs). For the avoidance of doubt, in addition to the provision of this Section 7.4.4, all reductions of Royalty Payments set forth in Section 7.4 shall apply to any Licensed Product, including a Licensed Product that incorporates a Backup Compound.

7.4.5. Development Costs Reductions .

(a) On a Licensed Product-by-Licensed Product basis, Allergan shall be entitled to deduct from Development Milestone Payments the amounts described in Section 4.8.2(b), as applicable.

(b) On a Licensed Product-by-Licensed Product basis, Allergan shall be entitled to deduct from Development Milestone Payments with respect to the applicable Licensed Product the amounts described in Section 4.8.3(b), as applicable

7.5. Taxes . Each Party shall be responsible for its own taxes, duties, levies, imposts, assessments, deductions, fees, withholdings or similar charges imposed on or measured by net income or overall gross income (including branch profits), gross receipts, capital, ability or right to do business, property, and franchise or similar taxes pursuant to applicable Law. If Allergan is required to deduct or withhold from any payment due hereunder any taxes, duties, levies, imposts, assessments, deductions, fees, and other similar charges by applicable Law or any Governmental Authority (" **Withholding Taxes** "), then Allergan shall pay such Withholding Taxes to the local applicable Governmental Authority and make the payment to Assembly of the net amount due after deduction or withholding of such taxes. Such Withholding Taxes shall be treated for all purposes of this Agreement as having been paid to Assembly hereunder. Allergan shall submit reasonable proof of payment of the Withholding Taxes within a reasonable period of time after such Withholding Taxes are remitted to the Governmental Authority. The Parties shall reasonably cooperate to eliminate or minimize any such Withholding Taxes. Assembly shall indemnify and hold harmless Allergan for any taxes, including Withholding Taxes, Assembly owes to a Governmental Authority for which Allergan is held responsible and for which prior withholding has not been made, and Allergan shall hold Assembly harmless for any fees, penalties and interest that are imposed on Assembly arising out of Allergan's failure to withhold and remit Withholding Taxes to Governmental Authorities in accordance with this Section and applicable Laws, unless such failure arises from the acts or omissions of Assembly (for example, the provision of incorrect beneficial owner information or invalid forms). The Parties will reasonably cooperate to provide sufficient documentation to enable Assembly to receive any credits available under applicable Law. Assembly represents and agrees that it is the beneficial owner of the payments and is a resident of the United States by virtue of the applicable Law of the United States, and does not have a fixed base, office or permanent establishment in Ireland through which it carries on a trade or business.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

7.6. Value Added Tax . Notwithstanding anything contained in Section 7.5, this Section 7.6 shall apply with respect to VAT. All Payments are exclusive of VAT. If any VAT is required in respect of any payments under applicable Law, the payor shall pay VAT at the applicable rate in respect of any such payments following the receipt of a valid VAT invoice in the appropriate form issued by the payee in respect of those payments, such VAT to be payable on the later of the due date of the payment of the payments to which such VAT relates and forty-five (45) days after the receipt by the payor of the applicable valid invoice relating to that VAT payment. The Parties will reasonably cooperate to issue valid VAT invoices for all amounts due under this Agreement consistent with VAT requirements. The payor shall not be responsible for any penalties and interest resulting from the failure by the payee to collect (if not included on a valid VAT invoice) or remit any such VAT. The Parties shall reasonably cooperate to report, eliminate or minimize the amount of any such VAT imposed on the transactions contemplated in this Agreement.

7.7. Allergan Statements and Payment . Allergan shall, on and from the date of Launch, deliver to Assembly, within [* * *] days after the end of each Calendar Quarter, a report setting forth for such Calendar Quarter the following information for Licensed Products for such portion of Net Sales from the United States and such portion of Net Sales from outside of the United States: (a) Net Sales of Licensed Products on a Licensed Product-by-Licensed Product, (b) the Royalty Payments due to Assembly on account of Net Sales of Licensed Products, (c) the exchange rates used in calculating any of the foregoing, and (d) any deductions provided for under this Agreement. If no Royalty Payments were payable for any Calendar Quarter, Allergan's report shall so state. Allergan shall pay such Royalty Payments within simultaneously with the delivery of each such report.

7.8. Currency Exchange . For any currency conversion required in determining the amount of payments due hereunder, such conversion shall be made as follows: (a) when calculating Net Sales, the amount of such sales in foreign currencies shall be converted into USD using the average of the daily last price rate of exchange for such currencies for the relevant month utilized by Allergan for public financial accounting purposes in accordance with GAAP and (b) when calculating all other sums due under this Agreement, the amount in foreign currencies shall be converted into USD using the average of daily last price rate of exchange for such currencies for the relevant month utilized by Allergan for public financial accounting purposes in accordance with GAAP.

7.9. Payment Method . All payments due to a Party hereunder shall be made via wire transfer of immediately available USD funds to an account designated in writing by that Party to the other Party.

7.10. Records Retention; Financial Audit; Consolidation Reporting .

7.10.1. Record Retention . Each Party shall maintain complete and accurate books, records and accounts for the calculation of Development Costs, reporting and payment of Withholding Taxes, and, with respect to Allergan, Milestone Payments and Royalty Payments due, in sufficient detail to confirm whether any Milestone Payments are payable and the accuracy of any Development Cost reports and any Royalty Payments required under this Agreement, which books, records and accounts shall be retained until the later of (a) three (3) years after the end of the period to which such books and records pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or longer as is required by applicable Law.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

7.10.2. Financial Audit . Each Party (the " **Auditing Party** ") shall have the right to have an independent certified public accounting firm of internationally recognized standing reasonably acceptable to the Auditing Party have access during normal business hours, upon reasonable prior written notice, to such of the records of the other Party (the " **Audited Party** ") and its Affiliates as may be required to verify the accuracy of the calculation of Development Costs, Milestone Payments, Net Sales and Royalty Payments incurred or due for any year ending not more than three (3) years prior to the date of such request. Such verifications may not (a) be conducted for any Calendar Quarter more than three (3) years after the end of such quarter, (b) be conducted more than once in any twelve (12) month period or (c) be repeated for any period unless, subject to the foregoing clauses (a) and (b), a subsequent verification uncovers a material error that is reasonable for the Auditing Party to assume existed in previously audited records. The independent certified public accounting firm shall disclose to the Auditing Party only the amounts which the independent certified public accounting firm believes to be inaccurate, with respect to Development Costs, or due and payable hereunder to Assembly, with respect to Milestone Payments and Royalty Payments, shall provide a copy of same to the Audited Party, and shall disclose no other information revealed in such audit. Any and all records of the Audited Party and its Affiliates examined by such independent certified public accounting firm shall be deemed the Audited Party's Confidential Information, which may not be disclosed by said independent certified public accounting firm to any Third Party or (except for the information expressly sought to be confirmed by the Auditing Party as set forth in this Section 7.10.2) to the Auditing Party. The Auditing Party shall bear all costs of such audit, unless the audit reveals a discrepancy in its favor of more than five percent (5%), in which case the Audited Party shall bear the cost of the audit. The result of the audit shall, in the absence of manifest error, be final and binding on the Parties.

7.10.3. Payment of Additional Amounts . If, based on the results of any audit conducted under Section 7.10.2, additional payments are owed to a Party under this Agreement, then the other Party shall make such additional payments within thirty (30) Business Days after the accounting firm's written report is delivered to the Parties, with interest calculated thereon in accordance with Section 7.11. If the report is contested by either, the Parties shall follow the dispute resolution procedures described in Section 13.4. The responsible Party shall pay any amount ultimately found due within ten (10) Business Days after resolution of the dispute.

7.11. Interest on Late Payments . Any failure by either Party to make a payment of any undisputed amount when due shall obligate that Party to pay interest to the other Party on the amount unpaid at the most recently published LIBOR plus two percent (2%) per annum (or, if lower, the maximum rate permitted by applicable Law) calculated on a daily basis and payable for the period from the date payment is due until the date payment is actually made, without prejudice to recipient's right to receive payment on the due date.

7.12. Right to Offset . Each Party shall have the right to offset any amount owed by the other Party to such first Party under or in connection with this Agreement, including pursuant to ARTICLE 10 or in connection with any breach, against any payments owed by such first Party to such other Party under this Agreement, in each case based on a final determination by an independent certified public accounting firm pursuant to Section 7.10.2, any agreement of the Parties as to amounts owed or pursuant to an arbitration proceeding pursuant to Section 13.4, as applicable. Such offsets shall be in addition to any other rights or remedies available under this Agreement and applicable Law.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

ARTICLE 8
CONFIDENTIALITY

8.1. Protection of Confidential Information . The Receiving Party shall not, and shall cause its Affiliates and its and their officers, directors, employees and agents not to, disclose or disseminate Confidential Information of the Disclosing Party to any Third Party unless expressly permitted hereunder, and shall not use such Confidential Information for any purpose other than in performing the Receiving Party's obligations or exercising the Receiving Party's rights hereunder. In addition, the Receiving Party shall take, and shall cause its Affiliates to take, reasonable steps to protect the Confidential Information of the Disclosing Party from unauthorized use or disclosure, which steps shall be no less than those the Receiving Party takes to protect its own confidential and/or proprietary material of a similar nature. The foregoing obligations shall apply equally to all copies, extracts and summaries of the Disclosing Party's Confidential Information.

8.2. Certain Permitted Disclosures .

8.2.1. Disclosure Required by Law . Notwithstanding the foregoing, each of Assembly and Allergan may disclose Confidential Information of the other Party to a Third Party to the extent such disclosure is reasonably necessary to exercise the rights granted to or retained by it under this Agreement, including in preparing, filing, maintaining or prosecuting Patents, prosecuting or defending litigation, complying with applicable Law, submitting information to Governmental Authorities or to acquirers; provided , that if a Party is required by Law to make any such disclosure of the Disclosing Party's Confidential Information, to the extent it may legally do so it shall: (a) give reasonable advance notice to the Disclosing Party of such disclosure to permit the Disclosing Party to use its reasonable efforts to secure confidential treatment of such Confidential Information prior to disclosure to the extent such treatment is applicable (whether through protective orders or otherwise), (b) cooperates with the Disclosing Party in the exercise of its right to protect the confidentiality of the Confidential Information and (c) discloses only that Confidential Information that is required to be disclosed. Each Party shall be responsible for any breach of its confidentiality obligations by its respective employees and agents.

8.2.2. Disclosure to Certain Third Parties . The Receiving Party may disclose such of the Disclosing Party's Confidential Information to (a) its Affiliates, employees, directors, consultants, subcontractors and permitted sublicensees who have a need to know such Confidential Information, (b) Sublicensees or existing or potential Distributors or vendors acting on such Party's behalf, (c) with respect to Confidential Information that is Licensed Compound Know-How, to existing or potential licensees and collaboration partners who are granted, or are evaluating in good faith the possibility of receiving, rights under such Licensed Compound Know-How, in each case of clauses (a) through (c) who are bound by obligations of confidentiality and non-use substantially at least as stringent as those by which the Receiving Party is bound hereunder.

8.3. Return of Confidential Information . Upon termination of this Agreement, the Receiving Party shall promptly return all of the Disclosing Party's Confidential Information, including all information relating to Licensed Products, unless, and solely for so long as, the Receiving Party has continuing rights to use the foregoing pursuant to ARTICLE 10, received hereunder and copies thereof in any medium, except that the Receiving Party may retain one copy for its legal files.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

8.4. Unauthorized Use . If either Party becomes aware or has Knowledge of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, it shall promptly notify the Disclosing Party of such unauthorized use or disclosure.

8.5. Public Disclosure .

8.5.1. Neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their sublicensees or any abbreviation or adaptation thereof in any advertising, marketing, promotional or sales literature or other form of publicity or in any document employed to obtain funds or financing without the prior written approval of the Party whose name is to be used, except as follows:

(a) Allergan, its Affiliates and Sublicensees may state that they are licensed under the Licensed Compound Patents, and Assembly and its Affiliates may state that they have licensed the Licensed Compound Patents to Allergan, its Affiliates and Sublicensees. For this purpose, each Party may use the name and logo of the other Party, and may make a high level non-confidential statement about the existence, scope and key terms of this contractual relationship that is consistent with and limited to the information that is included within the press releases set out in Schedule 8.5.1 or any other communication content that the Parties agree is acceptable for general public use.

(b) Either Party or its Affiliates may make such a disclosure (i) to the extent required by the rules of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded, (ii) as required by applicable Law, or (iii) to any acquirers, potential acquirers, investors, prospective investors, lenders and other potential financing sources who are obligated to (A) keep such information confidential and (B) use such information solely to evaluate the applicable transaction.

(c) The Parties have agreed upon the content of one (1) or more press releases which shall be issued substantially in the form(s) attached hereto as Schedule 8.5.1, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

8.5.2. Assembly shall use Commercially Reasonable Efforts to secure confidential treatment of this Agreement for filing with the U.S. Securities and Exchange Commission (or any successor or replacement agency) to the extent set forth in **Schedule 8.5.2** .

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

8.6. Publications . During the R&D Term neither Party shall make any publication, presentation or other announcement regarding the R&D Plan, a Licensed Compound or a Licensed Product unless such publication, presentation or announcement has been previously approved by the other Party (such consent not to be unreasonably withheld, conditioned or delayed) or unless required by applicable Law; provided that in no event shall Assembly make any publication, presentation or other announcement regarding any Permitted Indication without the prior written consent of Allergan. Where any such publication, presentation or announcement is required by applicable Law the Party subject to such requirement shall use its commercially reasonable efforts to give prior written notice of any such proposed publication, presentation or announcement to the other Party. Such other Party shall respond promptly through its designated representative and in any event no later than fifteen (15) Business Days after receipt of such proposed publication, presentation or other announcement or such shorter period as may be required by the publication, presentation or announcement. The Party desiring to make such publication, presentation or announcement agrees to allow a reasonable period (not to exceed sixty (60) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of the other Party. All publications, presentations and announcements regarding the Licensed Compounds or Licensed Products shall be controlled by Allergan except that Assembly shall be entitled to make such an announcement if Assembly or its Affiliates is required to do so by applicable Law.

ARTICLE 9
INTELLECTUAL PROPERTY

9.1. Maintenance, Prosecution and Enforcement of Patents .

9.1.1. Preparation, Filing, Prosecution and Maintenance of Product Only Patents . Allergan will have the first right, and will use Commercially Reasonable Efforts, to identify, prepare, file, prosecute and maintain Product Only Patents in the Territory at its sole expense. Allergan will (a) provide Assembly with reasonable time to provide comments in respect of any submission to a Governmental Authority and (b) consider in good faith such comments in Allergan's preparation, filing and prosecution of Product Only Patents. On a country-by-country basis, if Allergan elects not to file, prosecute, maintain or undertake such other activities with respect to any Product Only Patent, then Allergan will inform Assembly of such election in writing sufficiently in advance of any required action in connection with such preparation, filing, prosecution or maintenance, and Assembly will have the right to identify, prepare, file, prosecute and maintain, in its sole discretion and at its sole expense, Product Only Patents where Allergan elects not to undertake such activities.

9.1.2. Preparation, Filing, Prosecution and Maintenance of Product Related Patents . Assembly will have the first right, and will use Commercially Reasonable Efforts, to identify, prepare, file, prosecute and maintain Product Related Patents in the Territory at its own expense. Assembly will (a) provide Allergan with reasonable time to provide comments in respect of any submission to a Governmental Authority and (b) reasonably consider such comments in its identification, preparation, filing and prosecution of Product Related Patents. On a country-by-country basis, if Assembly elects not to file, prosecute, maintain or undertake such other activities with respect to any Product Related Patent, then Assembly will inform Allergan of such election in writing sufficiently in advance of any required action in connection with such preparation, filing, prosecution or maintenance and, with Assembly's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), Allergan will have the right to identify, prepare, file and prosecute Product Related Patents, in Assembly's name at its own expense. If a Product Related Patent recites one or more claims that, if presented in a separate patent or application, would make that separate patent or application a Product Only Patent (such claims, " **Product Only Claims** "), then (x) Assembly will use Commercially Reasonable Efforts to file such claim(s) in a continuation, divisional, or other application as Product Only Patents; and (y) the Parties will have those rights and obligations set forth in Section 9.1.1 as to the Product Only Claims as if they were Product Only Patents, notwithstanding their presentation in a Product Related Patent.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.1.3. Preparation, Filing, Prosecution and Maintenance of Other Patents . Except as otherwise expressly set forth in this Section 9.1, each Party shall have the sole right (but not the obligation), in its sole discretion, to prepare, file, prosecute and maintain all Patents owned by such Party; provided , that, Assembly shall keep Allergan reasonably informed regarding the preparation, filing, prosecution and maintenance of Licensed Compound Patents that are not Product Only Patents or Product Related Patents.

9.1.4. Cooperation Regarding Prosecution of Patents . Each Party shall cooperate with the other Party to the extent reasonably necessary for such Party to prosecute the Product Only Patents and/or the Product Related Patents in the Territory, including the execution and delivery of documents to such Prosecuting Party at such other Party's cost and expense, including providing access to relevant documents (including laboratory notebooks) and other evidence and making its employees available at reasonable business hours.

9.1.5. Enforcement of Product Only Patents .

(a) Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of any Product Only Patent or Product Only Claim in the Territory of which such Party becomes aware.

(b) Allergan shall have the first right to enforce Product Only Patents and Product Only Claims against actual or potential infringers in the Field, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at its sole cost and expense, using counsel of its choice. If Allergan fails to take commercially reasonable steps to prosecute or settle the infringement of a Product Only Patent or Product Only Claim within ninety (90) days of receiving a notice with respect to such infringement pursuant to Section 9.1.5(a) (or twenty-five (25) days in the case of an action brought under the Biologics Price Competition and Innovation Act of 2009 (or any amendment or successor statute thereto) or within ten (10) Business Days before the time limit, if any, under applicable Law for taking any action with respect to the timeframe of any other relevant regulatory or statutory framework that may govern), or earlier notifies Assembly in writing of its intent not to bring such action or proceeding, Assembly may enforce the Product Only Patents and Product Only Claims unless Allergan notifies Assembly of a strategic rationale in good faith for non-enforcement. Any strategic rationale will be considered as made in good faith by Allergan if such strategic rationale is for any reason other than to avoid or reduce any payments payable to Assembly as set forth in ARTICLE 7.

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(c) Assembly and its Affiliates shall (i) use Commercially Reasonable Efforts to negotiate the terms of the enforcement rights in any license agreement with a Third Party that includes rights to a Product Only Patent or Product Only Claim such that the enforcement rights granted to Assembly permit Allergan to exercise its enforcement rights set forth in Section 9.1.5(b) in respect of such Product Only Patent or Product Only Claim and (ii) (A) keep Allergan reasonably informed, on a prompt basis, of the status and details of any discussions or negotiations with such Third Party in respect of such Product Only Patent or Product Only Claim, (B) promptly furnish to Allergan copies of all draft documentation relating to the terms of any agreement in respect of the such Product Only Patent or Product Only Claim, (C) provide Allergan with a reasonable opportunity to review and comment on such draft documentation relating to the terms of any agreement in respect of such Product Only Patent or Product Only Claim and (D) implement all reasonable modifications suggested thereto by Allergan. Without limiting the foregoing, Assembly and its Affiliates shall not enter into any agreement with a Third Party pursuant to which it acquires rights to a Product Only Patent or Product Only Claim under which enforcement rights granted to Assembly with respect to such Product Only Patent or Product Only Claim restrict Allergan from fully exercising its enforcement rights set forth in Section 9.1.5(b) in respect of such Product Only Patent or Product Only Claim, without the prior written consent of Allergan.

9.1.6. Enforcement of Product Related Patents .

(a) Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of any Product Related Patent in the Territory of which such Party becomes aware.

(b) Subject to Section 9.1.5, with respect to the claims of any Product Related Patent (i) that Cover a Competing Compound and are in the same patent family (that is, are based on the same specification) as a Product Only Patent that Covers a Competing Compound or (ii) that Cover a Competing Compound, but do not recite a [* * *], Allergan shall have the first right to enforce such claims against actual or potential infringers Exploiting Competing Compounds in the Field only with Assembly's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If Allergan elects not to enforce any such Product Related Patent against a Competing Compound, Assembly may enforce such Product Related Patent.

(c) Subject to Section 9.1.5, with respect to any Product Related Patent not described in Section 9.1.6(b), Allergan shall have the right to enforce such Product Related Patent(s) against infringers Exploiting Competing Compounds in the Field with Assembly's prior written consent; provided , that, if Assembly objects to such enforcement by Allergan within five (5) business days of Allergan's request for consent, then the following procedures shall apply (for the avoidance of doubt, the dispute resolution procedures set forth in Sections 10.4 and 13.4 shall not apply):

(i) The matter shall be referred to the Joint Patent Committee, which shall consider and balance the interests of, and potential harm to, Allergan, on the one hand, and Assembly and other licensees, if any, of such Product Related Patent(s), on the other hand, in the event of enforcement or non-enforcement of such Product Related Patent(s);

(ii) If the Joint Patent Committee cannot resolve the matter by consensus within ten (10) Business Days, or such other time as determined by Allergan and Assembly, then the Joint Patent Committee shall escalate the matter to each of the general counsels of Allergan and Assembly for resolution; and

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(iii) If the general counsels of Allergan and Assembly cannot resolve the matter within ten (10) Business Days, or such other time as determined by Allergan and Assembly, then Allergan shall have the final decision on such matter; provided , that, to the extent Allergan seeks to enforce such Product Related Patent(s), Allergan shall take into consideration Assembly's business and other interests, and shall use reasonable efforts to minimize any potential adverse impact to Assembly or its other licensees of such Product Related Patent resulting from enforcement of such Product Related Patent(s); provided , further, that if Allergan elects not to enforce any such Product Related Patent against a Competing Compound, Assembly may enforce such Product Related Patent.

(d) The time periods set forth in Section 9.1.6(c) shall be shortened to the extent necessary to meet deadlines required by applicable Law.

(e) Assembly and its Affiliates shall not enter into any agreement with a Third Party that includes enforcement rights in respect of Product Related Patents that are more favorable to such Third Party than the comparable provisions set forth herein are with respect to Allergan.

(f) Assembly and its Affiliates shall (i) use good faith efforts to negotiate the terms of the enforcement rights in any license agreement with a Third Party that includes rights to a Product Related Patent such that the enforcement rights granted to Assembly permit Allergan to exercise its enforcement rights set forth in Section 9.1.6(b) and 9.1.6(c) in respect of such Product Related Patent and (ii) (A) keep Allergan reasonably informed, on a prompt basis, of the status and details of any discussions or negotiations with such Third Party in respect of such Product Related Patent, (B) promptly furnish to Allergan copies of all draft documentation relating to the terms of any agreement in respect of the such Product Related Patent, (C) provide Allergan with a reasonable opportunity to review and comment on such draft documentation relating to the terms of any agreement in respect of such Product Related Patent and (D) implement all reasonable modifications suggested thereto by Allergan. Assembly and its Affiliates shall not enter into any agreement with a Third Party in respect of a Product Related Patent pursuant to which such enforcement rights granted to Assembly restrict Allergan from exercising its enforcement rights set forth in Section 9.1.6(b) and 9.1.6(c) in respect of such Product Related Patent, without the prior written consent of Allergan, which consent shall not be unreasonably withheld, conditioned or delayed; provided , that, Allergan's consent shall not be required to the extent such agreement grants Assembly a license to such Product Related Patent solely on a non-exclusive basis.

9.1.7. Enforcement of Other Patents . Except as otherwise expressly set forth in this Section 9.1, each Party shall have the sole right (but not the obligation), in its sole discretion, to enforce Patents owned by such Party; provided , that, Assembly shall keep Allergan reasonably informed regarding the enforcement of Licensed Compound Patents that are not Product Only Patents and Product Related Patents.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.1.8. Cooperation Regarding Enforcement of Patents . The Parties shall cooperate fully in any enforcement action pursuant to this Section 9.1, including by making the inventors, applicable records, and documents (including laboratory notebooks) with respect to the relevant Patents available to the enforcing Party and its advisors at the enforcing Party's request. The non-enforcing Party shall, and shall cause its Affiliates to, assist and cooperate with the enforcing Party, as the enforcing Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.1, including, where necessary, joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and executing any settlement agreement as requested by the enforcing Party; provided , that, the enforcing Party shall reimburse the non-enforcing Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Unless otherwise set forth herein, the enforcing Party shall have the right to settle such claim; provided , that, neither Party shall have the right to settle any litigation or claim under this Section 9.1 in a manner that (a) imposes any costs or liability on the other Party or its Affiliates or its or their sublicensees, (b) involves any admission by the other Party or its Affiliates or its or their sublicensees, (c) admits the invalidity or unenforceability of intellectual property owned by a Party or its Affiliates or its or their sublicensees, or (d) imposes restrictions or obligation on the other Party or its Affiliates or its or their sublicensees not otherwise permitted under this Agreement, in each case ((a) through (d)), without the express written consent of such other Party, which consent shall not be unreasonably withheld, conditioned or delayed. In connection with any activities with respect to an action prosecuted by the applicable enforcing Party pursuant to this Section 9.1 involving Patents Controlled by or licensed under this Agreement to the other Party, the enforcing Party shall keep the non-enforcing Party reasonably informed of any material steps taken in connection with such action.

9.1.9. Enforcement of Biosimilars .

(a) Patent Exclusivity Listing . If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the Public Health Service Act (a " **Biosimilar Application** ") naming a Licensed Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (including by the receipt of information disclosed pursuant to Section 351(l)(2) of the Public Health Service Act, or in an instance described in Section 351(l)(9)(C) of the Public Health Service Act), either Party shall, within ten (10) Business Days, notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the Public Health Service Act. If either Party receives any equivalent or similar certification or notice in any other jurisdiction in the Territory naming a Licensed Product, either Party shall, within ten (10) Business Days, notify and provide the other Party with copies of such communication. Regardless of the Party that is the "reference product sponsor" for purposes of such Biosimilar Application, (i) Allergan shall have the sole right to designate pursuant to Section 351(l)(1)(B)(ii) of the Public Health Service Act the outside counsel and in-house counsel who shall receive confidential access to the Biosimilar Application, (ii) Allergan shall have the sole right to (A) list any Licensed Compound Patents, Joint Patents, and any other Patents, as required pursuant to Section 351(l)(3)(A), Section 351(l)(5)(b)(i)(II), or Section 351(l)(7) of the Public Health Service Act, (B) respond to any communications with respect to such lists from the filer of the Biosimilar Application, and (C) negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange than that specified in Section 351(l) of the Public Health Service Act; and (iii) Allergan shall have the sole right to identify Licensed Compound Patents, Joint Patents, and any other Patents, and to respond to communications under any equivalent or similar listing in any other jurisdiction in the Territory.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(b) Conduct of Patent Litigation Under the Biologics Price Competition and Innovation Act . Allergan shall have the right to bring an action for infringement of Product Only Patents, Product Related Patents, and Joint Patents, to the extent set forth in Sections 9.1.5 and 9.1.6 of this Agreement, with respect to Licensed Products as required under Section 351(l)(6) of the Public Health Service Act following the agreement on a list of patents for litigation under Section 351(l)(4) or exchange of Patent lists pursuant to Section 351(l)(5)(B) of such act, or as required following any equivalent or similar certification or notice in any other jurisdiction. Either Party shall, within ten (10) Business Days, notify and provide the other Party with copies of any notice of commercial marketing provided by the filer of a Biosimilar Application pursuant to Section 351(l)(8)(A) of the Public Health Service Act, or any equivalent or similar certification or notice in any other jurisdiction.

9.1.10. Recoveries . Except as otherwise agreed by the Parties in writing, any recovery realized as a result of enforcing a Patent under this Section 9.1 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by (or paid to) Allergan and treated as Net Sales under this Agreement except for the purposes of Section 7.2.2.

9.2. Invalidity or Unenforceability Actions .

9.2.1. Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability, including any inter partes review, post-grant review, reexamination, opposition or any other similar action before a patent office, of any of the Licensed Compounds Patents by a Third Party of which such Party becomes aware (an " **Invalidity/Unenforceability Action** ").

9.2.2. Control of Invalidity or Unenforceability Actions . The Party that is prosecuting the Licensed Compounds Patent that is the subject of an Invalidity/Unenforceability Action (the " **Prosecuting Party** ") with respect to a Patent shall have the first right (but not the obligation) to defend any Invalidity/Unenforceability Action with respect to such Patent, using counsel of its choice and at its sole cost and expense, including when such Invalidity/Unenforceability Action is raised as a defense or counterclaim in connection with an infringement action initiated pursuant to Section 9.1. The Party having the first right to defend an Invalidity/Unenforceability Action with respect to a Patent pursuant to this Section 9.2.2 shall be the " **Controlling Party** ." If the Controlling Party does not take commercially reasonable steps to defend against an Invalidity/Unenforceability Action by the earlier of (w) ninety (90) days after notice of such Invalidity/Unenforceability Action, and (x) ten (10) Business Days before the time limit, if any, under applicable Law for taking any action with respect to the defense of such Invalidity/Unenforceability Action, then (y) such Party shall so notify the non-Controlling Party and (z) the non-Controlling Party shall have the right (but not the obligation) to defend against such Invalidity/Unenforceability Action at its sole cost and expense, using counsel of its choice, and shall thereafter be deemed the Controlling Party with respect to such Invalidity/Unenforceability Action. The non-Controlling Party may participate in the defense of any Invalidity/Unenforceability Action, at its sole cost and expense and using counsel of its choice; provided , that, the Controlling Party shall retain the right to control the defense of such Invalidity/Unenforceability Action.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.2.3. Cooperation . The Parties shall cooperate fully in defense of any Invalidity/Unenforceability Action pursuant to this Section 9.2, including by making applicable records and documents (including laboratory notebooks) with respect to the relevant Invalidity/Unenforceability Action available to the Controlling Party on the Controlling Party's request. The non-Controlling Party shall, and shall cause its Affiliates to, assist and cooperate with the Controlling Party, as the Controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.2, including, where necessary, joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours, and executing any settlement agreement as requested by the Controlling Party; provided , that the Controlling Party shall reimburse the non-Controlling Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Unless otherwise set forth herein, the Controlling Party shall have the right to settle an Invalidity/Unenforceability Action; provided , that, neither Party shall have the right to settle any Invalidity/Unenforceability Action under this Section 9.2 in a manner that imposes any costs or liability on, or involves any admission of infringement or invalidity by, the other Party or its Affiliates or its or their sublicensees, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed). In connection with any activities with respect to defense of an Invalidity/Unenforceability Action, the Controlling Party shall (a) consult with the non-Controlling Party as to the strategy for the defense of such Invalidity/Unenforceability Action, (b) consider in good faith any comments from the non-Controlling Party with respect thereto, and (c) keep the non-Controlling Party reasonably informed of any material steps taken, and provide copies of all material documents filed, in connection with such action.

9.3. Infringement Claims by Third Parties .

9.3.1. Notice . If the Exploitation of a Licensed Product in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement by Allergan or any of its Affiliates or its or their Sublicensees, distributors or customers (a " **Third Party Infringement Claim** "), including any defense or counterclaim in connection with an infringement action initiated pursuant to Section 9.1, the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing.

9.3.2. Defense of Third Party Infringement Claims . Allergan shall have the first right (but not the obligation) to defend against any Third Party Infringement Claim at its sole cost and expense, using counsel of its choice. The Party having the right under this Section 9.3.2 to defend against a Third Party Infringement Claim shall be the " **Defending Party** ". If Allergan does not take commercially reasonable steps to defend against a Third Party Infringement Claim by the earlier of (w) ninety (90) days after notice of such Third Party Infringement Claim, and (x) ten (10) Business Days before the time limit, if any, under applicable Law for taking any action with respect to the defense of such Third Party Infringement Claim, then (y) Allergan shall so notify Assembly and (z) Assembly shall have the right (but not the obligation) to defend against such Third Party Infringement Claim at its sole cost and expense, using counsel of its choice, and shall thereafter be deemed the Defending Party with respect to such Third Party Infringement Claim. The non-Defending Party may participate in the defense of any Third Party Infringement Claim, at its sole cost and expense and using counsel of its choice; provided , that, the Defending Party shall retain the right to control the defense of such Third Party Infringement Claim.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.3.3. Cooperation. The Parties shall cooperate fully in defense of any Third Party Infringement Claim pursuant to this Section 9.3, including by making applicable records and documents (including laboratory notebooks) with respect to the relevant Third Party Infringement Claim available to the Defending Party on the Defending Party's request. The non-Defending Party shall, and shall cause its Affiliates to, assist and cooperate with the Defending Party, as the Defending Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.3, including, where necessary, joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours, and executing any settlement agreement as requested by the Defending Party; provided, that, the Defending Party shall reimburse the non-Defending Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Unless otherwise set forth herein, the Defending Party shall have the right to settle a Third Party Infringement Claim; provided, that, neither Party shall have the right to settle any Third Party Infringement Claim under this Section 9.3 in a manner that imposes any costs or liability on, or involves any admission (other than an admission limited to the subject matter of the settlement agreement) by, the other Party or its Affiliates or its or their sublicensees, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed). In connection with any activities with respect to defense of a Third Party Infringement Claim, the Defending Party shall (a) consult with the non-Defending Party as to the strategy for the defense of such Third Party Infringement Claim, (b) consider in good faith any comments from the non-Defending Party with respect thereto, and (c) keep the non-Defending Party reasonably informed of any material steps taken, and provide copies of all material documents filed, in connection with such action.

9.4. Damages. Any damages or other awards, including royalties, incurred in connection with any Third Party Infringement Claim defended by Allergan under Section 9.3 shall be for the sole account of Allergan, subject to and without prejudice to Allergan's rights under Section 7.4.3 and ARTICLE 12.

9.5. Conflicts with Existing In-License Agreements. The Parties acknowledge that the Existing In-License Agreements may not permit Allergan to directly exercise any of its rights under Sections 9.1 through 9.3 with respect to the Patents licensed to Assembly thereunder. Without limiting any other provision of this Agreement, in the event that the terms of any other In-License Agreement prohibits Allergan from directly exercising any of its rights under Sections 9.1 through 9.3 with respect to any Patents licensed to Assembly thereunder, (a) Assembly shall so notify Allergan promptly after entering into any such In-License Agreement (such In-License Agreement, along with the Existing In-License Agreement, the "**Restricted In-License Agreements**"), (b) unless Allergan otherwise specifies, Assembly shall act as Allergan's agent and shall conduct all activities under the Restricted In-License Agreements to exercise all applicable rights under the Restricted In-License Agreements on Allergan's behalf as required to provide Allergan with all rights to which Allergan is entitled pursuant to Sections 9.1 through 9.3, at Allergan's sole direction, and shall take all other actions necessary to provide Allergan with the full benefit of Sections 9.1 through 9.3 with respect to the Patents licensed under the Restricted In-License Agreements, in all cases to the extent Assembly has sufficient rights under the applicable Restricted In-License Agreement, and subject to reimbursement by Allergan of Assembly's reasonable out-of-pocket costs and expenses incurred in connection therewith, (c) Assembly shall not terminate, waive or amend any rights under an In-License Agreement required for Assembly to act as Allergan's agent pursuant to the preceding sentence, (d) all activities conducted by Assembly on Allergan's behalf pursuant to this Section 9.1 shall be deemed to have been conducted by Allergan for the purposes of this Agreement, including Section 9.1.10 and (e) at Allergan's request, Assembly shall use Commercially Reasonable Efforts to amend the terms of any In-License Agreement to permit Allergan itself to directly exercise its rights under Section 9.1, 9.2 or 9.3.

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9.6. Ownership of IP . Subject to the licenses and other rights granted herein and subject to Section 9.9, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all Know-How, improvements and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party (or its Affiliates or its or their sublicensees (including Sublicensees)) under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto.

9.7. Ownership of Joint Intellectual Property Rights . Subject to the licenses and other rights granted herein, as between the Parties, the Parties shall each own an equal, undivided interest in any and all: (a) Know-How, information and other inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of Assembly or its Affiliates or its or their sublicensees, on the one hand, and Allergan or its Affiliates or its or their Sublicensees, on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable (the " **Joint Know-How** "); and (b) Patents (the " **Joint Patents** ") and other intellectual property rights with respect to the Know-How, improvements and inventions described in clause (a) (together with Joint Know-How and Joint Patents, the " **Joint Intellectual Property Rights** "). Each Party shall promptly disclose to the other Party in writing and shall cause its Affiliates, and its and their licensees and sublicensees to so disclose, the Development, making, conception or reduction to practice of any Joint Know-How or Joint Patents. Subject to the licenses granted under Sections 2.1 and 2.2 and the other provisions of this Agreement, including the Parties' respective exclusivity obligations hereunder, each Party shall have the right to Exploit the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

9.8. United States Law . The determination of whether Know-How, improvements and other inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable Law in the USA as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs. Each Party shall, and does hereby, assign, and shall cause its Affiliates to, and use good faith efforts to cause its and their (sub)licensees and Sublicensees to, so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How, improvements and other inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the joint ownership provided for in Sections 9.7.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.9. Assignment Obligation. Each Party shall use commercially reasonable efforts to cause all Persons who perform Development activities, manufacturing activities or regulatory activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Know-How, improvement or inventions by or on behalf of either Party or its Affiliates or its or their sublicensees under or in connection with this Agreement to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, to use commercially reasonable efforts to provide an exclusive license under) their rights in any Know-How, improvement and inventions resulting therefrom to such Party, to the extent such Know-How, improvements and inventions are related to Licensed Compounds or Licensed Products except where applicable Law requires otherwise. If applicable Law prohibits a Party from securing such assignment or exclusive license and the other Party requests that such Party obtain any such assignment or exclusive license, such other Party shall use commercially reasonable efforts to obtain any such assignment or exclusive license; provided, that if any such assignment or exclusive license cannot be obtained with respect to any such Know-How, improvement and inventions, at such other Party's request, such Party shall, and shall cause its Affiliates to, use commercially reasonable efforts to obtain for such other Party equivalent rights with respect to such Know-How, improvement and inventions to the extent applicable to the Licensed Products, including by entering into appropriate and reasonable alternative arrangements on terms reasonably agreed to by the Parties except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a suitable license, or option to obtain such a license, shall be obtained).

9.10. Patent Term Extension and Supplementary Protection Certificate. Allergan shall have the sole right to make decisions regarding, and Allergan shall have the sole right to apply for, patent term extensions, in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. § 156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for Product Only Patents and Product Related Patents with respect to the Licensed Compounds and the Licensed Products, in each case including whether or not to so apply; provided, that, Allergan shall consult with Assembly to determine the course of action with respect to such filings. Any Product Related Patent, the term of which is extended under this Section 9.6, shall, as of the date the extension is granted, be a Product Only Patent for all purposes under this Agreement. Assembly shall provide prompt and reasonable assistance, as requested by Allergan, including by taking such action as is required of the Regulatory Approval holder under any applicable Law to obtain such extension or supplementary protection certificate.

9.11. Trademarks for Licensed Product.

9.11.1. Ownership. Allergan shall be solely responsible for developing, selecting, searching, registering and maintaining, and shall be the exclusive owner of, all Product Trademarks, trade dress, logos, slogans, designs, copyrights and domain names used on and/or in connection with Licensed Products, together with all goodwill associated with, or symbolized by, any of the foregoing.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

9.11.2. Notice . Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

9.11.3. Prosecution of Product Trademarks . Allergan shall have the sole right to register, prosecute and maintain the Product Trademarks using counsel of its own choice. All costs and expenses of registering, prosecuting and maintaining the Product Trademarks shall be borne solely by Allergan.

9.11.4. Enforcement of Product Trademarks . Allergan shall have the sole right to take such action as Allergan deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice. Allergan shall retain any damages or other amounts collected in connection therewith.

9.11.5. Third Party Claims . Allergan shall have the sole right to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Licensed Product in the Territory at its sole cost and expense and using counsel of its own choice. Allergan shall retain any damages or other amounts collected in connection therewith.

9.11.6. Cooperation . Assembly shall, and shall cause its Affiliates to, assist and cooperate with Allergan, as Allergan may reasonably request from time to time, in connection with its activities set forth in this Section 9.7.6, including where necessary, joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; provided , that Allergan shall reimburse Assembly for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

ARTICLE 10
TERM AND TERMINATION

10.1. Term . Unless terminated earlier pursuant to this ARTICLE 10, the term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until (i) the end of the R&D Term, if Allergan is not Developing at least one Licensed Compound or Licensed Product as of such date or, (ii) if Allergan is Developing at least one (1) Licensed Compound or Licensed Product as of the end of the R&D Term, then, as determined on a Licensed Product-by-Licensed Product and country-by-country basis, until the expiration of the Royalty Term for such Licensed Product in such country (the " **Term** "). Upon expiration of the Royalty Term, on a Licensed Product-by-Licensed Product, Permitted Indication-by-Permitted Indication and country-by-country basis, the license granted to Allergan pursuant to Section 2.1 shall become worldwide, fully paid, irrevocable and perpetual. Notwithstanding anything herein to the contrary, Sections 10.1, 10.7, 10.9, 10.10, 10.11, 10.12 and ARTICLE 13 shall become effective on the Execution Date.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.2. Termination at Will by Allergan . Allergan shall have the right to terminate this Agreement for any reason or no reason, at any time, on ninety (90) days' prior written notice to Assembly if such termination occurs prior to the Initiation of the first POC Trial of a Licensed Product or one hundred and twenty (120) days' prior written notice if after the Initiation of the first POC Trial of a Licensed Product.

10.3. Material Breach . In the event of a material breach of this Agreement, the non-breaching Party shall have the right to terminate this Agreement in its entirety in each case by written notice to the breaching Party specifying the nature of such breach in reasonable detail. Such termination shall become effective ninety (90) days from receipt of such notice by the breaching Party, unless the breaching Party has cured such breach within such ninety (90) period. Notwithstanding the foregoing, such ninety (90)-day cure period shall be extended for an additional ninety (90) days or such longer period as is reasonably required to cure such breach if such breach is not a failure to pay amounts due under this Agreement and the breaching Party is employing ongoing, Commercially Reasonable Efforts to cure such alleged material breach; provided that the non-breaching Party may, pursuant to Sections 10.4 and 13.4, request that an arbiter determine a time period reasonably required for the breaching Party to cure such breach (which shall not, in any event, be less than ninety (90) days from the receipt of notice of such breach) and, if the breaching Party does not cure such breach within such determined time period, the termination shall become effective. Notwithstanding the foregoing, the foregoing applicable cure period shall be tolled upon the commencement and during the conduct of any dispute resolution initiated by a Party under Section 10.4 or Section 13.4 with respect to a Party's right to terminate this Agreement pursuant to this Section 10.3 if the other Party initiates such a dispute resolution procedure before the end of the applicable cure period.

10.4. Material Breach Dispute Resolution . Notwithstanding anything to the contrary herein, any (a) dispute with respect to a Party's right to terminate this Agreement pursuant to Section 10.3 and (b) demand by a non-breaching Party for an arbiter to determine a time period reasonably required for the breaching Party to cure such breach under Section 10.3 shall be resolved as follows:

10.4.1. the Senior Officers will meet to attempt to resolve the dispute by good faith negotiations. If the Senior Officers cannot resolve the dispute within thirty (30) days after a Party requests such a meeting, then either Party may initiate an arbitration pursuant to Section 13.4; and

10.4.2. notwithstanding anything to the contrary in this Agreement, if either Party in its sole judgment believes that any such dispute could cause it irreparable harm, such Party shall be entitled to seek equitable relief in order to avoid such irreparable harm and will not be required to follow the procedures set forth in this Section 10.4.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.5. Termination for Patent Challenge . If Allergan (A) commences or actively, directly and voluntarily participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of any Licensed Compound Patent that is licensed to Allergan under this Agreement or (B) actively, directly and voluntarily assists any other person or entity in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of any such Licensed Compound Patent (each of (A) and (B), a " **Patent Challenge** "), then Assembly shall have the right, in its sole discretion, to give notice to Allergan that Assembly may terminate the licenses granted under such Licensed Compound Patents to Allergan ninety (90) days following such notice, and, unless Allergan withdraws or causes to be withdrawn all such challenge(s) or in the case of *ex-parte* proceedings, multi-party proceedings, or other Patent Challenges that Allergan does not have the power to unilaterally withdraw or cause to be withdrawn, Allergan ceases assisting any other party to such Patent Challenge and, to the extent Allergan is a party to such Patent Challenge, it withdraws from such Patent Challenge within such ninety (90) day period, Assembly shall have the right to terminate this Agreement by providing written notice thereof to Allergan. The foregoing right to terminate shall not apply where the Patent Challenge is the assertion of a defense or counterclaim to an action first brought by Assembly against Allergan. For the avoidance of doubt, any participation by Allergan or its employees in any claim, challenge or proceeding in response to a subpoena or as required under a pre-existing agreement between Allergan's employee(s) or consultant(s) and their prior employer(s) shall not constitute active and voluntary participation or assistance and shall not give rise to Assembly's right to terminate any license hereunder.

10.6. Termination for Insolvency .

10.6.1. Either Party may terminate this Agreement in its entirety effective immediately upon written notice to the other Party if, at any time such other Party (a) files in any court or agency pursuant to any statute or regulation of any state or country a petition in bankruptcy or insolvency or for reorganization (except for solvent reorganization or solvent reconstruction) or for an arrangement or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, (b) proposes a written agreement of composition or extension of substantially all of its debts, (c) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not be dismissed within ninety (90) days after the filing thereof, (d) proposes to be a party to any dissolution or liquidation, (e) admits in writing its inability generally to meet its obligations as they fall due in the general course or (f) makes an assignment of substantially all of its assets for the benefit of creditors.

10.6.2. All rights and licenses granted under or pursuant to any section of this Agreement are for purposes of Section 365(n) of Title 11, United States Code or any analogous provisions in any other country or jurisdiction (the " **Bankruptcy Code** ") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code (and any equivalent provisions under the bankruptcy or insolvency laws of any other relevant jurisdiction). The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. The non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property and all embodiments of such intellectual property, which, if not already in its possession, shall be promptly delivered to the non-bankrupt Party (a) upon the commencement of a bankruptcy proceeding upon the non-bankrupt Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-bankrupt Party.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.7. Termination for Failure or Delay to obtain HSR Clearance. This Agreement shall terminate upon (a) notice given by one Party to the other Party if the HSR Clearance is not obtained within one hundred eighty (180) days after the Execution Date and such Party delivers notice of termination within ten (10) Business Days after the end of such one hundred eighty (180)-day period or (b) notice given by Allergan to Assembly if (i) the Parties receive a request for information or documentary material pursuant to the HSR Act or (ii) the FTC or the Antitrust Division of the DOJ shall have commenced, the staff of the FTC or the Antitrust Division of the DOJ recommends commencing, or the FTC votes to commence, in each case any action (A) challenging or seeking to restrain, prohibit, prevent, enjoin, alter or delay the transactions contemplated by this Agreement or (B) seeking to impose any of the restrictions described in Section 13.13.2.

10.8. Effect of Expiration or Termination of this Agreement.

10.8.1. Accrued Obligations. Except as provided in Section 10.8.3, upon expiration or termination of this Agreement for any reason, neither Party shall be released from any obligation or liability that, at the time of such expiration or the Termination Date, has already accrued to the other Party or that is attributable to a period prior to such expiration or the Termination Date.

10.8.2. In-Process Clinical Trials. Notwithstanding any other provision in this Section 10.8, if there are any Clinical Trials being conducted at the Termination Date, Allergan shall have the right and obligation to continue such Clinical Trials to the extent and for the period necessary to effect an orderly transfer or wind down of such Clinical Trials, at Assembly's election, in a timely manner and in accordance with applicable Laws.

10.8.3. Milestone Payments. Allergan shall remain liable to pay (a) any Sales Milestone Payments that have become due for payment and (b) Royalty Payments on Net Sales booked by Allergan (in accordance with GAAP), in each case (a) and (b) on or before the Termination Date. If Allergan provides notice of termination pursuant to Section 10.2 or 10.6, no Milestone Payments shall be due on Development Milestone Events that occur after the date on which the notice of termination is first delivered to Assembly unless the Agreement is not terminated under Section 10.6 due to a dismissal of a petition within ninety (90) days after the filing. If Allergan provides notice of termination pursuant to Section 10.3, no Milestone Payments shall be due on Development Milestone Events that occur after the date on which the notice of termination is first delivered to Assembly unless (a) Allergan elects to exercise its rights under Section 10.9, in which case Milestone Payments due on Development Milestone Events shall be payable but reduced according to Section 10.9 or (b) Assembly cures the breach subject to the termination notice within the time period specified or determined in accordance with Section 10.3.

10.8.4. Termination of the Agreement. In addition to the rights and obligations of the Parties that survive a termination of this Agreement pursuant to Sections 10.8.1, 10.8.2 and 10.12, on any termination of this Agreement:

(a) except as otherwise expressly provided herein, all rights and obligations of each Party hereunder will cease with respect to all Licensed Compounds or Licensed Products, including all rights, licenses and sublicenses granted by a Party to the other hereunder, provided, that ARTICLE 7 will survive with regard to any then outstanding payment obligations;

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(b) Allergan's rights with respect to the Licensed Compound Patents, including Allergan's patent prosecution, maintenance and enforcement rights set forth in Section 9.1, shall cease;

(c) With respect to any Licensed Product that is being Developed (in a Clinical Trial) or Commercialized as of the Termination Date (each, a " **Reversion Product** "), Allergan hereby grants Assembly an exclusive, sublicensable (through multiple tiers of sublicensees) license, throughout the Territory, under the Patents and Know-How Controlled by Allergan or its Affiliates as of the Termination Date that, absent a license, would be infringed by the Exploitation of the Reversion Product in the form that it is being clinically Developed or Commercialized as of the Termination Date (collectively, the " **Reversion IP** ") to Exploit such Reversion Product; provided , that, in consideration for such license, on a Reversion Product-by-Reversion Product and country-by-country basis, Assembly or its Affiliates shall pay Allergan a royalty on annual net sales of each Reversion Product in the Territory as set forth herein. The term "net sales" with respect to such Reversion Products has the same meaning as "Net Sales" under this Agreement, and such royalty shall be paid in accordance with Sections 7.5, 7.6, 7.7, 7.8, 7.9, 7.10 and 7.11, in each case *mutatis mutandis,* except as otherwise provided herein.

(i) If such termination is by Allergan pursuant to Section 10.3, the royalty payable by Assembly to Allergan under this Section 10.8.4 shall be equal to: [* * *]. If such termination is by Allergan pursuant to Section 10.3, the royalty payable by Assembly to Allergan under this Section 10.8.4 shall be payable until the last to occur of the following events as applicable: (i) the expiration or termination of the last Patent included in the Reversion IP that Covers the Exploitation of the Reversion Product by Assembly, its Affiliates or sublicensees, in the relevant country and (ii) (a) for such countries where there is [* * *] or more of Regulatory Exclusivity, the expiry of Regulatory Exclusivity granted by the applicable Governmental Authority for such Reversion Product in such country and (b) for such countries in which there is less than [* * *] of Regulatory Exclusivity, [* * *] after the expiration of such Regulatory Exclusivity for such Reversion Product; provided that if the royalty term for the royalty payable as set forth in this Section 10.8.4(c)(i) is extended by application of the foregoing clause (ii)(b) then the royalty rate payable on net sales in any such country under this Section 10.8.4(c)(i) shall be reduced by [* * *] percent ([* * *]%) for the remainder of the applicable royalty term.

(ii) If such termination is by Assembly pursuant to Section 10.3, the royalty payable by Assembly to Allergan under this Section 10.8.4 shall be equal to: [* * *] and shall be payable until the first to occur of the following events as applicable: (i) the expiration or termination of the last Patent included in the Reversion IP that Covers the Exploitation of the Reversion Product by Assembly, its Affiliates or sublicensees, in the relevant country and (ii) (a) for such countries where there is [* * *] or more of Regulatory Exclusivity, the expiry of Regulatory Exclusivity granted by the applicable Governmental Authority for such Reversion Product in such country and (b) for such countries in which there is less than [* * *] of Regulatory Exclusivity, [* * *] after the expiration of such Regulatory Exclusivity for such Reversion Product; provided that if the royalty term for the royalty payable as set forth in this Section 10.8.4(c)(ii) is extended by application of the foregoing clause (ii)(b) then the royalty rate payable on net sales in any such country under this Section 10.8.4(c)(ii) shall be reduced by [* * *] percent ([* * *]%) for the remainder of the applicable royalty term.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(iii) If such termination is for any reason other than by Allergan or Assembly pursuant to Section 10.3, the royalty payable by Assembly to Allergan under this Section 10.8.4 shall be equal to [* * *] and shall be payable until the last to occur of the following events as applicable: (i) the expiration or termination of the last Patent included in the Reversion IP that Covers the Exploitation of the Reversion Product by Assembly, its Affiliates or sublicensees, in the relevant country and (ii) (a) for such countries where there is [* * *] or more of Regulatory Exclusivity, the expiry of Regulatory Exclusivity granted by the applicable Governmental Authority for such Reversion Product in such country and (b) for such countries in which there is less than [* * *] of Regulatory Exclusivity, [* * *] after the expiration of such Regulatory Exclusivity for such Reversion Product; provided that if the royalty term for the royalty payable as set forth in this Section 10.8.4(c)(iii) is extended by application of the foregoing clause (ii)(b) then the royalty rate payable on net sales in any such country under this Section 10.8.4(c)(iii) shall be reduced by [* * *] percent ([* * *]%) for the remainder of the applicable royalty term.

(d) Allergan will at Assembly's request and cost (i) transfer to Assembly any IND and Regulatory Approval (of filing therefor) and Regulatory Documentation solely related to any Reversion Products, (ii) provide access to Know-How Controlled by Allergan and its Affiliates that are licensed to Assembly under this Section 10.8.4, and (iii) to the extent owned and possessed by Allergan or its Affiliates, transfer to Assembly all tangible chemical or biological material embodying the Reversion Products and reasonable quantities of other Materials Controlled by Allergan and its Affiliates that are licensed to Assembly under Section 10.8.4(c) above; and

(e) Allergan shall grant Assembly an exclusive, worldwide, sublicensable (through multiple tiers of sublicensees) license under any Product Trademark (if any) (i) Controlled by Allergan, (ii) that is solely related to the Reversion Product in its form as of the effective date of termination, (iii) is not a trademark otherwise used in connection with Allergan or its Affiliates' business or any other product and (iv) is used by or on behalf of Allergan in the Exploitation of any Reversion Product as of the effective date of termination exclusively to Exploit a Reversion Product as of the Termination Date; provided , that Allergan shall, at its or Assembly's election, instead of granting such exclusive license, transfer such Product Trademark to Assembly.

(f) To the extent that any Reversion IP is in-licensed by Allergan or any of its Affiliates, any license to Assembly under such Reversion IP pursuant to this Section 10.8 shall be subject to the terms and conditions of such license and Assembly shall be solely responsible for any payments (including all royalty, milestone or other payments) to Third Parties with respect to Assembly's Development, manufacture, Commercialization or other Exploitation of Reversion Products, including under any agreements Allergan or its Affiliates may have with such Third Parties. Notwithstanding anything in this Agreement to the contrary, the licenses granted by Allergan pursuant to this Section 10.8.4 do not include any intellectual property rights relating to compounds that are not Licensed Compounds.

10.9. Allergan Option to Continue In-Lieu of Termination . If Allergan has the right to terminate this Agreement under Section 10.3, but does not desire to exercise such right, Allergan may elect to exercise its rights under this Section 10.9 in lieu of exercising its right to terminate the Agreement under Section 10.3 by providing written notice of such election to Assembly prior to the date that otherwise would have been the effective date of termination had Allergan exercised its right under Section 10.3 to terminate this Agreement. In the event of such an election, the Agreement shall continue in full force and effect except as follows:

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(a) if such right to terminate accrued during the R&D Term, Allergan shall have the right to terminate the R&D Plan, and Allergan shall have the right to conduct all activities that would otherwise have been conducted by Assembly under the R&D Plan (whether alone or through one or more Third Parties);

(b) The JDC shall no longer be a decision-making body with respect to Licensed Compounds and Licensed Products in the Field in the Territory and Allergan shall have final decision-making authority over matters previously determined by the JDC;

(c) without limitation of Allergan's other remedies hereunder, any Milestone Payments or Royalty Payments that are due after Allergan's notice of breach shall be reduced by [* * *];

(d) Allergan's diligence obligations under Section 4.7.2 shall cease; and

(e) upon the request of Allergan, Assembly shall, and shall cause its Affiliates to, at Assembly's cost and expense, provide Allergan with such assistance as Allergan may reasonably require in order to transfer the ongoing Development, manufacture and Commercialization of any Licensed Compounds or Licensed Products to Allergan, including providing such assistance as may be necessary or useful for Allergan to conduct the activities under the R&D Plan as contemplated under this Section 10.9.

10.10. Termination by Either Party for Failure or Delay to obtain HSR Clearance . If either Party terminates this Agreement pursuant to Section 10.7, then, subject to Section 10.12, this Agreement shall be of no further force or effect.

10.11. Termination for Failure of Representations . If any of the supplements or amendments to Assembly's representations and warranties contemplated under Section 11.6 are, in Allergan's opinion, reasonably likely to materially diminish any of Allergan's rights or materially increase any liabilities of Allergan with respect to any Licensed Compound or Licensed Product, Allergan shall have the right, in its sole discretion, prior to the expiration of five (5) Business Days following its receipt of any supplement or amendment from Assembly in accordance with Section 11.6, by written notice to Assembly, to cause this Agreement not to take effect as of the Effective Date and to be of no further effect. If Allergan exercises such right neither Party shall have any liability to the other arising out of or in connection with this Agreement.

10.12. Survival . Upon the expiration or termination of this Agreement for any reason, all rights and obligations of the Parties under this Agreement shall terminate. Notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in ARTICLE 1 (to the extent necessary to give effect to the other sections listed in this Section 10.12), ARTICLE 8 (until the fifth anniversary of the termination of this Agreement, except Sections 8.5.1 and 8.6 and except that, upon termination of this Agreement (a) any Licensed Compound Know-How other than any Joint Know-How that was deemed to be the Confidential Information of Allergan pursuant to Section 1.39 shall cease to be deemed to be the Confidential Information of Allergan and (b) any such Joint Know-How shall be deemed to be the Confidential Information of both Parties and each Party shall be free to exploit such Joint Know-How without the consent of or accounting to the other Party), ARTICLE 9 (to the extent applicable to Joint Know-How and Joint Patents), ARTICLE 12, ARTICLE 13 (except Section 13.13) and Sections 2.5.1, 2.5.2, 4.11 (other than the first sentence), 4.9 (for final accounting), 7.4.3 to 7.12 (for final accounting), ARTICLE 8, 9.1.10, 9.3, 9.4, 10.1, 10.8, 10.13, and this Section 10.12 shall survive the expiration or termination of this Agreement for any reason, as well as any rights or obligations otherwise accrued hereunder shall survive the expiration or termination of the term of this Agreement, as well as any other provisions that, by their intent or meaning under the circumstances, are intended to survive.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

10.13. Effect of Termination on Sublicenses . If this Agreement terminates for any reason, any Sublicensee will, from the Termination Date, automatically and without any additional consideration become a direct licensee of Assembly with respect to the rights sublicensed to the Sublicensee by Allergan under this Agreement, so long as such Sublicensee is not in breach of its sublicense agreement. In order to effect this provision, at the request of the Sublicensee, Assembly will enter into a direct license with the Sublicensee on substantially the same terms as this Agreement (taking into account the scope of the license granted under such sublicense); provided that Assembly will not be required to undertake obligations in addition to those required by this Agreement, and that Assembly's rights under such direct license will be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license. The foregoing shall not apply if a Sublicensee provides written notice to Assembly that it does not wish to receive and retain the rights afforded to it pursuant to this Section 10.13.

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1. Mutual Representations and Warranties and Covenants . Each of Assembly and Allergan represents and warrants to the other Party, as of the Execution Date and the Effective Date, and covenants, that:

11.1.1. such Party is an entity duly organized, validly existing and in good standing under the Laws of the state or country (as applicable) of its organization, is qualified to do business and is in good standing as a foreign entity in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent it from performing its obligations under this Agreement, and has full power and authority to enter into this Agreement and to carry out the provisions hereof;

11.1.2. such Party is duly authorized, by all requisite action, to execute and deliver this Agreement and the execution, delivery and performance of this Agreement by such Party does not require any shareholder action or approval, and the Person executing this Agreement on behalf of such Party is duly authorized to do so by all requisite action;

11.1.3. except as contemplated by this Agreement, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority or a Third Party is required on the part of such Party in connection with the valid execution, delivery and performance of this Agreement;

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.1.4. such Party has not employed (and, to its Knowledge, has not used a contractor or consultant that has employed) and in the future shall not employ (or, to its Knowledge, use any contractor or consultant that employs, provided , that, such Party may reasonably rely on a representation made by such contractor or consultant) any Person debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act (or subject to a similar sanction of EMA or foreign equivalent), or any Person that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent), in the conduct of its activities under this Agreement and such Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder;

11.1.5. this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms except as enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting the enforcement of creditors' rights; and (b) equitable principles of general applicability;

11.1.6. the execution, delivery and performance by it of this Agreement and its compliance with the terms and provisions of this Agreement does not and shall not conflict with or result in a breach of any of the material terms or provisions of (a) any other contractual or other obligations of such Party, (b) the provisions of its operating documents or bylaws, or (c) any order, writ, injunction or decree of any Governmental Authority entered against it or by which it or any of its property is bound.

11.2. Assembly's Additional Representations and Warranties and Covenants . Except as provided in Schedule 11.2, Assembly represents and warrants to Allergan as of the Execution Date and (subject to Section 11.6) the Effective Date, and covenants, as applicable, that:

11.2.1. it has full right and authority to grant the licenses and rights granted under this Agreement, it has the right to Exploit the Initial Compound Candidates, and will have the right to Exploit any Licensed Product or Licensed Compound, as contemplated under this Agreement without any conflicting contractual obligation to any other Person and no rights or licenses are required from Assembly or its Affiliates, or, to its Knowledge, any other Person, for Allergan to Exploit the Licensed Compounds or Licensed Products as contemplated under this Agreement other than those granted under ARTICLE 2;

11.2.2. there are no Patents of a Third Party that, to Assembly's Knowledge, would be infringed by practicing the Licensed Compound Patents or Exploiting the Licensed Compounds, and no claim or litigation has been brought or asserted (and Assembly has no Knowledge of any claim, whether or not brought or asserted, or of any facts or circumstances that exist that would reasonably be expected to give rise to any such claim or litigation) by any Person alleging that (a) the Licensed Compound Patents are invalid or unenforceable or (b) the conception, Development, reduction to practice, disclosing, copying, making, assigning or licensing of the Licensed Compound Patents or the Licensed Compound Know-How existing as of the Effective Date or the Exploitation of the Initial Compound Candidates in the Initial Indications as contemplated herein, violates, infringes, constitutes misappropriation of or otherwise conflicts or interferes with or would violate, infringe or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person;

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.2.3. [* * *];

11.2.4. to the Knowledge of Assembly, no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the Licensed Compound Patents existing as of the Effective Date;

11.2.5. with respect to any Patent or Know-How that would be a Licensed Compound Patent or Licensed Compound Know-How if Controlled by Assembly or its Affiliates, Assembly or its Affiliate Control all such Patents and Know-How that Assembly or its Affiliates own;

11.2.6. Assembly (a) shall provide written notice to Allergan within ten (10) Business Days after entering into any agreement with a Third Party to acquire or license any Patent that, if Controlled by Assembly or its Affiliates, would be a Licensed Compound Patent as set forth in Section 1.108(b), and (b) acknowledges and agrees that such Patent shall be considered a Licensed Compound Patent under this Agreement;

11.2.7. it has not received notice of any claims, and there are no judgments or settlements against or owed by Assembly or, to the Knowledge of Assembly, any pending or threatened claims or litigation, in each case relating to the Licensed Compounds;

11.2.8. except pursuant to license agreements identified on Schedule 11.2.8 (the " **Current In-License Agreements** "), it is the exclusive owner of all of the Licensed Compound Patents set out in **Schedule 1.108** and true, complete, correct and unredacted copies of key documents from the file wrappers and other key documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of such Licensed Compound Patents have been provided to Allergan prior to the Effective Date;

11.2.9. it has the exclusive right to grant, all rights and licenses (or sublicenses, as the case may be) it purports to grant to Allergan with respect to the Initial Compound Candidates, Licensed Compound Know-How and the Licensed Compound Patents under this Agreement as of the Effective Date and neither such rights and licenses nor any other provision of this Agreement are subject to any in-license and other similar agreements with another Person regarding any intellectual property rights licensed hereunder, including the Licensed Compound Patents existing as of the Effective Date, other than the In-License Agreements;

11.2.10. Assembly has provided to Allergan true, complete and correct copies of all Current In-License Agreements [* * *] (collectively, the " **Existing In-License Agreements** "), in their current form;

11.2.11. without the prior written consent of Allergan, Assembly will not (a) amend any In-License Agreement in a manner that adversely affects Allergan's rights or obligations pursuant to this Agreement or (b) terminate any In-License Agreement;

11.2.12. Assembly will comply in all material respects with its obligations under the In-License Agreements and shall enforce its rights with respect to In-License Agreements with respect to the Licensed Compounds or Licensed Products in consultation with Allergan;

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.2.13. Assembly shall be solely responsible for any payments (including all royalty, milestone or other payments) under the In-License Agreements in respect of the Licensed Compounds and Licensed Products;

11.2.14. Assembly shall notify Allergan as soon as reasonably practicable of (a) the receipt by Assembly of any notice of breach of any In-License Agreement with respect to the Licensed Compounds or Licensed Products, (b) the occurrence of any acts or omissions of Assembly or any of its Affiliates that give rise to a right of the other Party to any In-License Agreement to terminate such In-License Agreement or (c) any termination, or receipt by Assembly of any notice of termination, of an In-License Agreement.

11.2.15. the Licensed Compound Patents in **Schedule 1.108** have not been challenged by any Third Party in any judicial or administrative proceeding and, to Assembly's Knowledge, such Licensed Compound Patents are valid and enforceable and Assembly has complied with all applicable Laws with respect to the filing, prosecution and maintenance of the Licensed Compound Patents owned or Controlled by it. Assembly and its Affiliates have presented all relevant references, documents and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office. Assembly has paid all maintenance and annuity fees with respect to the Licensed Compound Patents due. Assembly has not received written notice of any dispute regarding inventorship of any Licensed Compound Patent and to Assembly's Knowledge, no such dispute has been alleged or threatened;

11.2.16. Each of the Licensed Compound Patents in Schedule 1.108 properly identifies each and every inventor of the claims thereof as determined in accordance with the Laws of the jurisdiction in which such Licensed Compound Patent is issued or such application is pending;

11.2.17. All current and former officers, employees, agents and consultants of Assembly or any of its Affiliates who are inventors of or have otherwise contributed in a material manner to the creation or development of any Licensed Compound Patents in **Schedule 1.108** or Licensed Compound Know-How or who are or will be performing Assembly's Development activities hereunder, or who otherwise have access to any Confidential Information of Allergan, have executed and delivered to Assembly or such Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Assembly or such Affiliate of any Licensed Compound Patents, Licensed Compound Know-How and any and all other information that relates to the Licensed Compounds or Licensed Products, the current form of which has been made available for review by Allergan unless such an assignment is not required under applicable Law. To Assembly's Knowledge, no current officer, employee, agent or consultant of Assembly or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Assembly or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Assembly;

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.2.18. there are no amounts that will be required to be paid to a Third Party as a result of the Exploitation of the Licensed Compounds or Licensed Products that arise out of any agreement to which Assembly or any of its Affiliates is a party;

11.2.19. the Development of the Licensed Compound Know-How, the Licensed Compound Patents and the Initial Compounds has been conducted by Assembly and its Affiliates and its and their subcontractors, in compliance with all applicable Law in all material respects. Neither Assembly nor any of its Affiliates, nor any of their respective officers, employees, or to Assembly's Knowledge, agents, have made an untrue statement of a material fact or fraudulent statement to the United States Patent and Trademark Office or any similar patent or trademark office in the Territory or failed to disclose a material fact required to be disclosed to the United States Patent and Trademark Office or any similar patent or trademark office in the Territory;

11.2.20. it has provided to Allergan all material information in its possession regarding the safety and efficacy of the Initial Compounds;

11.2.21. it has not misappropriated, and will not misappropriate, any intellectual property of a Third Party in connection with Developing the Licensed Compounds or Licensed Products or the performance of the R&D Plan or its other obligations under this Agreement;

11.2.22. the Licensed Compound Patents listed on **Schedule 1.108** are all of the Licensed Compound Patents Controlled by Assembly as of the Effective Date;

11.2.23. true, complete, correct and unredacted copies of all agreements set forth in Schedule 11.2.23 have been provided to Allergan prior to the Effective Date, and except as set forth in Schedule 11.2.23 and except with regard to any subcontracts or work orders entered into by Assembly after the Execution Date but before the Effective Date in accordance with Section 4.10, (a) Assembly has not subcontracted to any Third Party any activities contemplated to be conducted by Assembly under the R&D Plan or any manufacturing activities, and (b) there are no agreements relating to the Licensed Compounds;

11.2.24. without limitation to Assembly's obligations under Section 4.3.1, Assembly has maintained all records, and shall continue to maintain, all records of material activities conducted by it or its Affiliates under or in connection with [* * *];

11.2.25. each of the Permitted Indications as of the Effective Date is part of the "Field" [* * *];

11.2.26. each Compound Candidate, Product Candidate, Licensed Compound and Licensed Product manufactured by Assembly or its CMO(s) for use in Clinical Trials under the R&D Plan (a) will have been manufactured, stored and shipped in accordance with GMP and all applicable Laws; (b) will conform to the Specifications for such Licensed Compound or Licensed Product, (c) will be free from defects; (d) will not be adulterated or misbranded within the meaning of the FD&C Act to the extent applicable; and (e) will have been shipped and stored in accordance with the procedures set forth under this Agreement and the Clinical Quality Agreement;

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11.2.27. (a) neither Assembly nor any of its Affiliates, nor any of its or their respective officers or employees, has (i) committed an act, (ii) made a statement or (iii) failed to act or make a statement, in any case ((i), (ii) or (iii)), that (A) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Exploitation of the Licensed Compounds or Licensed Products or (B) could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory, with respect the Exploitation of the Licensed Compounds or Licensed Products and (b) neither Assembly nor any of its Affiliates shall during the R&D Term with respect to activities under the R&D Plan (i) commit an act, (ii) make a statement or (iii) fail to act or make a statement, in any case ((i), (ii) or (iii)), that (A) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Exploitation of the Licensed Compounds or Licensed Products or (B) could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory, with respect to the Exploitation of the Licensed Compounds or Licensed Products;

11.2.28. the inventions claimed by the Licensed Compound Patents existing as of the Effective Date (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the US or any agency thereof and (b) are not a "subject invention" as that term is described in 35 U.S.C. §§ Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401; and

11.2.29. [* * *].

11.3. Allergan Additional Representations and Warranties .

11.3.1. Allergan represents and warrants to Assembly of the Execution Date and (subject to Section 11.6), and covenants, that all officers, employees, agents and consultants of Allergan or any of its Affiliates who will perform Development activities hereunder, or who otherwise have access to any Confidential Information of Assembly, have executed and delivered to Allergan or such Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Allergan or such Affiliate of any Patents or Know-How that may arise out of or relate to such activities.

11.3.2. Allergan shall comply with those terms and conditions under the In-License Agreements that are applicable to Allergan as a sublicensee of any of Assembly's rights thereunder, in each case to the extent such terms and conditions have been disclosed by Assembly to Allergan (and, in the case of the Current In-License Agreement, to the extent such terms and conditions have been disclosed to Allergan prior to the Execution Date) and Allergan has agreed in writing to receive a sublicense to any Licensed Compound Patent or Licensed Compound Know-How under such agreement.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.4. Compliance with Laws . Each Party shall perform its responsibilities under this Agreement in accordance with all applicable Laws.

11.5. Privacy; Transparency; Anti-Corruption . Without limitation to Section 11.4, the Parties agree as follows.

11.5.1. Data Privacy . Each Party shall comply with all applicable Law with respect to the collection, use, transfer, storage, destruction, aggregation or other use of subject health information or other personal information (collectively, " **Personal Information** ") in connection with its activities under or in connection with the R&D Plan. Each Party shall take such steps as necessary to comply with applicable Law to permit such Party to disclose Personal Information to the other Party and to permit the other Party to use and disclose such Personal Information for its own purposes in accordance with this Agreement.

11.5.2. Compliance . Each Party shall implement appropriate processes and controls with respect to technology and work flow methodologies in connection with its activities under or in connection with the R&D Plan so as to protect the security and privacy of personally identifiable information in accordance with applicable Law.

11.5.3. Sunshine Act . Allergan and Assembly acknowledge that, under the provisions of Section 1128G of the Social Security Act, 42 U.S.C. § 1320a-7h and other similar provisions of applicable Law, Allergan and Assembly may be required to disclose certain payments and other transfers of value provided to health care professionals and institutions, including payments, reimbursements, Materials or equipment made or provided under or in connection with this Agreement or the R&D Plan. Each of Assembly and Allergan will provide the other or its designee/s with all information necessary for the other to comply with such applicable Laws in the form reasonably requested by the requesting Party and at such times as the requesting Party may reasonably request to satisfy its obligations.

11.5.4. Anti-Corruption . Assembly and Allergan will strictly comply with all applicable Laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any official, agent or employee of any government, political party or public international organization, candidate for public office, health care professional, or to any officer, director, employee or representative of any other organization specifically including the U.S. Foreign Corrupt Practices Act, and the UK Bribery Act, in each case in connection with the activities conducted pursuant to this Agreement. Assembly shall require any contractors, subcontractors or other persons or entities that provide services to Assembly or Allergan in connection with this Agreement to comply with Assembly's obligations under this Section 11.5.4.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

11.6. Updates to Representations and Warranties . Either (a) on the date that is the Business Day following HSR Clearance Assembly shall deliver to Allergan representations and warranties under Section 11.2 that are identical to such representations and warranties delivered as of the Execution Date or (b) on the date that is two (2) Business Days following HSR Clearance, Assembly shall deliver to Allergan representations and warranties under Section 11.2 that are identical to such representations and warranties delivered as of the Execution Date, except for any supplement or amendment to such representations and warranties with respect to any event, condition, fact or circumstance occurring after the Execution Date that, if existing or occurring on or prior to the Execution Date, would have been required to be set forth or described in such representations and warranties as of the Execution Date, or that is necessary to correct or modify any information in such representations and warranties that has been rendered inaccurate by an event, condition, fact or circumstance occurring after the Execution Date. If Assembly does not deliver representations and warranties under the foregoing clause (a) or (b), Assembly shall be deemed to have delivered to Allergan on the date that is two (2) Business Days following HSR Clearance representations and warranties under Section 11.2 that are identical to such representations and warranties delivered as of the Execution Date.

ARTICLE 12
INDEMNIFICATION

12.1. Assembly . Assembly shall defend, indemnify and hold Allergan, its Affiliates and their respective directors, officers, employees and agents (the " **Allergan Indemnitees** "), at Assembly's cost and expense, harmless from and against any and all losses, costs, damages, fees or expenses (including reasonable attorney's fees and expenses) (" **Losses** ") incurred in connection with or arising out of any:

(a) Third Party claims, suits or demands (" **Third Party Claims** ") arising out of or in connection with any breach by Assembly of the representations, warranties or covenants contained in this Agreement;

(b) Third Party Claims arising out of or in connection with the activities of Assembly or its Affiliates before the Effective Date;

(c) Third Party Claims arising out of or in connection with the Exploitation of a Compound Candidate, Product Candidate, Licensed Compound or Licensed Product by Assembly, its Affiliate or their respective designees (including a subcontractor) but, for avoidance of doubt, excluding Allergan, its Affiliates and their respective designees (including subcontractors) except to the extent such relevant act of Exploitation was taken with respect to a Licensed Product in a Permitted Indication following the Completion of a POC Trial for such Licensed Product in such Permitted Indication at Allergan's direction and in accordance with Allergan's written instructions, including any such direction and written instructions provided pursuant to and in accordance with a Co-Promotion Agreement but, for the avoidance of doubt, not including any activities not included in or consistent with Allergan's written instructions;

(d) Third Party Claims arising out of or in connection with Assembly's Exploitation of any Reversion Product;

(e) Third Party Claims arising out of or in connection with any negligence or willful misconduct of Assembly in the exercise of any of its rights or the performance of any of its obligations under this Agreement; or

(f) Third Party Claims arising under any In-License Agreement;

in each case except to the extent that such Losses are (A) subject to indemnification by Allergan pursuant to Section 12.2 below or (B) attributable to the negligence or willful misconduct of the Allergan Indemnitees.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

12.2. Allergan . Allergan shall defend, indemnify and hold Assembly, its Affiliates and their respective directors, officers, employees and agents (the " **Assembly Indemnitees** "), at Allergan's cost and expense, harmless from and against any and all Losses incurred in connection with or arising out of any:

(a) Third Party Claims resulting from either:

(i) the Development of Licensed Products by Allergan, its Affiliates, Sublicensees and their respective designees (including subcontractors but, for avoidance of doubt, excluding Assembly, its Affiliates and their respective designees) ; or

(ii) the Commercialization of Licensed Products by Allergan, its Affiliates, Sublicensees and their respective designees (including subcontractors but, for avoidance of doubt, excluding Assembly, its Affiliates and their respective designees); and

(b) Third Party Claims arising out of or in connection with any breach by Allergan of the representations, warranties or covenants contained in this Agreement; or

(c) Third Party Claims arising out of or in connection with any negligence or wilful misconduct of Allergan in the exercise of any of its rights or the performance of any of its obligations under this Agreement;

in each case except to the extent that such Losses are (A) subject to indemnification by Assembly pursuant to Section 12.1 above or (B) attributable to the negligence or willful misconduct of the Assembly Indemnitees.

12.3. Notice of Claim . All indemnification claims in respect of any person seeking indemnification under Section 12.1 or 12.2 (collectively, the " **Indemnitees** " and each an " **Indemnitee** ") shall be made by the corresponding Party (the " **Indemnified Party** "). The Indemnified Party shall give the indemnifying Party (the " **Indemnifying Party** ") prompt written notice (an " **Indemnification Claim Notice** ") of any Losses or the discovery of any fact upon which such Indemnified Party intends to base a request for indemnification under Section 12.1 or 12.2, but in no event shall the Indemnifying Party be liable for any Losses that result from any delay by the Indemnified Party in providing such notice that materially prejudices the defense of such Third Party Claim. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Losses (to the extent that the nature and amount of such Losses are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party shall furnish promptly to the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party materially prejudices the defense of such Third Party Claim.

12.4. Indemnification Procedure . In respect of Third Party Claims, the obligations of an Indemnifying Party under this Section 12.4 shall be governed by and contingent upon the following:

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(a) at its option, the Indemnifying Party may assume control of the defense of any Third Party Claim (which, for the avoidance of doubt, shall include the conduct of all dealings with such Third Party) by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of control of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgement that the Indemnifying Party is liable to indemnify any Indemnitee in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification.

(b) upon the assumption of the control of the defense of a Third Party Claim by the Indemnifying Party:

(i) subject to the provisions of Section 12.4(c), it shall have the right to and shall assume sole control and responsibility for dealing with the Third Party and the Third Party Claim, including the right to settle the claim on any terms the Indemnifying Party chooses, but at all times in accordance with the provisions of Section 12.4(c) and 12.4(d);

(ii) if it chooses, the Indemnifying Party may appoint as counsel in the defense of the Third Party Claim any law firm or counsel selected by the Indemnifying Party; and

(iii) except as expressly provided in Section 12.4(c), the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party or any Indemnitee in connection with the analysis, defense, or settlement of the Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless an Indemnitee from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including lawyers' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim with respect to such Indemnified Party or Indemnitee.

(c) without limiting the remainder of this Section 12.4, any Indemnitee shall be entitled to participate in, but not control, the defense of a Third Party Claim and to retain counsel of its choice for such purpose; provided , that such retention shall be at the Indemnitee's own cost and expense unless (i) the Indemnifying Party has failed to assume the defense and retain counsel in accordance with Section 12.4(a) (in which case the Indemnified Party shall control the defense), or (ii) the interests of the Indemnitee and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under any legal requirement, ethical rules or equitable principles.

(d) with respect to any Losses relating solely to the payment of money to the Third Party to settle the Third Party Claim and that will not result in the Indemnified Party or the Indemnitee becoming subject to injunctive relief, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnitee under Section 12.4(a), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Losses. With respect to all other Losses or where the Indemnified Party will be subject to injunctive relief, where the Indemnifying Party has assumed the defense of a Third Party Claim in accordance with Section 12.4(a), the Indemnifying Party must not consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Losses, unless it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed).

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(e) if the Indemnifying Party chooses not to take control of the defense or prosecute any Third Party Claim, the Indemnified Party shall retain control of the defense thereof, but no Indemnified Party or Indemnitee shall admit any liability with respect to, or settle, compromise or discharge, any such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall not be liable for any settlement or other disposition of Losses by an Indemnified Party or an Indemnitee under such a Third Party Claim that is reached without the written consent of the Indemnifying Party, which consent will not be unreasonably withheld, conditioned or delayed.

(f) if the Indemnifying Party chooses to control the defense of any Third Party Claim, the Indemnified Party shall, and shall cause each other Indemnitee to, reasonably cooperate in the defense thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making the Indemnified Party, the Indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information, to the extent the Third Party Claim is subject to indemnification hereunder.

12.5. Expenses . Except as expressly provided above, the reasonable and verifiable out-of-pocket costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party where it participates in the defense under Sections 12.4(b)(i) or 12.4(b)(ii) or cooperates pursuant to Section 12.4(f) shall be reimbursed on a quarterly basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

12.6. Insurance . Each Party shall have and maintain, at its sole cost and expense, an adequate liability insurance (including product liability insurance) obtained from a reputable insurer to protect against potential liabilities and risk arising out of activities to be performed under this Agreement and any agreement related hereto and upon such terms (including coverages and deductible limits) as are customary in the pharmaceutical industry generally for the activities to be conducted by such Party under this Agreement. Such liability insurance shall insure against all types of liability, including personal injury, physical injury or property damage arising out of such Party's activities hereunder. This Section 12.6 shall not create any limitation on the Parties' liability under this Agreement. Such insurance information shall be kept in confidence in the same manner as any other Confidential Information disclosed by the Parties hereunder.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

12.7. Consequential Damages .

12.7.1. EXCEPT IN THE EVENT OF THE GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD OF A PARTY, IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, TREBLE OR CONSEQUENTIAL DAMAGES OR INDIRECT LOST PROFITS, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY; PROVIDED, HOWEVER, THAT THIS LIMITATION SHALL NOT LIMIT (A) BREACHES OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 8, (B) THE INDEMNIFICATION OBLIGATION OF SUCH PARTY IN RESPECT OF AMOUNTS ACTUALLY AWARDED AGAINST AN INDEMNIFIED PARTY AS A PART OF A THIRD PARTY CLAIM UNDER THE PROVISIONS OF THIS ARTICLE 12 OR (C) A BREACH BY ASSEMBLY UNDER THIS AGREEMENT OR A CO-PROMOTION AGREEMENT OF ITS OBLIGATION TO PROVIDE ITS SHARE OF DETAILING EFFORTS IN CHINA OR THE UNITED STATES IN ACCORDANCE WITH THIS AGREEMETN OR ANY CO-PROMOTION AGREEMENT.

12.7.2. Nothing in this Agreement shall limit a Party's liability for death or personal injury caused by its negligence or for fraud.

ARTICLE 13
MISCELLANEOUS

13.1. Assignment . Neither Party may assign or transfer (whether by operation of applicable Law or otherwise) this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to an Affiliate or to a successor to substantially all of the business to which this Agreement relates, whether in a merger, sale of stock, sale of assets, reorganization or other transaction. Further, each Party shall have the right to cause the performance by an Affiliate of some or all of such Party's obligations hereunder, without the prior written consent of the other Party. In all cases, the assigning Party shall provide the other Party with prompt written notice of any such assignment and the permitted assignee shall assume the obligations of the assigning Party hereunder in writing. No assignment of this Agreement shall act as a novation or release of either Party from responsibility for the performance of any accrued obligations.

13.2. Non-Solicitation of Employees . During the R&D Term and for a period of three (3) years thereafter, each Party agrees that it will not directly recruit, solicit or induce any employee of the other Party who is directly associated with the performance under the R&D Plan to terminate his or her employment with such other Party. However, nothing set forth in this Section 13.2 shall prohibit a Party from indirectly recruiting, soliciting or inducing such employees to leave the other Party through the use of general searches, general advertisements and solicitations in trade journals and the like not targeting such employees, or from discussing employment opportunities with such employees to the extent such employees contact such Party first.

13.3. Governing Law . This Agreement and any dispute or claim arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by and construed in accordance with the laws of the State of New York, excluding: (a) any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; and (b) any dispute with respect to infringement, validity, or enforceability of any Patent, which shall be governed by and construed and enforced in accordance with the laws of the jurisdiction in which such Patent is issued or published.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.4. Dispute Resolution . Subject to Section 10.4, any dispute or claim arising out of or in connection with this Agreement other than a dispute or claim that (a) may arise under Section 9.2, (b) relates to the scope, construction, validity, or enforceability of any Patent in a country within the Territory, (c) otherwise requires the interpretation or application of applicable Law regarding Patents to resolve such dispute or claim or (d) for which a Party or other Person has been granted final decision-making authority hereunder (including Section 9.1.6(c)) (but excluding disputes about the applicability of such grant of final decision-making authority which shall be subject to this Section 13.4), including any question regarding the Agreement's existence, validity or termination shall be referred to and finally resolved by arbitration under the rules of the International Chamber of Commerce (" **ICC** "), which are deemed incorporated into this Section 13.4. The place of arbitration shall be New York. The language to be used in the arbitration procedures shall be English. The arbitration proceedings, including any outcome, shall be confidential. Nothing in this Section 13.4 will preclude either Party from seeking equitable interim or provisional relief from a court of competent jurisdiction including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. The number of arbitrators shall be three (3), of which each Party shall appoint one (1), the arbitrators so appointed will select the third and final arbitrator. The arbitrators shall have experience in pharmaceutical licensing disputes. In connection with a proceeding initiated by a Party seeking a more specific time period reasonably required by a breaching Party to cure a breach under Section 10.3, the arbitrators shall be instructed to consider the time period that would reasonably be required to cure the applicable material breach by the allegedly breaching Party using Commercially Reasonable Efforts.

13.5. Force Majeure . Neither Party shall be liable to the other for any failure or delay in the fulfillment of its obligations under this Agreement (other than the payment of monies due and owing to a Party under this Agreement), when any such failure or delay is caused by fire, flood, earthquakes, explosions, sabotage, terrorism, civil commotions, riots, invasions, wars, peril of the sea or requirements of Governmental Authorities (each, a " **Force Majeure Event** "). In the event that either Party is prevented from discharging its obligations under this Agreement on account of a Force Majeure Event, the performing Party shall promptly notify the other Party, and such other Party shall use good faith efforts to discharge its obligations, even if in a partial or compromised manner.

13.6. Expenses . Except as otherwise expressly provided herein or mutually agreed, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be borne by the Party incurring such costs and expenses.

13.7. No Agency . Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership or similar relationship between Assembly and Allergan. Notwithstanding any of the provisions of this Agreement, neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever, and all contracts, expenses and liabilities undertaken or incurred by one Party in connection with or relating to the Development, manufacture or Commercialization of a Licensed Compound or Licensed Product shall be undertaken, incurred or paid exclusively by that Party, and not as an agent or representative of the other Party.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.8. No Third Party Beneficiaries . The warranties and agreements contained in this Agreement are for the sole benefit of the Parties, and in Allergan's case, Allergan's Affiliates, and their respective successors and permitted assigns, and they shall not be construed as conferring any rights to any other Persons.

13.9. Entire Agreement; Amendment . This Agreement (including all schedules and exhibits hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements or understandings, oral or written, with respect to such matters. The Parties acknowledge that this Agreement has not been entered into wholly or partly in reliance on, nor has either party been given, any warranty, statement, promise or representation by the other or on its behalf other than as expressly set out in this Agreement. This Agreement may be amended or modified only by a writing signed by both Parties.

13.10. Severability . If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

13.11. Extension; Waiver . At any time, either Assembly or Allergan may (a) with respect to obligations owed to it or the performance of other acts for its benefit, extend the time for the performance of such obligations or such other acts to be performed hereunder by the other, (b) waive any inaccuracies in the representations and warranties of the other contained herein or in any document delivered pursuant hereto and (c) waive compliance with any of the conditions to the obligations of the other contained herein. Any agreement on the part of either Party to any such extension or waiver shall be valid only if set forth in an instrument executed by such Party. No such waiver shall be operative as a waiver of any other subsequent requirement of this Agreement. The failure of any Party to assert any of its rights under this Agreement or otherwise shall not constitute a waiver of such rights.

13.12. Notices . All communications required to be made under this Agreement shall be effective upon receipt, and shall be sent to the addresses set out below, or to such other addresses as may be designated by one Party to the other by notice pursuant hereto, by (a) internationally recognized overnight courier; (b) prepaid registered or certified US mail, return receipt requested; or (c) facsimile transmission or other electronic means of communication with confirmation by letter sent by the close of business on or before the next following Business Day at the address set forth below, or such other address as may be designated in writing hereafter, in the same manner, by such Party as follows:

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

If to Assembly, as follows :

Assembly Biosciences, Inc.
11711 N. Meridian street, Suite 310
Carmel, IN 46032
Attention: Chief Executive Officer

With copies (which shall not constitute notice) to:

Assembly Biosciences, Inc.
11711 N. Meridian street, Suite 310
Carmel, IN 46032
Attention: Chief Scientific Officer, Microbiome

Goodwin Procter
100 Northern Avenue
Boston, MA 02210
Attention: Christopher Denn

If to Allergan, as follows :

Allergan Pharmaceuticals International Limited
Clonshaugh Industrial Estate
Coolock
Dublin 17, Ireland
Attention: General Manager
Facsimile: 353 (0)1 435 7775

with copies (which shall not constitute notice) to:

Allergan Pharmaceuticals International Limited
Clonshaugh Industrial Estate
Coolock
Dublin 17, Ireland
Attention: Secretary
Facsimile: 353 (0)1 435 7775

and

Allergan, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054
Attention: General Counsel
Facsimile: (862) 261-7923

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.13 HSR Act Compliance .

13.13.1 HSR Filing . Each of Assembly and Allergan shall make an HSR Filing as soon as practicable and advisable (but no later than fifteen (15) Business Days, unless the Parties mutually agree otherwise) after the Execution Date. The Parties shall cooperate with one another to the extent necessary in the preparation of any such filings. Each Party shall be responsible for its own costs and expenses associated with any such filings and Allergan shall be responsible for the filing fee.

13.13.2 HSR Clearance . In connection with obtaining HSR Clearance, Assembly and Allergan shall use their respective commercially reasonable efforts (a) to secure the early termination or expiration of any waiting periods under the HSR Act and (b) to resolve as promptly as practicable any objections that may be asserted by the FTC or the Antitrust Division of the DOJ with respect to the transactions notified in the HSR Filing; provided , that (i) the term "commercially reasonable efforts" as used in this Section 13.13.1 shall not require Assembly or Allergan to (a) sell, divest (including through a license or a reversion of licensed or assigned rights), hold separate, transfer, or dispose of any portion of the assets, operations, rights, product lines, or businesses, or interests therein, of itself or any of its Affiliates (or consent to any of the foregoing actions), (b) restrain, restrict, prohibit or limit the ability of Allergan or Assembly to conduct its business or own its assets (or consent to any of the foregoing actions) or (c) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to challenge the transactions contemplated by this Agreement or impose any of the restrictions referenced in clause (a) or (b) above; provided , that (i) Allergan shall not be required to agree to or effectuate any remedy related to any Assembly assets and (ii) Assembly shall not agree to or effectuate any remedy without the prior written consent of Allergan. Without limiting the foregoing, Assembly and Allergan each hereby covenants and agrees to use its commercially reasonable efforts to comply as promptly as advisable with or, as advisable, request modifications to any requests for additional information by FTC or DOJ (and if such request is a Second Request, to certify substantial compliance as promptly as is practicable and advisable).

13.13.3 Cooperation . In connection with obtaining HSR Clearance, each of Assembly and Allergan shall (a) cooperate with each other in connection with any investigation or other inquiry relating to an HSR Filing and the transactions contemplated by this Agreement; (b) keep the other Party or its counsel informed of any material communication received from or given to the FTC or DOJ relating to the HSR Filing and the transactions contemplated by this Agreement (and provide a copy to the other Party if such material communication is in writing); (c) permit the other Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel concerning, any written submission or filing (and documents submitted therewith) intended to be given to the FTC or DOJ; and (d) not participate in any substantive meeting or substantive discussion with FTC or DOJ in respect of investigation or inquiry concerning the transactions contemplated hereby unless it consults with the other party in advance and, except as prohibited by applicable Law or Governmental Authority, gives the other party the opportunity to attend and participate thereat; provided , that after good faith consideration of any input from Assembly, Allergan shall make the final determination as to the appropriate strategy relating to any filing or submission that is necessary under the HSR Act, including with respect to any filings, notifications, submissions and communications with or to the FTC or the Antitrust Division of the DOJ.

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

13.14. Further Assurances . Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.

13.15. No Strict Construction . This Agreement shall be construed as if it were drafted jointly by the Parties.

13.16. Headings . The headings herein are for convenience purposes only and shall not be used to interpret any of the provisions hereof.

13.17. Counterparts . This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission or by electronic mail in "portable document format" (".pdf") shall be as effective as an original executed signature page.

13.18. Non-Exclusive Remedies . The remedies set forth in this Agreement shall be in addition to, and shall not be to the exclusion of, any other remedies available to the Parties at Law, in equity or under this Agreement; provided , that in assessing the remedies available to Assembly, the rights transferred to Assembly following a termination of this Agreement shall be taken into account and in assessing the remedies available to Allergan, any exercise of the right of set-off, and, any reduction in Allergan's payment obligations to Assembly and the imposition of payment obligations on Assembly to Allergan, on certain terminations of this Agreement, as applicable, shall be taken into account.

[Signature page follows]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF this Agreement has been signed by the duly authorized representatives of the Parties as of the Execution Date.

SIGNED for and by behalf of
ASSEMBLY BIOSCIENCES, INC.

/s/ Derek A. Small

Derek A. Small, President & CEO
Print Name and Title

SIGNED for and by behalf of
ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED

/s/ Tom Daunt

Tom Daunt, Director
Print Name and Title

[Signature Page to Research, Development, Collaboration and License Agreement]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Exhibit A

Indications

Irritable bowel syndrome – constipation, diarrhea and mixed (IBS-c, IBS-d and IBS-m)
Ulcerative colitis (UC)
Crohn's disease
[* * *]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 1.1
201 Compound Candidate (Initial Indication - ulcerative colitis)

201 Compound Candidate is under development. [* * *] for 201 Compound Candidate (Initial Indication - ulcerative colitis) [* * *]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 1.2
301 Compound Candidate (Initial Indication - Crohn's disease)

301 Compound Candidate is under development. [* * *] for 301 Compound Candidate (Initial Indication - Crohn's disease) [* * *]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 1.103

Knowledge

Knowledge – Assembly
[* * *]

Knowledge – Allergan
[* * *]

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 1.108
Licensed Compound Patents

[* * *]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

[* * *]

Patent/ Application Number	Patent Filing Date	Title	Remarks
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 1.153

R&D Plan

[* * *]

RESEARCH AND DEVELOPMENT PLAN

OUTLINE

[* * *]

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 8.5.1(c)

Press
Releases

NEWS RELEASE

CONTACTS:

ALLERGAN INVESTORS:
Lisa DeFrancesco
(862) 261-7152

ASSEMBLY INVESTORS:
Lauren Glaser
(415) 521-3828

MEDIA:
Mark Marmur
(862) 261-7558

MEDIA:
Barbara Lindheim
(212) 584-2276

Allergan Enters Into Licensing Agreement with Assembly Biosciences to Obtain Worldwide Rights to Microbiome Gastrointestinal Development Programs

— Expands Allergan's Innovative GI Pipeline with ABI-M201 and ABI-M301, Preclinical Compounds Targeting Ulcerative Colitis and Crohn's Disease, as well as Future Compounds for Irritable Bowel Syndrome —

DUBLIN, IRELAND and INDIANAPOLIS, INDIANA (USA) – January 9, 2017 – Allergan plc (NYSE: AGN) and Assembly Biosciences, Inc. (NASDAQ: ASMB) today announced that Allergan has entered into a research, development, collaboration and license agreement for the worldwide rights to Assembly's microbiome gastrointestinal (GI) development programs. The agreement provides Allergan with worldwide rights to preclinical compounds ABI-M201 and ABI-M301, targeting ulcerative colitis (UC) and Crohn's disease (CD), as well as two additional compounds to be identified by Assembly for Irritable Bowel Syndromes (IBS); with Diarrhea (IBS-D), with Constipation (IBS-C) or Mixed (IBS-M).

Under the terms of the agreement, Allergan will make an upfront payment to Assembly of $50 million for the exclusive, worldwide rights to develop and commercialize the UC, CD and IBS compounds. Additionally, Assembly will be entitled to receive success-based development and commercial milestone payments. Assembly is also eligible to receive tiered royalties based on net sales. Allergan and Assembly will generally share development costs through proof-of-concept (POC) studies, and Allergan will assume all post-POC development costs.

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

The Assembly 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 and a patent-pending delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract.

"The Microbiome — the microbial populations that colonize the human body — is rapidly gaining prominence in numerous fields of research relevant to Allergan's key areas of focus, including GI disorders," said David Nicholson, Chief R&D Officer, Allergan. "Assembly is well positioned to identify and select unique therapeutic candidates and deliver them to the optimal site in the GI tract through a novel oral delivery system."

This collaboration reinforces Allergan's commitment to building a robust portfolio through Open Science. As with most of our agreements, we enter into partnerships which, through creative structures, leverage the expertise of our partners to potentially deliver innovative treatments for improved patient care.

"Our fully-integrated microbiome platform reflects Assembly's commitment as one of the leaders in the exciting new field of microbiome therapeutics, which has the potential to address a range of diseases in entirely new ways," said Derek Small, Chief Executive Officer of Assembly. "We are delighted to enter into this collaboration with Allergan, an innovator in GI, as we work together to realize the potential of microbiome therapies and provide treatments to patients with serious GI disorders."

"Inflammatory diseases of the GI tract, including Crohn's disease and ulcerative colitis, are debilitating conditions that remain poorly treated for many patients," said Martin J. Blaser, MD, Director of the New York University Human Microbiome Program. "Therapies leveraging the microbiome may be able to address these disorders in fundamentally new ways. I am encouraged that microbiome innovators such as Assembly and Allergan are working to convert their promising new approaches into clinically useful products to help these patients."

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The transaction is expected to close in the first quarter of 2017, subject to customary closing conditions, including the expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

About Crohn's Disease and Ulcerative Colitis [1,2]

Crohn's disease and ulcerative colitis are chronic inflammatory conditions of the gastrointestinal tract. Crohn's disease most commonly affects the end of the small bowel (the ileum) and the colon (also called the large intestine), but it may affect any part of the gastrointestinal (GI) tract, from the mouth to the anus. Ulcerative colitis is limited to the colon. It is estimated that 1.6 million Americans and 2.2 million Europeans suffer from Crohn's disease or ulcerative colitis. The majority of patients are diagnosed in young adulthood and these incidence rates continue to rise, which will continue to place a significant burden on global healthcare systems.

About Allergan plc

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model – Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceuticals, devices and biologic products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 70+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 16,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at www.Allergan.com .

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

About Assembly Biosciences

Assembly Biosciences, Inc. is a clinical-stage public biotechnology company developing two innovative platform programs: an HBV program advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and a microbiome program developing novel oral biotherapeutics designed to address diseases associated with the microbiome. Assembly's HBV program is advancing multiple drug candidates with the aim of increasing cure rates in patients with chronic HBV. 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 and a patent-pending delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract. Assembly is developing a robust pipeline of product candidates in multiple disease indications. For more information, visit assemblybio.com.

Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting future clinical results based on prior clinical results; the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2015 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 (certain of such periodic public filings having been filed under the "Actavis plc" name). Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

The information in this press release contains estimates and other forward-looking statements regarding future events, including statements about the clinical and therapeutic potential of Assembly's development programs, its ability to receive payments from Allergan under the collaboration agreement and plans, strategies, and intentions related to Assembly's programs. Certain forward looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as "developing," "potential," "projected," "positioned," "eligible" or "may." Such forward-looking statements, which Assembly intends to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the components, timing, cost and results of clinical trials and other development activities involving Assembly's product candidates (including those licensed to Allergan); the unpredictability of the preclinical and clinical development of Assembly's product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; Assembly's anticipated capital expenditures, Assembly's estimates regarding its capital requirements, and its need for future capital; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the heading "Risk Factors" in Assembly's Annual Report on Form 10-K for the year ended December 31, 2015, and Quarterly Report on Form 10-Q for the quarter ending September 30, 2016 filed with the Securities and Exchange Commission. It is not possible for Assembly management to predict all risks nor can Assembly assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements Assembly may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

[1] Crohn's & Colitis Foundation of America: What are Crohn's Disease and Ulcerative Colitis?: http://www.ccfa.org/what-are-crohns-and-colitis/

[2] Nature Reviews Gastroenterology & Hepatology 12, 720-727 (2015): http://www.nature.com/nrgastro/journal/v12/n12/full/nrgastro.2015.150.html

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 8.5.2

Confidential Treatment of Agreement – [Redacted Agreement]

[This schedule 8.5.2 is reflected in the form of this agreement to which this Schedule is attached]

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CONFIDENTIAL TREATMENT REQUESTED
BY ASSEMBLY BIOSCIENCES, INC.

Schedule 11.2
Exception to Reps & Warranties

These Schedules are qualified in their entirety by reference to specific provisions of the Agreement and are not intended to constitute, and shall not be construed as constituting, any representation or warranty of Assembly, except as and to the extent expressly provided in the Agreement. The representations and warranties set forth in Sections 11.1 and 11.2 of the Agreement are the only representations and warranties of any kind being made to Allergan. Matters, facts or items disclosed in any section of these Schedules shall be deemed to be disclosed with respect to any other section of these Schedules.

[* * *]

[* * *] The confidential content of this Exhibit 10.1 has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

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: May 8, 2017

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: May 8, 2017

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended March 31, 2017 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

Date: May 8, 2017

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended March 31, 2017 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, David J. Barrett, Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ David J. Barrett
David J. Barrett
Chief Financial Officer and Chief Operating Officer

Date: May 8, 2017