UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015
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 specified in its charter)

Delaware	**2834**	**20-8729264**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

101 Sixth Avenue, Ninth Floor, New York, New York 10013
(Address of Principal Executive Offices)

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

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Name of Exchange on which Registered**
Common Stock, $0.001 Par Value	Nasdaq Capital Market

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer x
Non-accelerated filer ☐	Smaller reporting company ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2015, was approximately $236.86 million. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Nasdaq Capital Market on June 30, 2015. For purposes of making this calculation only, the registrant has defined affiliates as including only (i) directors, (ii) executive officers, and (iii) shareholders that hold greater than 10% of the voting stock of the registrant, in each case, as of June 30, 2015.

As of March 7, 2016 there were 17,225,662 shares of the registrant's common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference to portions of the definitive proxy statement for the Company's Annual Meeting of Stockholders to be held in 2016, to be filed within 120 days of the registrant's fiscal year ended December 31, 2015.

EXPLANATORY NOTE

The Company meets the "accelerated filer" requirements as of the end of its 2015 fiscal year pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the Company (as a smaller reporting company transitioning to the larger reporting company system based on its public float as of June 30, 2015) is not required to satisfy the larger reporting company requirements until its first

quarterly report on Form 10-Q for the 2016 fiscal year and thus remains eligible to use the scaled disclosure requirements applicable to smaller reporting companies under Item 10 of Regulation S-K under the Securities Act of 1933, as amended, in this Annual Report on Form 10-K.

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References to Assembly Biosciences, Inc.

Throughout this Annual Report on Form 10-K, the "Company," "Assembly," "we," "us," and "our," except where the context requires otherwise, refer to Assembly Biosciences, Inc. and its consolidated subsidiary, and "our board of directors" refers to the board of directors of Assembly Biosciences, Inc.

Forward Looking Information

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- the initiation, timing, progress and results of pre-clinical studies and clinical trials, and our research and development programs;
- our plans to develop and commercialize our product candidates;
- our ability to establish and maintain collaborations;
- our ability to obtain additional funding;
- the timing or likelihood of regulatory filings and approvals;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the rate and degree of market acceptance and clinical utility of our products;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

Item 1. Business

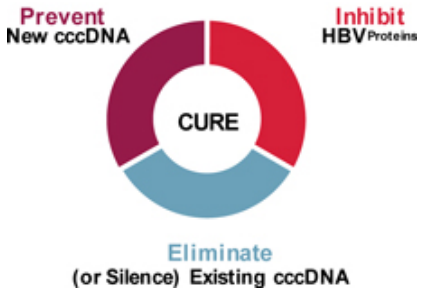
Overview

We are a 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 biological therapeutics, which are designed to restore health to a dysbiotic microbiome. Our HBV-cure program is aimed at increasing the current low cure rates for patients with HBV and is pursuing several drug candidates that inhibit multiple viral targets throughout the HBV lifecycle. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate a number of HBc functions. Our Microbiome Program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under cGMP conditions, and a patent pending delivery system, GEMICEL^{TM}, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal, or GI tract. The lead program from this platform, AB-M101, is in development for the treatment of C. difficile- infections (CDI). Using its microbiome platform, the Company is developing additional product candidates.

Business Strategy

Assembly is currently focused on advancing science and enhancing the health and well-being of patients with hard-to-treat infectious diseases by building a world class company focused on serious conditions that are inadequately treated. This commitment drives our efforts to forge a new and different path to treating these conditions, inspired by the needs of millions of affected patients with our platform technologies that may have the potential to overcome the limitations of conventional approaches. We have two promising proprietary technology platforms: a portfolio of novel, potentially curative CpAMs for HBV and a novel class of oral biological drugs designed to restore a dysbiotic microbiome. Both of these conditions include substantial numbers of patients with intractable disease who cannot be cured by current therapies. We intend to progress these programs using a variety of strategic arrangements, including potentially collaborations, licenses, partnerships and other types of business arrangements. These may provide non-dilutive funding for drug development, as well as clinical development and commercial expertise.

HBV-Cure Program



The target of our HBV cure program is a clinical cure for hepatitis B virus, a pathogen that infects approximately 350 million people worldwide and is associated with an estimated 650,000 deaths each year. Our HBV-Cure research team is working on discovering and developing multiple CpAMs with the potential to modulate the HBV core protein – an essential polyfunctional viral protein - at multiple points in the viral lifecycle.

HBc protein is involved in several steps of the HBV lifecycle and is essential for HBV's continued regeneration and prolonged survival. Modulation of HBc with Assembly's CpAMs has demonstrated preclinical proof of principle. In multiple cell-based models CpAMs selectively reduced viral load, which is the amount of infectious viral particles released from infected cells and modulated closed circular covalent DNA (cccDNA), a special DNA structure that arises in the cell nucleus of some viruses and is associated with viral persistence. Different CpAMs appear to have differentiated mechanisms, giving us a potential pipeline of differentiated early-stage products. This enables us to pursue both monotherapy and combination therapies that include molecules with differentiated mechanisms, potentially facilitating the achievement of improved cure rates. The goal is to eradicate the infection with an orally-administered regimen. We believe that Assembly is uniquely positioned to execute on this strategy, with a senior scientific team that has over 30 years of combined experience working on HBV.

Background

Hepatitis B virus (HBV) is a chronic infectious disease of the liver. It is a leading global cause of chronic liver disease and liver transplants. The World Health Organization estimates that nearly 350 million people worldwide, or approximately 6% of the world's population, are infected with HBV. An estimated 10 to 30 million people are newly infected each year and 650,000 people die annually from HBV-related liver disease. The Centers for Disease Control and Prevention (CDC) has reported that almost two million people in the United States have been infected with HBV. HBV is an underappreciated global epidemic with twice as many people infected and with a higher rate of mortality and morbidity than hepatitis C virus and HIV infections combined. While many HBV patients currently receive treatment, the majority do not, partly due to the lack of effective therapies. The cure rate with current therapies is estimated at only 3-5%. Despite the low rate of diagnosis and treatment, the current market for HBV therapies is estimated at $3.2 billion, with significant growth expected in the years ahead as more effective drugs are developed and launched.

Current Treatments

Current therapeutic options for HBV include:

- **Antiviral medications.** Several antiviral medications - including lamivudine (Epivir®), adefovir (Hepsera®), telbivudine (Tyzeka®) and entecavir (Baraclude®) – effectively reduce circulating virus. Chronic therapy with these agents results in reduced liver inflammation and fibrosis. Unfortunately, viral replication resumes when therapy is stopped.

- **Interferon alfa-2b (Intron A).** This synthetic version of a substance produced by the body to fight infection is used mainly for young people with hepatitis B who don't want to undergo long-term treatment or who might want to become pregnant within a few years. It is administered by injection. Side effects may include flu-like symptoms and depression.

Our HBV Focus: Leveraging HBV Core Protein to Achieve a Cure using Core Protein Allosteric Modulators (CpAMs)

HBV is a DNA-virus that establishes an intra-nuclear reservoir of cccDNA, which sustains infection in the liver through chronic and occult hepatitis B infection. No current oral therapies can target cccDNA activity directly, and thus orally available molecules that can modulate cccDNA are highly sought in the HBV field. A key focus of Assembly's cure effort is the HBV Core protein (HBc), a highly conserved viral structural protein that has no human homologue and is involved in numerous aspects of the HBV lifecycle, including interaction with the viral cccDNA. Assembly has discovered multiple novel series of CpAMs, which are small molecules that directly target and allosterically modulate a number of HBc functions. Assembly's HBV pipeline therefore offers the potential for both first in class and best in class opportunities for developing agents that target multiple aspects of the viral lifecycle, such as HBc/cccDNA interactions. We believe that our approaches to targeting multiple aspects of HBc provide a promising foundation for developing a clinical cure for HBV.

To successfully eradicate HBV infections, researchers need to address both the "downstream" inhibition of HBV viral replication and the "upstream" part of the lifecycle that reflects cccDNA activity. We define downstream inhibition of the HBV lifecycle as targeting HBV from the point of formation of the viral capsid to the release of viral particles from the cell for re-infection. We believe that our ability to develop CpAMs that target multiple aspects of the viral lifecycle may allow us to develop combination regimens that achieve better cure rates by targeting both target "upstream" and "downstream" components. Other core competencies and competitive advantages we bring to our lead program include our knowledge of HBV biology, our proprietary enabling assays, our highly experienced chemistry and our relevant clinical expertise.

A clinically and preclinically accepted benchmark for therapeutic agents aiming to affect cccDNA activity is the level of expression of several key viral antigens. On this basis, Assembly's CpAMs have shown preclinical proof of principle. In a variety of cell culture models, CpAMs have demonstrated the ability to reduce production of viral antigens: HBV E antigen (HBeAg) and HBV S antigen (HBsAg). Sustained (post treatment) inhibition of HBsAg in patients is considered a functional cure, and is a key endpoint for clinical development.

Our clinical strategy encompasses testing CpAMs as monotherapy and in combination. Our access to multiple classes of CpAMs allows us to explore their activity in combination across CpAM classes and with other classes of HBV therapies. Our planned clinical program will start with Phase I (safety) studies of CpAMs as single agents in healthy volunteers. Phase IB studies in patients would include assessments of CpAMs as single agents and in combination with approved therapies for HBV. The Phase II studies would explore duration of therapy in dose finding single agent and combination studies across CpAM classes and with other classes of therapy.

Assembly is planning to complete its preclinical studies in 2016. Clinical trials with its first lead molecule are planned to commence in the second half of 2016. Assembly's CpAM platform provides opportunities to create a pipeline encompassing multiple generations of antiviral drugs, and Assembly plans to advance second and third generation CpAMs into clinical development in 2017. Assembly also has research programs assessing other novel targets for HBV that are complementary to our programs focusing on Core protein.

License Agreement and Intellectual Property

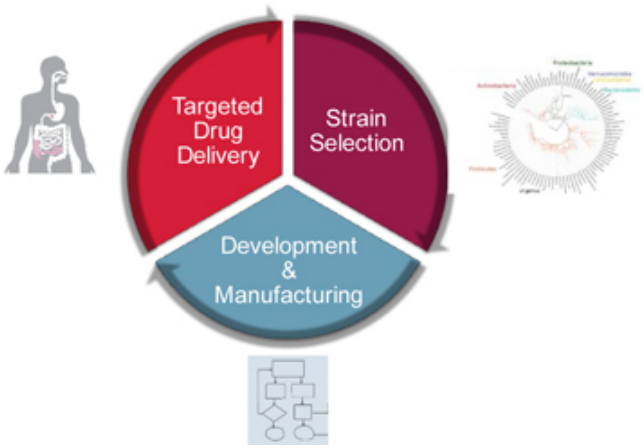
On September 3, 2013, we entered into a license agreement (the "IURTC License Agreement") with Indiana University Research and Technology Corporation ("IURTC") to acquire the rights to develop and commercialize products associated with multiple patent applications covering aspects of our HBV program held by IURTC. The licensed intellectual property includes platform patent applications covering aspects of HBc, our novel mechanisms of action, methods of treatment and the novel drug development assays our team is creating. As part of this agreement, we are obligated to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The total amount of all potential future milestone payments at the end of 2015 was $825,000. None of the criteria for these milestones have yet been met. Under the IURTC License Agreement, we are also obligated to pay IURTC royalty payments based on net sales of the licensed technology ranging from 0.5% to 1.75%.

In addition, the IURTC License Agreement requires an annual diligence maintenance fee as follows:

2015	$	50,000
2016 through the year in which first commercial sale occurs	$	75,000
Year following first commercial sale and all subsequent years	$	100,000

We also have filed composition of matter patent applications for our novel CpAM agents. We expect to file additional patent applications going forward.

Microbiome Program Platform



Background

Our Microbiome Program is based on the oral targeted delivery of novel microbiome-based therapies in a patent pending oral formulation, called Gemicel™ applying our novel coating and encapsulation technology that allows for targeted delivery of complex agents to select regions of the gastrointestinal, or GI, tract. Using this proprietary delivery platform, we aim to deliver selected combinations of monoculture strains of beneficial bacteria in novel "synthetic formats" to the GI tract. Our first indication is recalcitrant CDI, and we plan to leverage our Microbiome program into multiple other areas of high relevance to gut microbiome disorders including other infectious disease and GI disorders, indications in Oncology, Diabetes, Obesity, other Metabolic disorders, and CNS disorders.

Our approach builds upon experience reported in the literature of successfully treating CDI and other disease indications with fecal material transplants or FMT, and seeks to provide a potentially curative therapy using a far more "drug like" approach that delivers targeted and specific microbiome therapies in an oral capsule.

CDI is our first indication. In recent years, there has been increasing interest in the therapeutic potential of the human microbiome - the billions of microbes living in and on people - to impact health and disease. An early and obvious target was CDI, the most common nosocomial, or hospital acquired, infection, which has become a significant medical problem in hospitals and long-term care facilities as it becomes increasingly resistant to common antibiotics. CDI is estimated to afflict more than 500,000 people each year in the US alone. It is a serious illness resulting from infection of the inner lining of the colon by *C. difficile* bacteria, which produce toxins that cause inflammation, severe diarrhea and, in the most serious cases, death. Certain subpopulations, such as older patients, transplant patients, patients taking concomitant antibiotics and cancer patients, are at a higher risk of contracting CDI. Patients typically develop CDI from the use of broad-spectrum antibiotics that disrupt normal gastrointestinal (gut) flora, thus allowing *C. difficile* bacteria to flourish unchecked and produce toxins. *C. difficile* is a spore-forming bacterium. Spores released into the hospital environment by patients with active disease can survive for months on dry surfaces in hospital rooms such as beds and doors. It also spreads when spores from other patients are transmitted on the hands and clothing of healthcare workers.

Current Treatments

Current therapeutic options for CDI include fidaxomicin, oral vancomycin and the off-label use of metronidazole. However, approximately 35% of patients initially treated with these drugs either fail to respond or do not achieve a sustained response. About 50% of initially non-responsive patients fail to achieve a sustained response from second and third line treatment. Because of the difficulties in achieving a sustained response to treatment, we estimate that, in the U.S. alone, there are more than 800,000 treatments per year for CDI.

Microbiome Therapies May Represent an Effective New Treatment Option for CDI

There has been considerable experience reported in the literature of successfully treating CDI with FMT from healthy individuals. FMT is believed to act by restoring a healthy balance of microbes in the gut. Despite its clinical efficacy, broad acceptance of FMT has been problematic, because of the possibility of unknown and potentially damaging constituents in human derived materials. Other options have been sought. Preliminary CDI studies using selected bacterial strains or bacterial spores from processed FMT have been promising. These reports have demonstrated a significant and growing precedent of successful cures in patients who had failed all prior treatment, and provide a path to potentially curative therapy using a targeted and specific microbiome therapy-one that can achieve the therapeutic benefits of FMT but in a form that is more predictable, safe and drug-like.

Proof-of-concept for this approach was demonstrated using a preparation of fecal material from normal donors that contained only bacterial spores. In a U.S. Phase IB study, a single oral dose of spores administered in multiple capsules produced a 90% sustained response in 30 CDI patients who had failed three prior regimens. In addition, the carriage of antibiotic resistant bacteria substantially declined in these patients. In another small study, a selection of 32 specific viral strains achieved a sustained response in two elderly patients with chronic refractory CDI.

The concept has also been validated in animal studies. Several recent publications have demonstrated that administering even a few strains of bacteria may be sufficient to have a curative effect in mouse models of CDI, and one study suggested that even a single strain can be effective. In addition, testable mechanisms of how commensal bacteria may inhibit the growth and persistence of C. *difficile* have been reported or postulated.

Our CDI program is based on the premise that an oral capsule containing specific bacteria grown in monoculture and manufactured under pharmaceutical-like GMP conditions (in effect a ‘synthetic’ biologic product), has the potential to provide the therapeutic benefits of FMT therapy in a form that is economically viable and scalable for use in first line, as well as in second and third line treatment. In contrast, the commercial and clinical provision of whole or processed feces would require the provision of, or the purification and/or extraction from, human donor material, and as such is highly unlikely to be considered feasible except for a relatively small number of refractory CDI patients who have failed antibiotic treatment at least three times.

However, the development of a ‘synthetic’ bacterial product for the treatment of CDI, while promising, presents several basic challenges.

The first challenge is the selection of bacterial strains likely to be effective. We believe that our ongoing bacterial discovery program enhances the probability that we will identify strains that will be effective in humans. This program involves collaboration with leading academic medical centers with relevant expertise, and includes special methods of identifying colonic strains from CDI patients receiving FMT, along with bioinformatic assessment of relevant data from resolved patients, and the isolation, culture, and screening of promising strains.

A second challenge is the effective and reliable oral delivery of sufficient of organisms to the colon using a minimal number of capsules. To accomplish this, we in-licensed a delivery technology we call Gemicel™. Gemicel is a novel coating and encapsulation technology that allows controlled delivery of an oral formulation specifically designated to achieve targeted fpulsed release to selected portions of the GI system tract by leveraging differences in their pH environments.

We have demonstrated that our coating technology, which can be applied at body temperature ranges under aerobic or anaerobic conditions, does not cause any loss of a wide range of viable microorganisms. We have also demonstrated *in vitro* that, under conditions commonly accepted as representing conditions in each section of the GI tract lumen, the formulation can deliver its contents to the targeted sites. The results of a clinical scintigraphy study of Gemicel in healthy volunteers conducted in 2015 demonstrated that Gemicel can effectively release a bolus therapeutic payload at specific locations in the lower GI tract, including the ileum and ascending colon, two locations especially relevant for the treatment of *C. difficile* pathogens. The data were generated in three clinical cohorts that used radioisotope-based scintigraphy to precisely image the drug delivery properties of Gemicel.

A third challenge is achieving successful process, scale up, and reliable and economic manufacture of the strains we select for use in CDI therapy for clinical trials and, ultimately, commercialization. The Assembly team has considerable experience in industrial scale production of bacteria under pharmaceutical-like Good Manufacturing Practice (GMP) requirements, and there are several commercial scale vendors we have identified to facilitate this activity. However certain bacteria can be very difficult to freeze-dry (lyophilize) for encapsulation, and some can be very difficult to grow at a large scale. We believe that it is feasible to mitigate both clinical, regulatory and manufacturing risk by carefully selecting strains for clinical development that are effective in our preclinical assessments, that do not carry antibiotic resistance or virulence genes, and that can be lyophilized and grown at scale under standard anaerobic and/or aerobic conditions as required.

We anticipate that our clinical development program for CDI using systematically selected, bacterial strains will encompass both first line as well as second and third line treatment. We expect that our first clinical trial will be in CDI patients who have relapsed after two or three standard antibiotic regimens. We will explore various regimens for further clinical development in these initial studies. We plan to complete our IND enabling studies in 2016 and then initiate Phase Ib study for our lead product candidate AB-M101, in the second half of 2016.

Depending on the progress and success of our CDI program we may decide to further leverage our discovery program and formulation technology to pursue other microbiome-related indications such as inflammatory bowel disease, irritable bowel syndrome, and metabolic diseases, as new data becomes available clarifying the relationship of the gut microbiome to these conditions.

License Agreement and Intellectual Property

On November 8, 2013, we entered into a License and Collaboration Agreement with Therabiome, LLC, for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive release platform technology. Under the agreement, Therabiome granted Assembly the exclusive worldwide license, with rights to sublicense, to develop the intellectual property for commercialization (a) in the use of bacteria, complex proteins, viral antigens and small molecules by oral delivery in (i) gastro-intestinal dysbiosis, including but not limited to C. *difficile infections*, irritable bowel syndrome-constipation and inflammatory bowel disease, (ii) auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus, and (iii) orally delivered vaccines, including viral and bacterial, and (b) any oral delivery of small molecules using the licensed intellectual property. We will be solely responsible for all research and development activities with respect to any product we develop under the license.

For the license, we paid Therabiome an upfront non-refundable license fee of $300,000. In September 2014, we paid Therabiome $100,000 upon the occurrence of the first proof of principle for a bacteria strain. We will be required to pay an additional $100,000 upon the occurrence of the proof of principle for a virus. We must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform, for U.S. regulatory milestones, depending on whether the milestone occurs before the filing of the first new drug application, or NDA, for a product or after the first, second or third NDA filings, as follows:

Regulatory and Clinical Milestones	
Upon the filing of an IND with the FDA:	$100,000 - $130,000
First dose first patient - Phase I Clinical Trial	$250,000 - $325,000
First dose first patient - Phase II Clinical Trial	$500,000 - $650,000
First dose first patient - Phase III Clinical Trial	$750,000 - $975,000
Upon filing of an NDA or BLA with the FDA	$1,000,000 - $1,300,000
Upon marketing approval by the FDA	$3,000,000
Upon approval of a supplemental NDA (sNDA) for a new Indication, in the U.S	$1,000,000

We also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region, and which depend on whether the milestone occurs before the filing of the first NDA filing or after the first, second or third NDA filings. These payments will be: one-third of the U.S. milestones paid upon a foreign equivalent of an investigational new drug application, or IND and marketing approval for each product in the European Union or Japan; 10% of the U.S. milestones paid upon a foreign equivalent of an IND and marketing approval for each product in China; 10% of the U.S. milestone paid upon marketing approval for each product in India and Brazil; and 1% of the U.S. milestone paid upon marketing approval for each product in all other countries. We also must pay Therabiome royalties on annual net product sales in the low to mid-single digit percentages plus, once annual net sales exceed two specified thresholds, a one-time cash payment upon reaching each threshold.

Government Regulation

Government authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

U.S. drug approval process

In the U.S, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and untitled letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of a new drug application, or NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an Investigational New Drug application (IND). Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase 2:* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3:* The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Additionally, IND safety reports must be submitted for serious and unexpected suspected adverse reactions, findings from animal or *in vitro* testing or other studies that suggest a significant risk in humans, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently $2,374,200 and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $114,450 per product and $585,200 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the FDA has committed to review most applications for non-priority products within 10 months, and most applications for priority review products, that is, drugs that the FDA determines represent a significant improvement over existing therapy, within six months. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each trial may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA's evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA. Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including Risk Evaluation and Mitigation Strategies, or REMs, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast track designation

The FDA is required to facilitate and expedite the development and review of drugs that are intended for the treatment of serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address the unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review

Under FDA policies, a product candidate may be eligible for priority review, a review generally within a six-month time frame from the time a complete application is received. Products regulated by the FDA's Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they are intended for treatment of a serious or life-threatening condition and provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. A fast track designated product candidate would ordinarily meet the FDA's criteria for priority review.

Accelerated approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough therapy designation

Under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies also may be eligible for priority review. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product and indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity — if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Pediatric information

Under the Pediatric Research Equity Act of 2003, an NDA or supplement to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A sponsor of a new drug also is required to submit to the FDA a pediatric study plan generally 60 days after an end-of-Phase 2 meeting with the agency. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

Combination products

The FDA regulates combinations of products that cross FDA centers, such as drug, biologic or medical device components that are physically, chemically or otherwise combined into a single entity, as a combination product. The FDA center with primary jurisdiction for the combination product will take the lead in the premarket review of the product, with the other center consulting or collaborating with the lead center.

The FDA's Office of Combination Products, or OCP, determines which center will have primary jurisdiction for the combination product based on the combination product's "primary mode of action." A mode of action is the means by which a product achieves an intended therapeutic effect or action. The primary mode of action is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

Often it is difficult for the OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, the OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product.

A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute, to obtain a binding decision as to which center will regulate the combination product. If the sponsor objects to that decision, it may request that the agency reconsider that decision.

Other regulatory requirements

Any drug manufactured or distributed by us pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements, including REMs, as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Additional provisions

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

Foreign Regulation

In order to market any product outside of the U.S., we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations changed or what the effect of such changes, if any, may be.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the trials required to obtain FDA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of us placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we may receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act was enacted in the U.S. in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Competition

The pharmaceutical and biotechnology industry is very competitive and the development and commercialization of new drugs and biologics is influenced by rapid technological developments and innovation. We face competition from several companies developing and commercializing products that will be competitive with our drug candidates, including large pharmaceutical and smaller biotechnology companies. Additionally, new entrants may potentially enter the market. For our HBV cure program, potential competitors include Johnson & Johnson, Roche, Bristol Myers Squibb Co., GlaxoSmithKline PLC, Gilead Sciences Inc., and Arbutus Biopharma Corp., among others. Additionally, we may face competition from currently available treatments for HBV. For CDI, our microbiome program's first indication, our competitors include Seres Therapeutics, Inc. and Merck & Co, Inc. For our microbiome program more generally, our competitors include Johnson & Johnson, Novartis International AG, Abbvie Inc. and Pfizer Inc. Some of the competitive development programs from these companies may be based on scientific approaches that are similar to our approach, and others may be based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization of products similar to ours or that otherwise target indications that we are pursuing.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for pre-clinical and clinical testing, as well as for commercial manufacture of any products that we may commercialize.

Financial Information

We have not derived any revenue from product sales to date as it currently has no products.

Research and Development Expense

Our research and development expenses, excluding stock-based compensation expense, was $15,100,205 for fiscal year 2015, of which $10,810,517 was expended on the HBV Program and $4,296,309 was expended on our Microbiome Program, offset by $6,621 credit due to termination of VEN 307 study in 2014.

Employees

As of March 7, 2016, we had 51 employees, and various consultants and multiple research contract research organizations with whom we have contracted.

Corporate History

We were incorporated in Delaware in October 2005 under the name South Island Biosciences, Inc. (which was changed to Ventrus Biosciences, Inc. in April 2007). On July 11, 2014, we merged with Assembly Pharmaceuticals, Inc., a private company (the "Merger"). In connection with the Merger, we changed our name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc.

Corporate Information

Our principal executive office is at 101 Sixth Avenue, Ninth Floor, New York, NY, 10013. Our telephone number is (646) 706-5208.

Available Information

Our website address is www.assemblybio.com. We routinely post, or have posted, important information for investors on our website in the "Investor Relations" section. We use this website as a means of disclosing material information in compliance with our disclosure obligations under Regulation FD. Accordingly, investors should monitor the "Investor Relations" section of our website, in addition to following our press releases, SEC filings, presentations and webcasts. We make available free of charge through our website our press releases, Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after electronically filed with or furnished to the Securities and Exchange Commission.

The information contained on our website is not a part of, and should not be construed as being incorporated by reference, into this report.

Information about Segments and Geographic Areas

In accordance with *The Financial Accounting Standards Board (FASB) Accounting Standards Codification, or ASC, Topic 280, Segment Reporting*, we have determined that we operate as one operating segment. Decisions regarding our overall operating performance and allocation of our resources are assessed on a consolidated basis. Our operations and assets are predominantly located in the United States.

Item 1A. Risk Factors

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

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

Risks Related to Our Business

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

To date, we have no approved product on the market and have generated no product revenues. Our prospects are substantially dependent on our ability to develop and commercialize our HBV and microbiome therapies. Unless and until we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our product candidates and will not have product revenues. We will have to fund all of our operations and capital expenditures from cash on hand, any licensing fees and any future securities offerings or debt financings and any fees we may generate from out-licensing or other strategic arrangements.

In addition, all of our product candidates are in an early stage of development and their risk of failure is high. The data supporting our drug discovery and development programs are derived from either laboratory or pre-clinical studies. We cannot predict when or if any one of our product candidates will prove effective or safe in humans or will receive regulatory approval. The scientific evidence to support the feasibility of our product candidates is limited, and many companies, some with more resources than we have, are and may be developing competitive product candidates. For these and other reasons, our drug discovery and development may not be successful and we may not generate viable products or revenue.

We depend entirely on the success of product candidates from our HBV and microbiome programs, both of which are in late pre-clinical development. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, product candidates from either of our current programs or any of our other product candidates we may subsequently identify.

Our lead compounds for HBV and microbiome therapies are our only current product candidates. Both are in preclinical development. Neither of our current product candidates has advanced into a pivotal study, and it may be years before such a study is initiated, if ever. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must successfully meet a number of critical developmental milestones, including:

- developing dosages that will be tolerated, safe and effective;
- demonstrating through clinical trials that the product candidate is safe and effective in patients for the intended indication;
- determining the appropriate delivery mechanism;
- demonstrating that the product candidate formulation will be stable for commercially reasonable time periods; and
- completing the development and scale-up to permit manufacture of our product candidates in commercial quantities and at acceptable prices.

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

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

We were established in October 2005, began active operations in the spring of 2007 and have only a limited operating history. In addition, we have terminated our programs related to our three prior product candidates. Therefore, there is limited historical financial information upon which to base an evaluation of our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We, and Assembly Pharmaceuticals prior to our merger, have generated losses since we began operations and, as of December 31, 2015, the combined company had an accumulated deficit of $164.0 million. We expect to incur substantial additional losses over the next several years as we continue to pursue our research, development, preclinical studies and clinical trial activities. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products unless and until our HBV or microbiome therapies or any other product candidate is approved by the FDA for sale, and we might never generate revenues from the sale of products.

We are not currently profitable and might never become profitable.

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

· continue to undertake research and development to identify potential product candidates;
· continue to undertake preclinical studies and clinical trials for our product candidates; and
· seek regulatory approvals for our product candidates.

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

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

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

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

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

Preclinical studies and clinical testing are expensive, can take many years to complete and their outcome is highly uncertain. Failure can occur at any time during the preclinical study and clinical trial processes due to inadequate performance of a drug candidate or inadequate adherence by patients or investigators to clinical trial protocols.

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

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

· continuing to undertake research and development and preclinical studies and clinical trials;
· participating in regulatory approval processes;
· formulating and manufacturing products; and

· conducting sales, marketing and distribution activities.

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

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

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

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

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins 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 preclinical development.

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

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

We anticipate that we will incur operating losses for the next several years as we continue to develop our HBV therapy and our microbiome platform as well as initiate any development of any other product candidate and will require substantial funds during that time to support our operations. We expect that our current resources will provide us with sufficient capital to fund our operations into the fourth quarter of 2017. However, we might consume our available capital before that time if, for example, we are not efficient in managing our resources or if we encounter unforeseen costs, delays or other issues or if regulatory requirements change. If that happens, we may need additional financing to continue the development of our HBV therapy and our microbiome program. Thereafter, we will need additional capital to fund our operations in the future. However, there is no assurance that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If such event or other unforeseen circumstances occurred and we were unable to raise capital, we could be forced to discontinue product development, sacrifice attractive business opportunities, cease operations entirely and sell or otherwise transfer all or substantially all of our remaining assets.

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

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

We are dependent on a license relationship for each of our HBV 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 total amount of all potential future milestone payments at December 31, 2015 is $825,000. We also are obligated to pay IURTC royalty payments based on net sales of the licensed technology. We are also obligated to pay diligence maintenance fees ($25,000-$100,000) each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year. Our license with Therabiome, LLC, from whom we have licensed 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 our microbiome program. If we fail to comply with similar obligations to any other licensor, it would have the right to terminate the license, in which event we would not be able to commercialize drug candidates or technologies that were covered by the license. Also, the milestone and other payments associated with licenses will make it less profitable for us to develop our drug candidates than if we owned the technology ourselves.

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

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

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

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

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

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

Preclinical and clinical testing required for our product candidates is expensive and time-consuming, and the outcome is uncertain.

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

- the lack of effectiveness during clinical trials;
- the emergence of unforeseen safety issues;
- inability to manufacture sufficient quantities of qualified materials under current Good Manufacturing Practices, or cGMPs, for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients;
- modification of clinical trial protocols;
- changes in regulatory requirements for clinical trials;
- delays, suspension, or termination of clinical trials by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government, institutional review board, ethics committee, or other regulatory delays or clinical holds requiring suspension or termination of the trials.

The results from preclinical testing and early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain or have obtained positive results from preclinical studies or early clinical trials, we might not achieve the same success in future clinical trials. For example, positive results were observed in earlier clinical trials of each of our two prior product candidates, but the subsequent clinical trials were not successful. Further, clinical trials might not provide statistically significant data supporting a product candidate's safety and effectiveness to meet the requisite regulatory approvals.

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

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

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 regulatory approval process. As a result, there can be no assurance that we or any collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

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

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

If a product is approved, any limitation on use that might be necessary due to safety issues could hinder its adoption in the marketplace. In addition, if any product is approved, it could be used against any instructions that we publish that limit its use, which could subject us to litigation.

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

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

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

We will rely exclusively on third parties to formulate and manufacture our product candidates.

We do not have and do not intend to establish our own manufacturing facilities. Consequently, we lack the physical plant to formulate and manufacture our own product candidates for use in our planned clinical trials. In addition, if any product candidate we might develop or acquire in the future receives FDA approval, we will rely on one or more third-party contractors to manufacture our products. If, for any reason, we become unable to rely on any future source to manufacture our product candidates, either for clinical trials or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds for preclinical, clinical and commercial purposes. We might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our products and our financial performance might be materially affected.

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

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

- We might be unable to identify manufacturers for commercial supply on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and, if approved, commercial needs.
- Our contract manufacturers might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- One or more of our contract manufacturers could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. We would not have complete control over third-party manufacturers' compliance with these regulations and requirements.
- If any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors.
- We might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of March 7, 2016, we had 51 employees, and various consultants and multiple contract research organizations with whom we have contracted. We will need to hire or contract with additional qualified personnel with expertise in clinical research and testing, formulation and manufacturing and sales and marketing to commercialize our HBV therapy and our microbiome program or any other product candidate we may seek to develop. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

We might not successfully manage our growth.

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

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

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

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

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

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

Risks Related to Our Regulatory and Legal Environment

We are subject to extensive and costly government regulation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the U.S. and in other countries, there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the Patient Protection and Affordable Care Act and its amendment, the Health Care and Education Reconciliation Act. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

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

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs. If the use of one or more of our or our collaborators' product candidates or approved drugs, if any, harms people, we might be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We expect to obtain clinical trial insurance for our product candidates prior to beginning clinical trials. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we obtain, if any, in the future might not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include product liability insurance covering the sale of commercial products if we obtain marketing approval for our drug candidates in development, but we might be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products, our liability could exceed our total assets and our ability to pay the liability. Any successful product liability claims or series of claims brought against us would decrease our cash and could cause the value of our common stock to decrease.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures, and those of our contractors, for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations. We currently do not carry hazardous materials liability insurance. We intend to obtain such insurance in the future if necessary, but cannot give assurance that we could obtain such coverage.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

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

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

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

- Any patent rights, if obtained, might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the U.S. or in international markets;
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful; and
- Countries other than the U.S. might have patent laws that provide less protection than those governing U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

Our common stock is listed on The NASDAQ Capital Market under the symbol “ASMB.” We might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the “pink sheets” maintained by Pink OTC Markets, Inc. These alternative markets are generally considered to be markets that are less efficient and less broad than The NASDAQ Capital Market.

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 7, 2016, the closing price of our common stock has fluctuated between $4.30 and $101.25 (after giving effect to the 1-for-5 reverse stock split effected on July 11, 2014), with significant volatility after we announced on June 25, 2012 that our prior product candidate iferanserin failed to meet the endpoints of our Phase III trial, and after we announced in February 2014 that our prior product candidate diltiazem demonstrated no significant improvement compared to placebo. Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock might be volatile and subject to wide price fluctuations in response to various factors, including:

- the receipt or loss of required regulatory approvals for our product candidates;
- results of our preclinical studies and clinical trials and other studies involving our product candidates;
- availability of capital;
- future sales of our 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;
- success or failure of our product candidates;
- introduction of new products or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- threatened or actual litigation and government investigations;
- legislative, political or regulatory developments;
- the overall performance of the equity markets;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- general economic conditions;
- changes in interest rates; and
- changes in accounting standards, policies, guidance, interpretations or principles.

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

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

At March 7, 2016, our executive officers, directors and one of our founders beneficially owned approximately 28.3% 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 68.4% of our outstanding voting common stock Therefore, these stockholders, if acting together, have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of certain significant matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

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

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

As a public company, we face increased legal, accounting, administrative and other costs and expenses not faced by private companies. We are subject to the reporting requirements of the Securities Exchange Act of 1934, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act of 2002, and The NASDAQ Capital Market, each of which imposes additional reporting and other obligations on public companies. These rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. Complying with these requirements might divert management's attention from other business concerns, which could have a material adverse effect on our prospects, business, and financial condition.

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

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

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

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

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

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. 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 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease office space for corporate and administrative functions in New York, NY under an agreement with a monthly lease payment of $10,130 that expires in August 2016. We also lease office space in Carmel, IN under a lease agreement that expires in June 2021. The leased locations in New York, NY and Carmel, IN are for corporate and administrative functions supporting both the HBV and Microbiome Programs and are adequate for our current needs.

We lease office and laboratory space in San Francisco, California under a sublease that expires in December 2017. We believe these leased facilities are adequate for our current needs and that additional space will be available in the future on commercially reasonable terms as needed. Research activities for the HBV program are also being conducted at laboratory space leased from Indiana University at Bloomington, IN. We believe these leased facilities are adequate for our current needs.

Item 3. Legal Proceedings

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse effect on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

Our common stock is traded under the symbol "ASMB" and is quoted on the NASDAQ Capital Market. The following table sets forth the high and low sales prices for shares of our common stock, as reported by NASDAQ for the periods indicated (after giving effect to the 1-for-5 reverse stock split effected on July 11, 2014).

	2015		2014	
	High	Low	High	Low
First quarter	$ 17.00	$ 7.25	$ 23.45	$ 6.10
Second quarter	$ 20.50	$ 12.08	$ 8.30	$ 4.25
Third quarter	$ 19.91	$ 9.22	$ 9.68	$ 6.40
Fourth quarter	$ 11.49	$ 7.22	$ 9.47	$ 6.51

On March 7, 2016, the closing price for the common stock as reported on the NASDAQ Capital Market was $6.00.

Holders of Record

As of March 7, 2016, there were 113 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

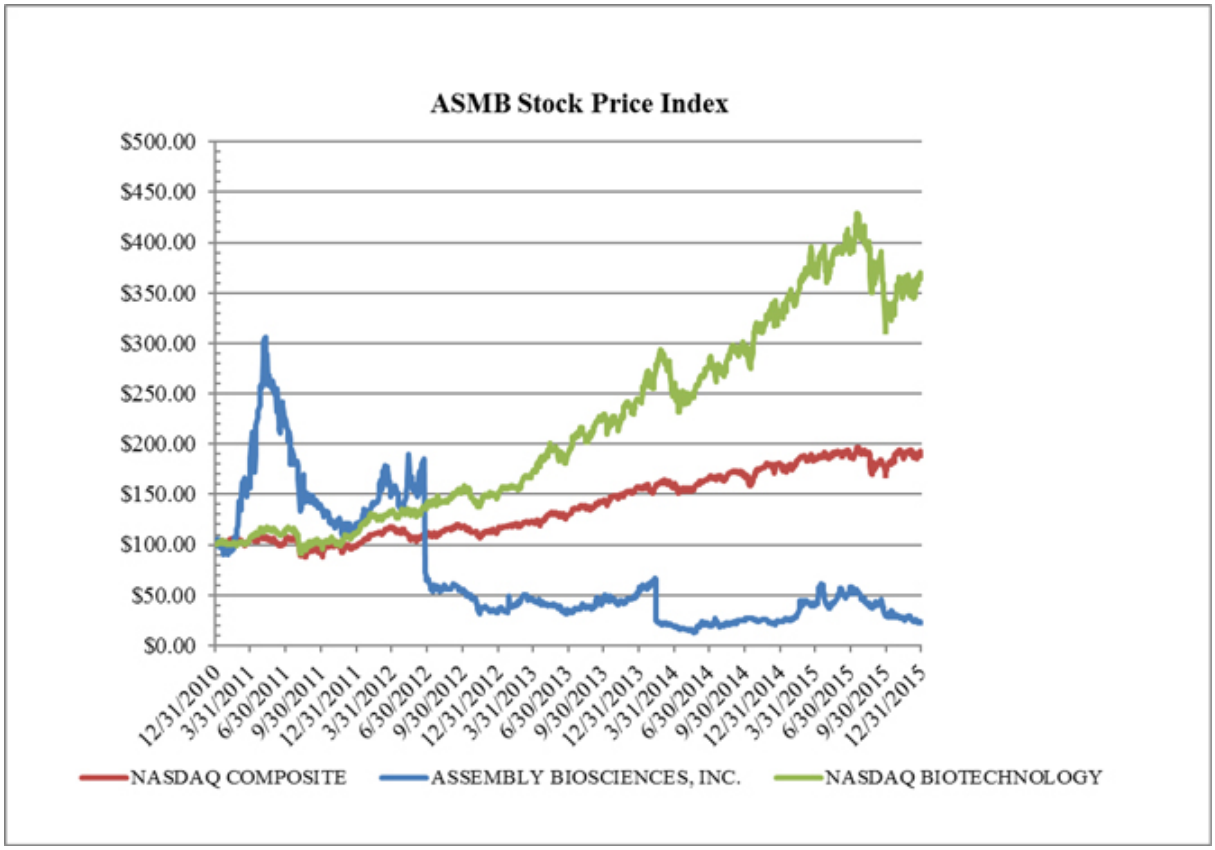
Dividends

We currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business.

Comparative Stock Performance Graph

The information included under the heading "Comparative Stock Performance Graph" in this Item 5 of Part II of this Form 10-K shall not be deemed to be "soliciting material" or subject to Regulation 14A or 14C, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act.

Set forth below is a graph comparing the total cumulative returns of our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes $100 was invested in our common stock and each of the indices on December 31, 2010 and that all dividends, if any, are reinvested.



	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
Assembly Biosciences, Inc.	$ 100	$ 121	$ 32.63	$ 57.7	$ 23.75	$ 22.69
NASDAQ Composite Index	$ 100	$ 98.2	$ 113.82	$ 157.44	$ 178.53	$ 188.75
NASDAQ Biotechnology Index	$ 100	$ 111.72	$ 147.61	$ 244.35	$ 327.02	$ 364.82

Equity Compensation Plans

The following table sets forth the indicated information as of December 31, 2015 with respect to our equity compensation plans :

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights (a)	Weighted average exercise price of outstanding options, warrants, and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by our stockholders:			
2014 Stock Incentive Plan	2,479,666	$ 9.56	8,245
2010 Equity Incentive Plan	266,467	$ 8.14	488,992
Option assumed in Assembly Pharmaceuticals Merger	621,651	$ 2.22	-
Equity compensation plans not approved by our stockholders:			
Consultant Warrants	16,909	$ 30.81	-
Total	3,384,693		497,237

Our equity compensation plan consists of the 2014 Stock Plan and 2010 Plan which were approved by our stockholders. Our equity compensation arrangements that have not been approved by our stockholders consist of warrants to purchase shares of our common stock issued to: Paramount BioCapital as placement agent in our 2008 common stock offering; S.L.A. Pharma to whom we issued a warrant for 13,605 shares of common stock as part of an amendment to the license agreement between us and S.L.A. Pharma for VEN 307 and VEN 308; three consultants; National Securities Corporation as placement agent in our 2010 convertible note offering; the underwriters of our initial public offering and warrants issued to Torreya Capital, our financial advisor in the Merger.

Shelf Registration

On December 30, 2015, we filed a registration statement on Form S-3 with the SEC using a "shelf" registration process, file number 333-208806, which became effective January 19, 2016. Under this shelf registration process, we may from time to time sell any combination of the securities described in the registration statement in one or more offerings for an aggregate offering price of up to $150,000,000. The amount to be registered under the shelf registration consists of up to $150,000,000 of an indeterminate amount of common stock, preferred stock, debt securities, warrants and/or units. There is also being registered under the shelf registration a currently indeterminate number of (i) shares of common stock or other securities of us as may be issued upon conversion of, or in exchange for, convertible or exchangeable debt securities and/or preferred stock registered under the registration statement, or (ii) shares of preferred stock, common stock, debt securities or units as may be issued upon exercise of warrants registered by the registration statement, as the case may be. We have not issued any securities under this registration statement.

Item 6. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the notes thereto included elsewhere in this report.

	December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
(In thousands)					
Balance Sheet Data:					
Total assets	$ 133,744	$ 71,225	$ 27,132	$ 20,556	$ 37,046
Total stockholders' equity	118,742	58,571	24,494	17,810	34,533
Statement of Operations Data:					
Operating expenses	$ 29,656	$ 23,956	$ 19,605	$ 24,855	$ 34,002
Loss from operations	(29,656)	(23,956)	(19,605)	(24,855)	(34,002)
Interest income	1,229	167	201	65	76
Interest expense	-	-	-	-	(419)
Realized loss from marketable securities	(27)	-	-	-	-
Net loss	$ (28,454)	$ (23,789)	$ (19,404)	$ (24,790)	$ (34,345)
Unrealized loss on marketable securities	(822)	-	-	-	-
Loss per Shares Data:					
Basic and dilutive loss per share data	$ (1.81)	$ (3.40)	$ (5.00)	$ (9.74)	$ (17.86)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth in this Form 10-K under "Item 1A. Risk Factors."

Overview

We are a 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 biological therapeutics, which are deigned to restore health to a dysbiotic microbiome. The company's HBV-cure program is aimed at increasing the current low cure rate for patients with HBV and is pursuing several drug candidates that inhibit multiple viral targets throughout the HBV lifecycle. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate a number of HBc functions. The Company's Microbiome Program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under cGMP conditions, and a patent pending delivery system, GEMICEL^{TM}, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal, or GI tract. The lead program from this platform is in development for the treatment of *C. difficile* infections (CDI). Using its microbiome platform, the Company is developing additional product candidates.

The target of our HBV program is to develop novel drugs that achieve higher cure rates than current therapies. To achieve this goal, we are developing a series of new compounds, known as core protein allosteric modulators, or CpAMs, with the potential to modulate the HBV core protein- -at multiple points in the viral lifecycle.

Our Microbiome Program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under cGMP conditions, and a patent pending delivery system, GEMICEL^{TM}, which allows for targeted oral delivery of live biologic as well as conventional therapies to the lower GI tract. The lead program from this platform, AB-M101, is in development for the treatment of CDI.

On July 11, 2014, Assembly Biosciences merged with a private company Assembly Pharmaceuticals, Inc., which was founded in 2012. The Merger resulted in a shift in strategic focus, the addition of a new lead drug development program for us, and changes in personnel. In connection with the Merger, our Board of Directors and stockholders approved a 1-for-5 reverse stock split of our common stock. The reverse stock split became effective on July 11, 2014. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverses stock split, including reclassifying an amount equal to the reduction in par value of common stock to the additional paid-in capital. In connection with the Merger, the shares of common stock issued and outstanding of Assembly Pharmaceuticals were converted into an aggregate of 4,008,848 shares of our common stock. Also pursuant to the terms of the Merger, the outstanding options to purchase shares of Assembly Pharmaceuticals' common stock were assumed by us and became exercisable for an aggregate of 621,651 shares of our common stock. Effective upon the consummation of the Merger, Assembly Acquisition, Inc., our wholly owned subsidiary (the "Merger Sub") was merged with and into Assembly Pharmaceuticals, with Assembly Pharmaceuticals being the surviving entity and becoming our wholly owned subsidiary.

We accounted for the acquisition of Assembly Pharmaceuticals, Inc. as a business combination under Accounting Standards Codification ("ASC") 805 with Ventrus Biosciences, Inc. as the accounting acquirer. We determined Ventrus Biosciences, Inc. was the accounting acquirer in accordance with ASC 805-10-25-5 as Ventrus Biosciences, Inc. gained control of Assembly Pharmaceuticals, Inc. upon completion of the Merger. To make this determination, we considered factors as indicated in ASC 805-10-55, including which entity issued equity interest to effect the combination, board of directors' composition, shareholder ownership, voting control, restrictions on shareholder voting rights, anticipated management positions and the relative size of the two companies.

We have not derived any revenue from product sales to date as we currently have no approved products. We anticipate initiating clinical trials in the second half of 2016 with our microbiome therapy for recurrent CDI and our lead antiviral compound for the treatment of HBV. Once a product has been developed, it will need to be approved for sale by the Federal Food and Drug Administration (FDA) or applicable foreign regulatory agency. Since inception, our operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options and issuance of debt. We have incurred losses from operations and negative cash flows from operating activities since inception and expect to continue to incur substantial losses for the next several years as we continue our product development efforts. Management believes we currently have sufficient funds to meet our operational requirements for at least the next twelve months. If we cannot generate significant cash from our operations, we intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, grants or other arrangements. We cannot assure such funding will be available on reasonable terms, if at all.

We currently have administrative offices in Carmel, Indiana and New York, New York and research facilities in Bloomington, Indiana and San Francisco, California. Research activities for the HBV program are also being conducted at Indiana University at Bloomington, under the aegis of Adam Zlotnick, PhD, Assembly co-founder and head of our HBV Scientific Advisory Board.

Since Assembly's inception, we have had no revenue from product sales, and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings since then. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, discovery and developing our product candidates, establishing initial manufacturing capabilities for our product candidates, maintaining and improving our patent portfolio and raising capital. We have generated significant losses to date, and we expect to continue to generate losses as we continue to develop our product candidates. As of December 31, 2015, we had an accumulated deficit of $163,965,905. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none is approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Financial Operations Overview

Research and Development Expense

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, target validation, lead optimization and the development of our product candidates, which include:

- employee-related expenses including salaries, benefits, and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research and development, preclinical and clinical activities on our behalf and the cost of consultants;
- the cost of lab supplies and acquiring, developing, and manufacturing preclinical study materials; and

· facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other operating costs.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We use our employee and infrastructure resources across multiple research and development programs, and we allocate internal employee-related and infrastructure costs, as well as certain third party costs, to each of our programs based on the personnel resources allocated to such program. Our research and development expenses, by major program, are outlined in the table below:

	YE 2014	YE 2015
HBV	$ 2,536,377	$ 10,810,517
Microbiome	$ 1,559,136	$ 4,296,309
Diltiazem	$ 3,913,887	$ (6,621)
Stock- Based Compensation	$ 2,707,337	$ 3,257,732

Diltiazem was a prior product candidate that the Company is no longer developing. Since the Merger in July 2014, the HBV platform and Microbiome platform are the sole focus of our company.

The successful discovery and development of our product candidates are highly uncertain. As such, at this time, we cannot reasonably estimate, or know the nature, timing and estimated costs, of the efforts that will be necessary to complete the remainder of their development. We are also unable to predict when, if ever, material net cash inflows will commence from our product candidates. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- successful completion of preclinical development and initiation of clinical development for each of the HBV and microbiome programs;
- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- launching commercial sales of the products, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the products following approval and wide use.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company including expenses related to services associated with maintaining compliance with exchange listing and SEC requirements, insurance, and investor relations costs.

Interest income

Interest income consists of interest earned on our cash and cash equivalents and available-for-sale securities.

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 consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. 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.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Marketable Securities

We have designated marketable securities as of December 31, 2015 as available-for-sale securities and measure these securities at their respective fair values. Marketable securities are classified as short-term or long-term based on the maturity date and their availability to meet current operating requirements. Marketable securities that mature in one year or less are classified as short-term available-for-sale securities and are reported as a component of current assets. Marketable securities that are not considered available for use in current operations are classified as long-term available-for-sale securities and are reported as a component of long-term assets.

Securities that are classified as available-for-sale are measured at fair value with temporary unrealized gains and losses reported in other comprehensive income (loss), and as a component of stockholders' equity until their disposition. We review all available-for-sale securities at each period end to determine if they remain available-for-sale based on then current intent and ability to sell the security if it is required to do so.

Marketable securities are subject to a periodic impairment review. We may recognize an impairment charge when a decline in the fair value of investments below the cost basis is determined to be other-than-temporary.

Goodwill and Other Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Our intangible assets with an indefinite life are related to in-process research and development ("IPR&D") programs acquired in the Merger, as we expect future research and development on these programs to provide us with substantial benefit for a period that extends beyond the foreseeable horizon. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite lived and would then be amortized based on their respective estimated useful lives at that point in time.

We review goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values. We test goodwill and indefinite-lived intangible assets each year on October 1. We review the carrying value of goodwill and indefinite-lived intangible assets utilizing a discounted cash flow model, and, where appropriate, a market value approach is also utilized to supplement the discounted cash flow model. We make assumptions regarding estimated future cash flows, discount rates, long-term growth rates and market values to determine each reporting unit's estimated fair value. We considered the adverse changes in the overall biotechnology sector and decline in our stock price to be triggering events as of December 31, 2015. Therefore, in addition to our annual goodwill impairment test as of October 1, 2015, we also performed a goodwill impairment test as of December 31, 2015. As of October 1, 2015 and December 31, 2015, the fair value of the Company's reporting unit was in excess of carrying value for all scenarios that were tested.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

Impairment of Long-lived Assets

We monitor the carrying value of long-lived assets for potential impairment and test the recoverability of such assets whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. If a change in circumstance occurs, we perform a test of recoverability by comparing the carrying value of the asset or asset group to its undiscounted expected future cash flows. If cash flows cannot be separately and independently identified for a single asset, we will determine whether impairment has occurred for the group of assets for which we can identify the projected cash flows. If the carrying values are in excess of undiscounted expected future cash flows, we measure any impairment by comparing the fair value of the asset or asset group to its carrying value. We deemed there was no impairment of long-lived assets during the years ended December 31, 2015 and 2014.

Fair Value Measurements

We follow accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We use the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value our financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.
Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.
Level 3: Significant unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires us to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that we or holders of the instruments could realize in a current market exchange.

Stock-Based Compensation

We apply the fair value recognition provisions of Financial Accounting Standards Board ("FASB") ASC Topic 718, *Compensation-Stock Compensation*, which we refer to as ASC 718, to account for stock-based compensation. We recognize stock-based compensation expense related to stock options granted to employees and directors for their services on the Board of Directors based on the estimated fair value of each stock option on the date of grant, net of estimated forfeitures, using the Black-Scholes option-pricing model. The grant date fair value of awards subject to service-based vesting, net of estimated forfeitures, is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. In accordance with the ASC 718, stock options subject to both performance- and service-based vesting conditions are recognized using an accelerated recognition model if achievement of the performance requirements is considered to be probable.

We account for stock options granted to non-employees, which primarily consist of consultants and members of our scientific advisory board, using the fair value method. Stock options granted to non-employees are subject to periodic revaluation over their vesting terms and stock-based compensation expense is recognized using an accelerated recognition model.

We use the Black-Scholes option pricing model to estimate the fair value of stock option awards using various assumptions that require management to apply judgment and make estimates, including:

- the expected term of the stock option award, which we calculate using the simplified method, as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment, as* we have insufficient historical information regarding our stock options to provide a basis for an estimate;
- the expected volatility of the underlying common stock, which we estimate based on the standard deviation of our underlying stock price's daily logarithmic returns since December 17, 2010, and then weighted after the historical volatility of a representative group of publicly traded biopharmaceutical companies with similar characteristics to us, including development candidates in earlier stages of drug development and areas of therapeutic focus;
- the risk-free interest rate, which we based on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued;
- the expected dividend yield, which we estimate to be zero based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends; and
- the fair value of our common stock on the date of grant.

If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

In addition to the assumptions used in our Black-Scholes option-pricing model, the amount of stock option expense we recognize in our consolidated statements of operations and comprehensive loss includes an estimate of stock option forfeitures. Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest. Due to the lack of historical forfeiture activity, we expect to estimate our forfeiture rate based on data from our representative group of companies. Changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation expense as the cumulative effect of adjusting the rate is recognized in the period the forfeiture estimate is changed. For example, if a revised forfeiture rate is higher than the previously estimated forfeiture rate, an adjustment is made that will result in a decrease to the stock-based compensation expense recognized in the consolidated financial statements. If a revised forfeiture rate is lower than the previously estimated forfeiture rate, an adjustment is made that will result in an increase to the stock-based compensation expense recognized in our consolidated financial statements. To date our forfeitures have not been material.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Contractual Obligations

We have contractual and commercial obligations under our operating leases and other obligations related to research and development activities, purchase commitments and licenses. The following table summarizes our future contractual obligations and commercial commitments at December 31, 2015.

	Less than 1 year	1-2 years
Operating leases	$ 1,676,000	$ 1,651,447
R&D and purchase commitments	808,307	183,725
License obligations	425,000	1,050,000
Total contractual obligations	$ 2,909,307	$ 2,885,172

In general, milestone and royalty payments associated with certain license agreements have not been included in the above table of contractual obligations as we cannot reasonably estimate if or when they will occur. The milestone payments included in the table of contractual obligations above are payments we believe are reasonably likely to occur during the indicated time periods.

Results of Operations

General

To date, we have not generated any revenues from operations and, at December 31, 2015, we had an accumulated deficit of approximately $164.0 million primarily as a result of research and development expenses, purchases of in-process research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues.

Comparison of the Years Ended December 31, 2015 and December 31, 2014

Research and Development Expense

Research and development expense was $18,357,937 for the year ended December 2015, an increase of $7,641,200 or 71.3% from $10,716,737 for the same period in 2014. The net increase in research and development expenses was primarily due to an increase of $8,274,140 in research expenses for our HBV program which was started in July 2014, an increase of $2,737,173 for preclinical development of our Microbiome program, additional stock-based compensation of $550,394 due to new options granted to employees and nonemployees, and offset by a decrease of $3,920,507 in expenses due to termination of the VEN 307 study in the second quarter of 2014.

General and Administrative Expense

General and administrative expense was $11,297,693 for the year ended December 2015, a decrease of $1,942,022 or 14.7% from $13,239,715 for the same period in 2014. The primary reason was a decrease of stock-based compensation expense of $3,311,304 due to the decrease of fair value of stock options granted to employees in 2015, offset by an increase of $1,369,282 in general and administrative expenses related to compensation and benefits, severance payments payable over twelve months to our former chief executive officer, bonuses, professional fees and corporate taxes.

Interest Expense and Income

There was no interest expense in 2015 or 2014. Interest income was $1,228,830 for the year ended 2015 compared to $167,653 for the same period in 2014. The interest income for the year ended December 31, 2015 was primarily related to the interest income on corporation bonds.

Liquidity and Capital Resources

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 December 31, 2015 principally with debt prior to our initial public offering, and thereafter with equity financing, raising an aggregate of $192.5 million in net proceeds from public offerings and private placements from inception to December 31, 2015.

In January 2014, we sold an aggregate of 92,472 shares of common stock under the amended at-the-market common equity sales program, resulting in net proceeds of approximately $1,763,000.

On October 6, 2014, we sold to various institutional investors an aggregate of 1,959,000 shares of common stock in a registered direct offering. The purchase price paid by the investors was $8.04 per share and an aggregate of approximately $14,963,000 in net proceeds were received. In connection with the offering, we entered into a placement agent agreement with William Blair & Company, L.L.C., who acted as sole placement agent in the offering, and pursuant to which we paid a placement agent fee equal to 5.0% of the gross proceeds of the offering.

On March 19, 2015, we sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by investors was $13.50 per share and an aggregate of $70.4 million (net of underwriting discounts and commissions and offering expenses) was received. In addition, we granted the underwriters a 30-day option to purchase up to an additional 833,333 shares of common stock.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of common stock at the public offering price of $13.50 per share, less underwriting discounts and commissions and offering expenses. Proceeds from the sale of shares on the exercise of the underwriters' option (net of underwriting discounts and commissions) were approximately $10.6 million.

Cash Flows for the Two Years Ended December 31, 2015 and 2014

	For the Year Ended December 31,	
(In thousands)	**2015**	**2014**
Statement of Cash Flows Data:		
Total cash (used in)/provided by:		
Operating activities	$ (18,697)	$ (14,974)
Investing activities	(64,855)	277
Financing activities	81,569	16,726
Net (decrease) increase in cash and cash equivalents	$ (1,983)	$ 2,029

Net Cash Used in Operating Activities

Net cash used in operating activities was $18.7 million for the year ended December 31, 2015 and funded our research and development program build out and general and administrative expenses. Net cash used in continuing operations for the year ended December 31, 2015 was primarily driven by a $28.5 million net loss and offset by $7.9 million non-cash expense recorded for the stock-based compensation, plus a $1.8 million increase in cash from changes in operating assets and liabilities. Net cash used in continuing operations for the year ended December 31, 2014 was primarily driven by a $23.8 million net loss and a $2.5 million decrease in cash from changes in operating assets and liabilities, and offset by the $10.6 million non-cash expense recorded for stock-based compensation and $0.7 million non-cash expense recorded for the issuance of warrants for services.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities from continuing operations for the year ended December 31, 2015 was primarily due to a purchase of $69.8 million of marketable securities and offset by a $5.0 million of redemption of marketable securities during the year. Net cash provided by investing activities from continuing operations for the year ended December 31, 2014 for $0.3 million was primarily from cash acquired in business combination of $0.5 million offset by purchase of $0.1 million of fixed assets and collection of $0.1 million of security deposits.

Net Cash Provided by Financing Activities

Net cash flows provided by financing activities from continuing operations in the year ended December 31, 2015 was primarily generated by the net proceeds of $81.0 million from our public offering and $0.6 million from the exercise of stock options to purchase 76,422 shares of common stock. Net cash provided by financing activities during the year ended December 31, 2014 consisted of the sale of 2,051,472 shares of common stock for net proceeds of $16.7 million.

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 would 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 numerous 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.

We expect that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and future clinical trials for our product candidates;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish collaborations on favorable terms, if at all.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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.

Recent Accounting Pronouncements

See Note 2 of notes to the consolidated financial statements for a discussion of recent accounting standards and pronouncements.

Cautionary Statement

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. The following statement highlights some of these risks. For more detail, see “Item 1A. Risk Factors.”

Statements contained in this Form 10-K that are not historical facts, are or might constitute forward-looking statements under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Although we believe the expectations reflected in such forward-looking statements are based on reasonable assumptions, our expectations might not be attained. Forward-looking statements involve known and unknown risks that could cause actual results to differ materially from expected results. Factors that could cause actual results to differ materially from our expectations expressed in the report include, among others: risks related to the costs, timing, regulatory review and results of our preclinical studies and clinical trials; our ability to obtain FDA approval of our product candidates; our anticipated capital expenditures, our estimates regarding our capital requirements, and our need for future capital; our liquidity and working capital requirements; our expectations regarding our revenues, expenses and other results of operations; the unpredictability of the size of the markets for, and market acceptance of, any of our products; our ability to sell any approved products and the price we are able realize; our ability to obtain future funding on acceptable terms; our ability to retain and hire necessary employees and to staff our operations appropriately; our ability to compete in our industry and innovation by our competitors; our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business; estimates and estimate methodologies used in preparing our financial statements; the future trading prices of our common stock and the impact of securities analysts' reports on these prices; and the risks set out in our filings with the SEC.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates.

We do not believe that our cash and equivalents have significant risk of default or illiquidity. Under our current investment policies, we invest our cash and cash equivalents in money market funds which invest in short-term U.S. Treasury securities with insignificant rates of return. While we believe our cash and equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and equivalents at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during 2015 or 2014.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities and 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 fiscal year ending December 31, 2015, we carried out an evaluation, under the supervision, and with the participation of, our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures for the fiscal year ending as of December 31, 2015 were effective at reasonable assurance levels.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all error and all fraud. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control-Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Our independent registered public accounting firm, Ernst & Young LLP, has audited the financial statements included in this Form 10-K and has issued an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2015. The report of Ernst & Young LLP is included with the financial statements appended to this Form 10-K pursuant to Item 8.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in the fourth quarter of 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Except as set forth below, the information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2015, or the Proxy Statement, and is incorporated in this Annual Report on Form 10-K by reference.

Code of Ethics

Our Board has adopted a Code of Ethics for our principal executive officer and all senior financial officers and a Code of Conduct applicable to all of our employees and our directors. Both Codes are available under the Investor Relations—Corporate Governance section of our website at www.assemblybio.com. If we make any substantive amendments to, or grant any waivers from, the Code of Ethics for our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Section 16(a) Beneficial Ownership Reporting Compliance

Pursuant to Section 16(a) of the Securities Exchange Act, our directors and executive officers are required to file reports with the SEC indicating their holdings of and transactions in our equity securities. To our knowledge, based solely on our review of the copies of such reports furnished to us and written representations that our officers, directors and holders of more than 10% of our common stock complied with all applicable filing requirements during the fiscal year ended December 31, 2015.

ITEM 11. Executive Compensation

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Except for the table regarding equity compensation plans, which is included in Part II Item 5 of this Annual Report on Form 10-K, the information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. Certain Relationships and Related Party Transactions, and Director Independence

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. Principal Accounting Fees and Services

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Item 15. Exhibits, Financial Statement Schedules

(a) *Exhibits.* The following exhibits are filed as part of this registration statement:

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit No.	Filed Herewith
1.1	Underwriting Agreement, dated March 19, 2015, by and Assembly Biosciences, Inc. and Credit Suisse Securities (USA) LLC and William Blair & Company, LLC, as representatives of the several underwriters named therein.	8-K	03/19/2015	1.6	
3.1	Amended and Restated Certificate of Incorporation dated November 11, 2010.	S-1/A	11/16/2010	3.1	
3.2	Amended and Restated Bylaws dated July 12, 2010.	S-1	07/20/2010	3.2	
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of Ventrus Biosciences, Inc. filed on January 30, 2013.	8-K	01/30/2013	4.14	
4.1	Specimen of Common Stock Certificate.	S-3	12/30/2015	4.1	
4.2	Form of Warrant issued to investors between June and September 2008.	S-1	07/20/2010	4.3	
4.3	Warrants issued to Paramount Credit Partners, LLC on January 23, March 25, June 1 and June 24, 2009.	S-1/A	10/04/2010	4.5	
4.4	Form of Warrant issued to investors in February and March, 2010.	S-1/A	10/04/2010	4.8	
4.5	Form of Warrant issued to investors in May 2010.	S-1/A	10/04/2010	4.9	
4.6	Form of Placement Agent Warrant issued to Paramount BioCapital, Inc. on March 11, 2008.	S-1	07/20/2010	4.10	
4.7	Placement Agent Warrants issued to National Securities Corporation on February 26, March 31 and May 6, 2010, as amended October 28, 2010 and November 30, 2010.	S-1/A	12/06/2010	4.11	
4.8	Warrant issued to S.L.A. Pharma AG on August 30, 2010.	S-1/A	10/04/2010	4.12	
4.9	Form of underwriters warrant dated December 22, 2010.	S-1/A	12/06/2010	4.13	
10.1*	Exclusive License Agreement dated March 23, 2007 by and between S.L.A. Pharma AG and Paramount Biosciences, LLC, as amended on July 24, 2008, November 20, 2008, June 1, 2009, December 18, 2009 and June 24, 2010 and letter agreements dated October 27, 2008, November 20, 2008 and January 22, 2009.	S-1/A	11/16/2010	10.1	
10.2	Assignment and Assumption Agreement dated August 2, 2007, by and between Paramount Biosciences LLC and Ventrus Biosciences, Inc.	S-1	07/20/2010	10.2	
10.3	Amended and Restated Employment Agreement dated July 19, 2010 by and between Russell H. Ellison and Ventrus Biosciences, Inc.	8-K	07/20/2010	10.5	
10.4	Amendment No. 6, dated August 30, 2010, to Exclusive License Agreement by and between S.L.A. Pharma AG and Paramount Biosciences, LLC (assigned to Ventrus Biosciences).	S-1/A	10/04/2010	10.10	
10.5	Amendment No. 7, dated June 6, 2011, to Exclusive License Agreement by and between S.L.A. Pharma AG and Paramount Biosciences, LLC (assigned to Ventrus Biosciences).	S-1	06/06/2011	10.16	
10.6	Employment Agreement dated January 15, 2014 and effective December 22, 2013, by and between Ventrus Biosciences, Inc. and Dr. Russell H. Ellison.	8-K	01/16/2014	10.20	
10.7	Employment Agreement dated January 15, 2014 and effective December 22, 2013, by and between Ventrus Biosciences, Inc. and David J. Barrett.	8-K	01/16/2014	10.21	
10.8*	License and Collaboration Agreement dated November 8, 2013, by and between Ventrus Biosciences, Inc. and Therabiome, LLC.	10-K	03/31/2014	10.22	
10.9#	Amendment dated July 11, 2014, to Employment Agreement, effective as of December 22, 2013 between Ventrus Biosciences, Inc. and Russell H. Ellison.	8-K	07/14/2014	10.23	
10.10#	Employment Agreement, dated July 11, 2014, between Ventrus Biosciences, Inc. and Derek A. Small.	8-K	07/14/2014	10.24	
10.11#	Employment Agreement, dated July 11, 2014, between Ventrus Biosciences, Inc. and Uri A. Lopatin.	8-K	07/14/2014	10.25	
10.12#	Employment Agreement, dated July 11, 2014, between Ventrus Biosciences, Inc. and Lee D. Arnold	8-K	07/14/2014	10.26	

10.13*	Exclusive License Agreement with Indiana University Research and Technology Corporation	10-Q	11/17/2014	10.29	
21.1	List of Subsidiaries of Assembly Biosciences, Inc.				X
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.				X
23.2	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney (included on signature page)				X
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S. C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of the Chief Financial Officer Pursuant to 18 U.S. C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Instance Document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document.				

*Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

Represents management compensatory plan, contract or arrangement.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASSEMBLY BIOSCIENCES, INC.

Date: March 11, 2016

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Derek Small and David J. Barrett, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Derek Small Derek Small	President, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2016
/s/ David J. Barrett David J. Barrett	Chief Financial Officer and Chief Operating Officer (Principal Financial and Accounting Officer)	March 11, 2016
/s/ Anthony E. Altig Anthony E. Altig	Director	March 11, 2016
/s/ Mark Auerbach Mark Auerbach	Director	March 11, 2016
/s/ Richard DiMarchi Richard DiMarchi	Director	March 11, 2016
/s/ Myron Z. Holubiak Myron Z. Holubiak	Director	March 11, 2016
/s/ Alan Lewis Alan Lewis	Director	March 11, 2016
/s/ William Ringo William Ringo	Director	March 11, 2016

ASSEMBLY BIOSCIENCES, INC.
FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Assembly Biosciences, Inc.

We have audited the accompanying consolidated balance sheet of Assembly Biosciences, Inc. and Subsidiary as of December 31, 2015, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Assembly Biosciences, Inc. and Subsidiary at December 31, 2015, and the consolidated results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Assembly Biosciences, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 11, 2016 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

New York, New York
March 11, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Assembly Biosciences, Inc.

We have audited Assembly Biosciences, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Assembly Biosciences Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Assembly Biosciences, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Assembly Biosciences, Inc. and Subsidiary as of December 31, 2015, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the year then ended of Assembly Biosciences, Inc. and Subsidiary and our report dated March 11, 2016 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

New York, New York
March 11, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Assembly Biosciences, Inc.

We have audited the accompanying consolidated balance sheet of Assembly Biosciences, Inc. and subsidiary (the "Company") as of December 31, 2014 and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year then ended. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Assembly Biosciences, Inc. and subsidiary as of December 31, 2014 and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
March 12, 2015

ASSEMBLY BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2015	**2014**
ASSETS		
Current assets		
Cash and cash equivalents	$ 27,107,526	$ 29,091,113
Marketable securities, at fair value	40,556,652	-
Other current assets	704,287	125,284
Total current assets	68,368,465	29,216,397
Long-term assets		
Marketable securities	23,392,129	-
Property, plant and equipment, net	148,609	156,441
Security deposits	197,158	115,005
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,737,350
Total long-term assets	65,376,032	42,008,796
Total assets	**$ 133,744,497**	**$ 71,225,193**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,363,698	$ 907,601
Accrued expenses	2,039,204	146,420
Total current liabilities	3,402,902	1,054,021
Long-term liabilities		
Deferred tax liabilities	11,600,000	11,600,000
Total long-term liabilities	11,600,000	11,600,000
Total liabilities	**15,002,902**	**12,654,021**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,225,662 and 10,672,059 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	17,226	10,672
Additional paid-in capital	283,511,859	194,072,572
Accumulated other comprehensive loss	(821,585)	-
Accumulated deficit	(163,965,905)	(135,512,072)
Total stockholders' equity	118,741,595	58,571,172
Total liabilities and stockholders' equity	**$ 133,744,497**	**$ 71,225,193**

The accompanying notes are an integral part of these consolidated financial statements

ASSEMBLY BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2015	**2014**
Operating expenses:		
Research and development	$ 18,357,937	$ 10,716,737
General and administrative	11,297,693	13,239,715
Total operating expenses	29,655,630	23,956,452
Loss from operations	**(29,655,630)**	**(23,956,452)**
Other income		
Interest and other income	1,228,830	167,653
Realized loss from marketable securities	(27,033)	-
Total other income	1,201,797	167,653
Net loss	**$ (28,453,833)**	**$ (23,788,799)**
Unrealized loss on marketable securities	(821,585)	-
Comprehensive loss	**$ (29,275,418)**	**$ (23,788,799)**
Net loss per share, basic and diluted	$ (1.81)	$ (3.40)
Weighted average common shares outstanding, basic and diluted	15,702,646	6,998,875

The accompanying notes are an integral part of these consolidated financial statements

ASSEMBLY BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Preferred Stock		Additional	Common Stock	Accumulated Other	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Issuable	Comprehensive Loss	Deficit	Equity
Balance as of December 31, 2013	**4,146,779**	**$ 4,147**	**44,000**	**$ 44**	**$ 135,844,320**	**$ 368,750**	**$ -**	**$ (111,723,273)**	**$ 24,493,988**
Proceeds from common stock sold, net of costs	2,051,472	2,051	-	-	16,723,895	-	-	-	16,725,946
Issuance of common stock for business combination	4,008,808	4,009	-	-	29,060,139	-	-	-	29,064,148
Issuance of common stock in exchange for restricted stock units	25,000	25	-	-	368,725	(368,750)	-	-	-
Conversion of preferred stock to common stock	440,000	440	(44,000)	(44)	(396)	-	-	-	-
Fair value of options assumed	-	-	-	-	758,948	-	-	-	758,948
Issuance of warrants for services	-	-	-	-	679,447	-	-	-	679,447
Stock-based compensation	-	-	-	-	10,637,494	-	-	-	10,637,494
Net loss	-	-	-	-	-	-	-	(23,788,799)	(23,788,799)
Balance as of December 31, 2014	**10,672,059**	**$ 10,672**	**-**	**$ -**	**$ 194,072,572**	**$ -**	**$ -**	**$ (135,512,072)**	**$ 58,571,172**
Proceeds from common stock sold, net of underwriters' discounts and cost	6,388,888	6,389	-	-	81,008,600	-	-	-	81,014,989
Exercise of stock options	76,422	77	-	-	554,191	-	-	-	554,268
Cashless exercise of warrants	88,293	88	-	-	(88)	-	-	-	-
Stock-based compensation	-	-	-	-	7,876,584	-	-	-	7,876,584
Change in unrealized loss on marketable securities	-	-	-	-	-	-	(821,585)	-	(821,585)
Net loss	-	-	-	-	-	-	-	(28,453,833)	(28,453,833)
Balance as of December 31, 2015	**17,225,662**	**$ 17,226**	**-**	**$ -**	**$ 283,511,859**	**$ -**	**$ (821,585)**	**$ (163,965,905)**	**$ 118,741,595**

The accompanying notes are an integral part of these consolidated financial statements

ASSEMBLY BIOSCIENCES, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (28,453,833)	$ (23,788,799)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	64,989	10,974
Stock-based compensation	7,876,584	10,637,494
Realized loss from marketable securities	27,033	-
Loss on sale of fixed assets	954	-
Issuance of warrants for services	-	679,447
Changes in operating assets and liabilities:		
Other current assets	(555,849)	(54,472)
Accounts payable	456,097	(2,481,917)
Accrued expenses	1,968,844	23,771
Security deposits	(82,153)	-
Net cash used in operating activities	(18,697,334)	(14,973,502)
Cash flows from investing activities		
Purchase of fixed assets	(58,261)	(149,963)
Sale of fixed assets	150	-
Cash acquired in business combination	-	509,363
Security deposits collected	-	(81,999)
Purchases of marketable securities	(69,781,176)	-
Redemption of marketable securities	4,983,777	-
Net cash (used in) provided by investing activities	(64,855,510)	277,401
Cash flows from financing activities		
Proceeds from common stock sold, net of underwriters' discounts and cost	81,014,989	16,725,946
Proceeds from exercise of stock options	554,268	-
Net cash provided by financing activities	81,569,257	16,725,946
Net (decrease) increase in cash and cash equivalents	(1,983,587)	2,029,845
Cash and cash equivalents at beginning of year	29,091,113	27,061,268
Cash and cash equivalents at end of year	**$ 27,107,526**	**$ 29,091,113**
Supplemental disclosure of cash flow information:		
Cashless exercise of warrants	$ 88	$ -
Change in unrealized loss on marketable securities available-for-sale	$ 821,585	$ -
Issuance of common stock in exchange for restricted stock units	$ -	$ 368,750
Conversion of preferred stock to common stock	$ -	$ 440
Supplemental disclosure of non-cash activities:		
Assembly business combination		
Other current assets	$ -	$ (23,540)
Equipment, net	-	(10,350)
Intangible assets	-	(29,000,000)
Goodwill	99,214	(12,737,350)
Security deposits	-	(16,606)
Accounts payable and accrued expenses	(99,214)	874,113
Share exchange - business combination	-	29,064,148
Fair value of vested options and restricted stock units - in connection with business combination	-	758,948
Deferred tax liability	-	11,600,000
Cash acquired in business combination	$ -	$ 509,363

The accompanying notes are an integral part of these consolidated financial statements

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc. ("Assembly" or the "Company") is a biotechnology company advancing two innovative platform programs: a new class of oral drugs for the treatment of hepatitis B virus (HBV) infection and novel class of oral biological drugs, which are designed to restore health to a dysbiotic microbiome. The Company's HBV-cure program is aimed at increasing the current low cure rates for patients with HBV and is pursuing multiple drug candidates that inhibit multiple viral targets throughout the HBV lifecycle. Assembly has discovered several novel core protein Allosteric Modulators (CpAMs), which are small molecules that directly target and allosterically modulate a number of HBc functions. The Company's Microbiome Program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under cGMP conditions, and a patent pending delivery system, GEMICEL^{TM}, which allows for targeted oral delivery of live biologic as well as conventional therapies to the lower GI tract. The lead program from this platform, AB-M101, is in development for the treatment of C. difficile- infections (CDI).

2015 Highlights

On March 19, 2015, the Company sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by the investors was $13.50 per share and an aggregate of $70.4 million (net of underwriters' discount and equity issuance costs) were received.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of common stock at the public offering price of $13.50 per share, less underwriting discounts and commissions and offering expenses. Proceeds from the sale of shares on the exercise of the underwriters' option (net of underwriting discounts and commissions) were approximately $10.6 million.

2014 Highlights

On July 11, 2014, Nasdaq listed Ventrus Biosciences, Inc. caused its wholly owned subsidiary to merge with and into Assembly Pharmaceuticals, Inc., a private company (the "Merger"), resulting in Assembly Pharmaceuticals, Inc. being the surviving entity and becoming a wholly owned subsidiary of Ventrus Biosciences, Inc. In connection with the Merger, Ventrus Biosciences, Inc. changed its name to Assembly Biosciences, Inc. The Merger resulted in a shift in strategic focus, the addition of a new lead drug development program and changes in personnel. In connection with the Merger, the Company's Board of Directors and stockholders approved a 1-for-5 reverse stock split of the Company's common stock. The reverse stock split became effective on July 11, 2014. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In connection with the Merger, the shares of common stock issued and outstanding of Assembly Pharmaceuticals, were converted into an aggregate of 4,008,848 shares of the Company's common stock. Also pursuant to the terms of the Merger, the outstanding options to purchase shares of Assembly Pharmaceuticals' common stock were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company's common stock.

The Company accounted for the acquisition of Assembly Pharmaceuticals, Inc. as a business combination under Accounting Standards Codification ("ASC") 805 with Ventrus Biosciences, Inc. as the accounting acquirer. The Company determined Ventrus Biosciences, Inc. was the accounting acquirer in accordance with ASC 805-10-25-5 as Ventrus Biosciences, Inc. gained control of Assembly Pharmaceuticals, Inc. upon completion of the Merger. To make this determination, the Company considered factors as indicated in ASC 805-10-55, including which entity issued equity interests to effect the combination, board of director composition, shareholder ownership, voting control, restrictions on shareholder voting rights, anticipated management positions and the relative size of the two companies.

On October 6, 2014, the Company sold to various institutional investors an aggregate of 1,959,000 shares of common stock in a registered direct offering. The purchase price paid by the investors was $8.04 per share and an aggregate of $15.0 million in net proceeds were received.

Liquidity

The Company has not derived any revenue from product sales to date as it currently has no products. Once a product has been developed, it will need to be approved for sale by the FDA or any foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options and issuance of debt. The Company has incurred losses from operations and negative cash flows 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, or other arrangements and it cannot assure such funding will be available on reasonable terms, if at all.

Capital resources

The Company has not derived any revenue from product sales to date as the products have not been approved for sale by the FDA or any foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, the proceeds from the exercise of warrants and stock options and issuance of debt. The Company has incurred losses from operations and negative cash flows 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 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, or other arrangements and it cannot assure such funding will be available on reasonable terms, or at all.

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

Basis of Presentation

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

Segments

The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein.

Use of Estimates

The preparation of financial statements in conformity with the accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying 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.

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.

Reclassification

Certain reclassifications have been made to prior year amounts to conform to the current year presentation. The Company reclassified certain non-cash activities in the consolidated statements of cash flows to conform to the Assembly Pharmaceutical's final purchase price allocation.

Cash and cash equivalents

All highly liquid investments with maturities of three months or less at the time of purchase are considered to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company maintains its cash in bank deposit and other accounts, the balances of which, at times and at December 31, 2015, exceed federally insured limits.

Marketable Securities

The Company has designated marketable securities as of December 31, 2015 as available-for-sale securities and measures these securities at their respective fair values. Marketable securities are classified as short-term or long-term based on the maturity date and their availability to meet current operating requirements. Marketable securities that mature in one year or less are classified as short-term available-for-sale securities and are reported as a component of current assets. Marketable securities that are not considered available for use in current operations are classified as long-term available-for-sale securities and are reported as a component of long-term assets.

Securities that are classified as available-for-sale are measured at fair value with temporary unrealized gains and losses reported in other comprehensive income (loss), and as a component of stockholders' equity until their disposition. The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on then current intent and ability to sell the security if it is required to do so. The cost of securities sold is based on the specific identification method.

Marketable securities are subject to a periodic impairment review. The Company may recognize an impairment charge when a decline in the fair value of investments below the cost basis is determined to be other-than-temporary.

Goodwill and Other Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. The Company's intangible assets with an indefinite life are related to in-process research and development ("IPR&D") programs acquired in the Merger, as the Company expects future research and development on these programs to provide the Company with substantial benefit for a period that extends beyond the foreseeable horizon. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. The Company does not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite lived and would then be amortized based on their respective estimated useful lives at that point in time.

The Company reviews goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values. The Company tests its goodwill and indefinite-lived intangible assets each year on October 1. The Company reviews the carrying value of goodwill and indefinite-lived intangible assets utilizing a discounted cash flow model, and, where appropriate, a market value approach is also utilized to supplement the discounted cash flow model. The Company makes assumptions regarding estimated future cash flows, discount rates, long-term growth rates and market values to determine each reporting unit's estimated fair value. The Company considered the adverse changes in the overall biotechnology sector and decline in the Company's stock price to be triggering events as of December 31, 2015. Therefore, in addition to the annual goodwill impairment test as of October 1, 2015, the Company also performed a goodwill impairment test as of December 31, 2015. As of October 1, 2015 and December 31, 2015, the fair value of the Company's reporting unit was in excess of carrying value for all scenarios that were tested.

Impairment of Long-lived Assets

The Company monitors the carrying value of long-lived assets for potential impairment and tests the recoverability of such assets whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. If a change in circumstance occurs, the Company performs a test of recoverability by comparing the carrying value of the asset or asset group to its undiscounted expected future cash flows. If cash flows cannot be separately and independently identified for a single asset, the Company will determine whether impairment has occurred for the group of assets for which the Company can identify the projected cash flows. If the carrying values are in excess of undiscounted expected future cash flows, the Company measures any impairment by comparing the fair value of the asset or asset group to its carrying value. The Company performed its annual impairment test as of October 1, 2015 and deemed there was no impairment of long-lived assets during the year ended December 31, 2015.

Business Combinations

The Merger (see Note 3) was made at a price above the fair value of the assets acquired and liabilities assumed including deferred tax liability, resulting in goodwill, based on the Company's expectations of synergies and other benefits of combining the acquired business. These synergies and benefits include elimination of redundant functions and staffing and use of the Company's existing infrastructure to expand development of the product candidates of the acquired business in a cost efficient manner.

Significant judgment is required in estimating the fair value of intangible assets and in assigning their respective useful lives. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management, but which are inherently uncertain.

Net assets acquired are recorded at their fair values on the date of acquisition.

Property and Equipment

Property and equipment are stated at cost and consist of lab equipment and computer hardware and software. The Company computes depreciation under the straight-line method over the following estimated useful life of the related assets:

· Lab equipment	3 to 5 years
· Computer hardware and software	3 to 5 years

Fair Value Measurements

The Company follows accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company use the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value our financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

Level 3: Significant unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement in its entirety requires us to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable and accrued expenses.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For stock-based compensation awards to non-employees, the Company remeasures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Warrants

For the purpose of valuing the warrants (see Note 8), the Company used the Black-Scholes option pricing model utilizing the assumptions for risk free interest rate, the expected term, expected volatility, and expected dividend yield. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company estimated the expected life of the warrants based on the full term of the warrant. The expected dividend yield reflects the Company's current and expected future policy for dividends on its common stock. The expected stock price volatility for the Company's stock was calculated by examining historical volatilities for publicly traded industry peers as the Company did not have any trading history for its common stock at the time the grants were issued.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, fees paid to clinical research organizations and other third parties associated with clinical trials, the costs of laboratory equipment and facilities, and other external costs.

Income taxes

The Company's income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company had adopted the provisions that tax positions must meet a "more-likely-than-not" recognition threshold to be recognized. The Company has no unrecognized tax benefits recorded for the years ended December 31, 2015 and 2014. When an accrual for interest and penalties is required, interest and penalties will be recognized in tax expense. The Company files income tax returns in the U.S. federal jurisdiction and in various states. There are currently no federal income tax examinations in process. Tax years beginning in 2012 are generally subject to examination by taxing authorities, although net operating losses from all years are subject to examinations and adjustments for at least three years following the year in which the attributes are used.

Loss per common share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share 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 dilute loss per share in the future that was not included in the computation of diluted loss per share at December 31, 2015 and 2014 are as follows:

	Year Ended December 31,	
	2015	**2014**
Warrants to purchase common stock	16,909	270,761
Options to purchase common stock	3,367,784	3,249,651
Total	**3,384,693**	**3,520,412**

Comprehensive Loss

Comprehensive loss is comprised of net loss and adjustments for the change in unrealized gains and losses on investments in available-for-sale marketable securities. The Company displays comprehensive loss and its components in the consolidated statements of operations and comprehensive loss.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds these investments in highly rated financial institutions, and, by policy, limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Recent Accounting Pronouncements

In the first quarter of 2015, the Company adopted Accounting Standard Update ("ASU") 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity* issued by the Financial Accounting Standards Board ("FASB"). ASU 2014-08 changes the definition of a discontinued operation to include only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results (e.g., a disposal of a major geographical area, a major line of business, a major equity method investment or other major parts of an entity). The Company's adoption of ASU 2014-08 did not have a material impact on the Company's consolidated financial statements.

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

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915) — Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this update remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. A public entity is required to apply the amendments for annual reporting periods beginning after December 15, 2014, and interim periods therein. An entity should apply the amendments retrospectively for all comparative periods presented. Early adoption is permitted. The guidance was adopted by the Company in the second quarter of 2014. Adoption of this standard did not have a material impact on the Company's consolidated financial statements.

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

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-16 explicitly requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management will assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date. Management will consider relevant conditions that are known, and reasonably knowable, at the issuance date. Substantial doubt exists if it is probable that the entity will be unable to meet its obligations within one year after the issuance date. Disclosures will be required if conditions give rise to substantial doubt. The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. Adoption of this standard did not have a material impact on the Company's consolidated financial statements.

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

Note 3 - Assembly Pharmaceuticals, Inc. Transaction

On July 11, 2014, the Company completed the Merger, whereby Assembly Pharmaceuticals became the Company's wholly-owned subsidiary. Pursuant to the terms of the Merger, the shares of Assembly Pharmaceuticals were converted into an aggregate of 4,008,848 shares of the Company's common stock. Also pursuant to the terms of the Merger, the options to purchase shares of Assembly Pharmaceuticals were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company's common stock.

The allocation of the purchase price to the Assembly balance sheet is shown below:

Cash and cash equivalents	$ 509,363
Other current assets	23,540
Equipment, net	10,350
IPR&D	29,000,000
Goodwill (as adjusted)	12,638,136
Security deposits	16,606
Total assets	42,197,995
Accrued expenses (as adjusted)	774,899
Deferred tax liability	11,600,000
Total liabilities	12,374,899
Net assets acquired	**$ 29,823,096**

The transaction was accounted for using the acquisition method. Accordingly, goodwill has been measured as the excess of the total consideration over the amounts assigned to the identifiable assets acquired and liabilities assumed including the related deferred tax liability. Goodwill is not deductible for tax purposes.

On the acquisition date, the fair value of net assets acquired was $29,823,096. The fair value of stock issued to the Assembly Pharmaceuticals' shareholders as part of the consideration of $29,064,148 was based on reference to quoted market values of the Company's common stock as of the date of acquisition. The options assumed in the Merger were valued at $758,948. As of June 30, 2015, the Company finalized its purchase price allocation. The Company adjusted certain accrued expenses, resulting in a decrease of goodwill and accrued expenses of approximately $99,000 in the second quarter of 2015.

Note 4 - Marketable Securities

Marketable securities consist of the following as of December 31, 2015:

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

The contractual term to maturity of short-term marketable securities held by the Company as of December 31, 2015 is less than one year. The contractual term to maturity of long-term marketable securities held by the Company as of December 31, 2015 is from 1 to 2 years.

The fair value of marketable securities was classified into fair value measurement categories as follows:

Quoted prices in active markets for identical assets (Level 1)	$ -
Quoted prices for similar assets observable in the marketplace (Level 2)	63,948,781
Significant unobservable inputs (Level 3)	-
Total	$ 63,948,781

The fair values of marketable securities are determined using quoted market prices from daily exchange traded markets based on the closing price as of December 31, 2015 and are classified as Level 2.

There were no transfers between levels 1, 2 and 3 for the year ended December 31, 2015.

Note 5 - Goodwill and Intangible Assets

Goodwill

In July 2014, the Company completed its merger with Assembly Pharmaceuticals (see Note 3). The fair value of consideration paid, common stock and assumed options, totaled $29,823,096, which, net of amounts allocated to assets and liabilities acquired at fair value, resulted in an allocation to goodwill (as adjusted) of $12,638,136. The Company only has one operating segment.

Goodwill is recorded as an indefinite-lived asset and is not amortized for financial reporting purposes but is tested for impairment on an annual basis or when indications of impairment exist. No goodwill impairment losses have been recognized. Goodwill is not deductible for income tax purposes since the tax basis is $0. The Company performed an impairment test of the carrying value of the Company's goodwill at October 1, 2015 and December 31, 2015 and deemed there was no goodwill impairment.

The net book value of goodwill decreased by $99,214 from December 31, 2014 to December 31, 2015, as a result of the adjustment to purchase price accounting within the measurement period.

Intangible Assets

In July 2014, the Company completed its acquisition of Assembly Pharmaceuticals (see Notes 1 and 3). The Company acquired in-process research and development related to Assembly Pharmaceuticals' technology which is an indefinite lived intangible asset. The Company performed its annual impairment test as of October 1, 2015 and deemed there was no impairment of long-lived assets during the year ended December 31, 2015.

No intangible assets existed prior to the Merger. The change in intangible assets from July 11, 2014 to December 31, 2015 is shown in the table below:

Merger on July 11, 2014	$ 29,000,000
As of December 31, 2014	$ 29,000,000
2015 activity	-
As of December 31, 2015	$ 29,000,000

Note 6 - Property, Plant and Equipment, Net

Property, plant and equipment, consists of the following:

		Year Ended December 31,	
	Useful life (Years)	**2015**	**2014**
Computer hardware and software	3	$ 84,065	$ 75,196
Lab equipment	3 to 5	177,782	130,377
Office equipment	3 to 5	1,109	1,109
Total property, plant and equipment		262,956	206,682
Less: Accumulated depreciation and amortization		(114,347)	(50,241)
Property, plant and equipment, net		$ 148,609	$ 156,441

Depreciation expense for the years ended December 31, 2015 and 2014 was approximately $65,000 and $11,000, respectively, and was recorded in both research and development expense and general and administrative expense in the consolidated statements of operations and comprehensive loss. There was $883 of accumulated depreciation expense reversed due to the disposal of a fixed asset to Russell Ellison, the Company's former CEO, in 2015.

Note 7 - Accrued Expenses

Accrued expenses consist of the following:

	Year Ended December 31,	
	2015	2014
Accrued expenses:		
Salaries, bonuses and employee benefits	$ 1,628,975	$ -
Severance accrued for former CEO	106,777	-
Research and development expenses	120,700	-
Other	182,752	146,420
Total accrued expenses	$ 2,039,204	$ 146,420

Note 8 - Stockholders' Equity

Common and Preferred Stock Transactions

2014 Activity

In January 2014, the Company sold an aggregate of 92,472 shares of its common stock in its amended at-the-market common equity offering program, resulting in net proceeds of approximately $1.8 million or $19.07 per share.

In February 2014, all 44,000 outstanding shares of the Company's Series A non-voting convertible preferred stock converted into an aggregate 440,000 shares of common stock.

In July 2014, the Company issued 25,000 shares of common stock upon vesting of the restricted stock units.

On October 6, 2014, the Company sold to various institutional investors an aggregate of 1,959,000 shares of common stock in a registered direct offering. The purchase price paid by the investors was $8.04 per share and an aggregate of approximately $15.0 million in net proceeds were received. In connection with the offering, the Company entered into a placement agent agreement with William Blair & Company, L.L.C., who acted as sole placement agent in the offering, and pursuant to which the Company paid a placement agent fee equal to 5.0% of the gross proceeds of the offering.

The Company's Board of Directors and stockholders approved a 1-for-5 reverse stock split of the Company's common stock. The reverse stock split became effective on July 11, 2014. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

On July 11, 2014, the Company completed the Merger, whereby Assembly Pharmaceuticals became the Company's wholly-owned subsidiary. Pursuant to the terms of the Merger, the shares of Assembly Pharmaceuticals, common stock issued and outstanding were converted into an aggregate of 4,008,848 shares of the Company's common stock. Also pursuant to the terms of the Merger, 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. The fully vested assumed options in the Merger were valued at $758,948 using the Black-Scholes model. The fair value of the options was recorded as a component of stockholders' equity. The fair value of the options was determined using the Black-Scholes model with the following assumptions: risk free interest rate 1.66% - 2.15%, volatility 97.33% - 102.8%, expected term 5 - 6.1 years, and no expected dividends.

2015 Activity

On March 19, 2015, the Company sold to various investors an aggregate of 5,555,555 shares of common stock in a public offering. The purchase price paid by the investors was $13.50 per share and an aggregate of $70.4 million in net proceeds were received, after deducting underwriting discounts and commissions and estimated offering expenses. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 833,333 shares of common stock.

On April 6, 2015, the underwriters exercised in full their option to purchase an additional 833,333 shares of common stock at the public offering price of $13.50 per share, less underwriting discounts and commissions and offering expenses. The closing of the option exercise resulted in net proceeds of approximately $10.6 million. Exercise of the underwriters' option increased the net proceeds (net of underwriting discounts and commissions) of the public offering, from $70.4 million to $81.0 million.

On December 30, 2015, the Company filed a registration statement on Form S-3 with the SEC using a "shelf" registration process, file number 333-208806, which became effective January 19, 2016. Under this shelf registration process, the Company may from time to time sell any combination of the securities described in the registration statement in one or more offerings for an aggregate offering price of up to $150,000,000. The Company has not issued any securities under this registration statement as of this date.

Options, Warrants and Restricted Stock Units

Options

The Company has two equity incentive plans available for the granting of equity awards. In July 2010, the stockholders approved the 2010 Equity Incentive Plan, under which, as of December 31, 2015, there were outstanding options for an aggregate of 266,467 shares of common stock and an aggregate of 488,992 shares available for grant. In July 2014, the stockholders approved the 2014 Stock Incentive Plan (the "2014 Plan"), under which, as of December 31, 2015, there were options for an aggregate of 2,479,666 shares of common stock outstanding and 8,245 shares available for grant.

On February 10, 2015, the Company's former Chief Executive Officer, Dr. Russell Ellison, transitioned to service as a consultant. The Company accelerated 266,667 of his options on March 3, 2015 in accordance with the original terms of his employment agreement. The corresponding charge related to these options was also accelerated in the first quarter of 2015. The exercise period for Dr. Ellison's vested options were also extended until the end of their term, or July 9, 2024 in accordance with the original terms of his employment agreement. The remainder of 266,666 unvested options were forfeited in accordance with the original terms of his employment agreement.

A summary of the Company's option activity and related information for the year ended December 31, 2015 is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value
Outstanding as of December 31, 2014	3,249,651	$ 6.26	$ 5,187,924
Granted	500,300	13.02	-
Exercised	(76,422)	7.25	22,348
Expired	(11,800)	7.20	-
Forfeited	(293,945)	7.26	-
Outstanding as of December 31, 2015	3,367,784	$ 7.16	$ 3,971,205
Options vested and exercisable	2,080,280	$ 6.40	$ 2,538,210

The Company expects that all outstanding unvested options will vest. The fair value of the options granted for the year ended December 31, 2015 and 2014, was based on the following assumptions:

	Year Ended December 31,	
	2015	2014
Exercise price	$7.88 - $16.55	$2.22 - $8.13
Expected stock price volatility	88.62% - 95.55%	94.4% - 105.0%
Risk-free rate of interest	1.49% - 2.27%	1.65% - 2.57%
Term (years)	5.0 - 8.2	4.9 - 10.0

The weighted average remaining contractual life of options outstanding at December 31, 2015 is approximately 8.7 years. The weighted average remaining contractual life of options currently exercisable at December 31, 2015 is approximately 8.5 years.

Stock-based compensation expenses for the years ended December 31, 2015 and 2014 were as follows:

	Year Ended December 31,	
	2015	2014
Research and development	$ 3,257,732	$ 2,707,337
General and administrative	4,618,852	7,930,157
Total stock-based compensation expense	$ 7,876,584	$ 10,637,494

Warrants

In connection with the Company's financings from 2007 to 2010, the Company issued warrants to investors and/or placement agents, as well as certain consultants, to purchase shares of common stock. In connection with the Merger, the Company issued warrants to purchase up to 120,265 shares of its common stock to its financial advisor for the Merger. The warrants were valued at $679,447 and expensed during the quarter ended September 30, 2014.

On April 17, 2015, the Company issued an aggregate of 88,293 shares of common stock from the cashless exercise of 120,265 warrants. The Company did not receive any proceeds from this cashless exercise.

During the year ended December 31, 2015, 133,587 warrants to purchase common stock expired.

A summary of the Company's warrant activity and related information is as follows:

	Warrants	Weighted Average Exercise Price
Outstanding as of December 31, 2014	270,761	$ 24.34
Expired	(133,587)	39.34
Exercised	(120,265)	5.13
Outstanding as of December 31, 2015	16,909	$ 30.81

The weighted average remaining contractual life of outstanding warrants at December 31, 2015 was approximately 4.4 years.

Note 9 - Income Taxes

There was no current or deferred income tax provision for the years ended December 31, 2015 and 2014.

The Company's deferred tax assets as of December 31, 2015 and 2014 consist of the following:

	As of December 31,	
	2015	2014
Deferred tax assets:		
Net-operating loss carryforward	$ 46,365,000	$ 38,094,000
Stock-based compensation	10,397,000	11,691,000
In-Process R&D	5,282,000	5,697,000
R&D credit	3,068,000	2,600,000
Change in unrealized loss on marketable securities	368,000	-
Other	783,000	2,000
Total Deferred Tax Assets	66,263,000	58,084,000
Valuation allowance	(66,263,000)	(58,084,000)
Deferred Tax Asset, Net of Allowance	$ -	$ -
In-process research and development (Assembly Merger)	11,600,000	11,600,000
Deferred Tax Liability	$ 11,600,000	$ 11,600,000

The Company recognized a $11.6 million deferred tax liability in 2015 and 2014 as a result of the acquisition of Assembly Pharmaceuticals in July 2014. Due to the acquisition, a temporary difference between the book fair value and the tax basis of the other in-process research and development acquired created deferred tax liability of $11.6 million and additional goodwill was recorded.

At December 31, 2015, the Company had potentially utilizable gross Federal net operating loss carryforwards of approximately $105.0 million, State net operating loss carry-forwards of approximately $98.3 million and research and development credit carry forward of approximately $3.1 million, all of which expire between 2027 and 2035. During 2015, the Company reclassed approximately $2.9 million of prior period deferred tax assets related to non-deductible incentive stock options to non-deductible expenses. This reclass resulted in a 10.2% decrease to the effective tax rate and a corresponding 10.2% decrease to the change in valuation allowance.

Sections 382 and 383 of the Internal Revenue Rode of 1986 subject the future utilization of net operating losses and certain other tax attributes to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change study and has determined that a “change in ownership” as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended, and the rules and regulations promulgated thereunder, did occur in December 2010, January 2013 and October 2014. Accordingly, approximately $39.1million of the Company’s net operating loss carryforwards are limited. Based on the company having undergone multiple ownership changes throughout their history these net operating loss carryforwards will free up at varying rates each year.

The following is a reconciliation of the U.S. federal statutory rate to the effective income tax rates for the year ended December 31, 2015 and 2014:

	As of December 31,	
	2015	**2014**
Statutory Federal Income Tax Rate	(34.0)%	(34.0)%
State Taxes, Net of Federal Tax Benefit	(11.0)%	(11.0)%
Merger Cost	0.9%	0.0%
Stock based Compensation - ISOs	16.7%	0.0%
Other	0.1%	0.0%
Change in Valuation Allowance	27.3%	45.0%
Income Taxes Provision (Benefit)	0.0%	0.0%

Note 10 - License Agreements

HBV Research Agreement with Indiana University

The Company, through its wholly-owned subsidiary, Assembly Pharmaceuticals, is party to a license agreement with Indiana University Research and Technology Corporation (“IURTC”) from whom it has licensed the Company’s HBV therapy. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to the HBV therapy. The total amount of all potential future milestone payments at December 31, 2015 is $825,000. The Company also is obligated to pay IURTC royalty payments based on net sales of the licensed technology. The Company is also obligated to pay diligence maintenance fees (starting at $25,000 in 2014 and rising to $100,000 in the year following first commercial sale of licensed product) each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year.

Microbiome Targeted Colonic Delivery Platform

On November 8, 2013, Assembly entered into a License and Collaboration Agreement with Therabiome, LLC, for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. Under the agreement, Therabiome granted to Assembly the exclusive worldwide license, with rights to sublicense, to develop the intellectual property for commercialization (a) in the use of bacteria, viruses, proteins and small molecules by oral delivery in (i) gastro- intestinal dysbiosis, including but not limited to C. difficile, irritable bowel syndrome-constipation and inflammatory bowel disease, (ii) auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus, and (iii) orally delivered vaccines, including viral and bacterial, and (b) any oral delivery of small molecules using the licensed intellectual property. Assembly will be solely responsible for all research and development activities with respect to any product it develops under the license.

For the license, Assembly paid Therabiome an upfront non-refundable license fee of $300,000. Assembly must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. Assembly also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region. Assembly also must pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed two certain thresholds, a one-time cash payment upon reaching each threshold.

Therabiome must pay Assembly royalties on annual net sales of any product it develops, using the intellectual property, in the low double to mid-double digit percentages, depending on the level of development or involvement Assembly had in the product.

Diltiazem (VEN 307) and Phenylepherine (VEN 308)

The Company had an exclusive royalty-bearing license agreement with S.L.A. Pharma, AG ("S.L.A. Pharma") to sell, make and use diltiazem (VEN 307) for treatment, through topical administration, of anal fissures and phenylepherine (VEN 308) for treatment, through topical administration, of fecal incontinence (referred to collectively as the "Compound Technologies") in the United States, Canada and Mexico. In the event that the Compound Technologies were commercialized, Assembly was obligated to pay to S.L.A. Pharma annual royalties, based upon net sales of the products. In addition, Assembly was required to make payments to S.L.A. Pharma up to an aggregate amount of $20 million upon the achievement of various milestones related to regulatory events.

On July 24, 2014, the Company notified S.L.A. Pharma that it was terminating the license agreement. The termination was effective on October 22, 2014. There were no early termination penalties as a result of the termination and the Company has no continuing obligation to make payment to S.L.A. Pharma under the agreement. The Company terminated the agreement to focus on the development of its potentially curative programs for HBV, which program was acquired on July 11, 2014 in the merger with Assembly Pharmaceuticals, Inc., and CDI, which was licensed in November 2013 from Therabiome, LLC.

Note 11 - Commitments and Contingencies

Real Property Leases

The Company leases office space for corporate and administrative functions in New York, NY under an agreement with a monthly lease payment of $10,130 that expires in August 2016. The Company also leases office space in Carmel, IN under a lease agreement that expires in June 2021. The leased locations in New York, NY and Carmel, IN. are for corporate and administrative functions supporting both the HBV and Microbiome Programs and are adequate for the Company's current needs.

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

The total leasing expenses for the years ended December 31, 2015 and 2014 were approximately $0.7 and $0.2 million, respectively.

Future minimum rental payments required as of December 31, 2015 are as follows:

Year Ended December 31, 2016	$	1,086,783
Year Ended December 31, 2017		976,547
Year Ended December 31, 2018		104,093
Year Ended December 31, 2019		106,360
Year Ended December 31, 2020		108,627
Thereafter		55,353
	$	2,437,763

Equipment Lease

Pursuant to a Master Lease agreement dated November 25, 2014, the Company is leasing certain laboratory equipment. The equipment lease expense for the year ended December 31, 2015 and 2014 amounted to $107,000 and $18,928, respectively.

Employment Agreements

On January 15, 2014, the Company entered into an employment agreement with its Chief Financial Officer, with an effective date of December 22, 2013. The agreement has a term of two years and will be automatically extended for additional one-year periods unless the Company notifies the officer at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The employment agreement initially provided for a base salary of $300,000 for the Chief Financial Officer, and an annual discretionary bonus of up to 50% of the officer's base salary based on financial, clinical development and business milestones established by the Board of Directors. In December 2014, the compensation committee approved a change of base salary to $350,000 per year for the Chief Financial Officer. On February 10, 2015, the Company named Mr. Barrett its Chief Operating Officer, in addition to Chief Financial Officer. Mr. Barrett received a 3% salary increase, bringing his base salary to $360,500, in connection with this additional responsibility.

In connection with the Merger, effective July 11, 2014, the Company entered into employment agreements with its President and Chief Operating Officer, its Chief Medical Officer, and its Chief Scientific Officer. In February 2015, Mr. Small was appointed as our President and Chief Executive Officer and relinquished his title of Chief Operating Officer, and in January 2016, Dr. Arnold was appointed as our Chief Discovery Officer and Vice President, Research and Development. The President's employment agreement has a term of two years and will be automatically extended for additional one-year periods unless the Company notifies the President at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The other two employment agreements provide for at-will employment, subject to payment of severance benefits depending on the circumstances of termination. The employment agreements initially provided for a base salary of $350,000 per year for the President (increased to base salary of $420,000 in February 2015), $290,000 per year for the Chief Medical Officer (increased to base salary of $319,000 in 2015) and $315,000 per year for the Chief Scientific Officer. Each employee is also eligible for an annual discretionary bonus based on achievement of financial, clinical development and business milestones established by the Board of Directors, with the President eligible for a bonus of up to 50% of his base salary, and the Chief Medical Officer and the Chief Scientific Officer eligible for a bonus of up to 30% of their respective base salaries. In 2014, the President and the Chief Medical Officer also received a retention bonus payable after three months of employment in the amount of $150,000 and $100,000, respectively.

The Company has employment agreements with its Chief Executive Officer and Chief Financial Officer/Chief Operating Officer which provide for an aggregate annual base salary of approximately $780,500 in 2015.

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 12 - Subsequent Event

Effective January 5, 2016, the Company entered into an employment agreement with its new Chief Scientific Officer. The agreement has a term of five years and will be automatically extended for additional one-year periods unless the Company notifies the officer at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The employment agreement initially provides for a base salary of $380,000 per year. The Chief Scientific Officer is also eligible for an annual discretionary bonus based on achievement of financial, clinical development and business milestones established by the Board of Directors, with the Chief Scientific Officer eligible for a bonus of up to 35% of his base salary. The Chief Scientific Officer also received a signing bonus payable after 30 days of employment in the amount of $75,000, which signing bonus is subject to repayment in the event his employment terminates for certain reasons prior to January 5, 2017. The employment agreement also provides for severance in connection with the termination of employment.

On January 9, 2016, the Company entered into an at-will employment letter agreement with its new Chief Development Officer and Head of Microbiome Program. The employment agreement provides for at-will employment, subject to payment of severance benefits depending on the circumstances of termination. The employment agreements initially provided for a base salary of $360,000 per year and the employee is also eligible for an annual discretionary bonus based on achievement of financial, clinical development and business milestones established by the Board of Directors of up to 35% of his base salary.

Exhibit 21.1

Subsidiaries of Assembly Biosciences, Inc.

Subsidiary	Jurisdiction of Incorporation
Assembly Pharmaceuticals, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) S-8 filed on April 20, 2011, file number 333-173613;
(2) S-8 filed on June 15, 2012, file number 333-182167;
(3) S-8 filed on September 17, 2014, file number 333-198803;
(4) S-3 filed on December 30, 2015, file number 333-208806;

of our reports dated March 11, 2016, with respect to the consolidated financial statements of Assembly Biosciences, Inc. and Subsidiary and the effectiveness of internal control over financial reporting of Assembly Biosciences, Inc. and Subsidiary included in this Annual Report (Form 10-K) of Assembly Biosciences, Inc. for the year ended December 31, 2015.

/s/ Ernst & Young LLP

New York, New York
March 11, 2016

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Assembly Biosciences, Inc. on Form S-3 (No. 333-208806) and Form S-8 (Nos. 333-173613, 333-182167 and 333-198803) of our report dated March 12, 2015, on our audit of the consolidated financial statements as of December 31 2014 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 11, 2016.

/s/ EisnerAmper LLP

New York, New York
March 11, 2016

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Derek Small, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2015 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 this 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 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.

Dated: March 11, 2016
/s/ Derek Small

Derek Small
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David J. Barrett, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended December 31, 2015 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 this 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.

Dated: March 11, 2016
/s/ David J. Barrett

David J. Barrett
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
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 annual report on Form 10-K of Assembly Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Derek Small, President and Chief Executive Officer (Principal Executive Officer) of the Company, 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.

Dated: March 11, 2016
/s/ Derek Small

Derek Small
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
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 annual report on Form 10-K of Assembly Biosciences, Inc. (the "Company") for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David J. Barrett, Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, 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.

Dated: March 11, 2016
/s/ David J. Barrett

David J. Barrett
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)